The MassHealth Drug List

MassHealth Drug List

The MassHealth Drug List ("the List") is an alphabetical list of commonly prescribed drugs and therapeutic class tables. The List specifies which drugs need prior authorization (PA) when prescribed for MassHealth members. The PA requirements specified in the List reflect MassHealth's policy described in the pharmacy regulations and other communications from MassHealth, as well as MassHealth's and the Drug Utilization Review (DUR) Board's review of drugs within certain therapeutic classes. The List also specifies the generic over-the-counter drugs that are payable under MassHealth. Additional information can be found in the section titled "Prior Authorization Status of Drugs."

The MassHealth Drug List (MHDL) Therapeutic Tables provide a view of drugs within their respective therapeutic classes, along with PA requirements, clinical information about the drug, and evaluation criteria for PA for select therapeutic classes. The tables may not include all medications, dosage forms, and combination products within that therapeutic class. The criteria for PA identify the clinical information MassHealth considers when determining medical necessity for selected medications. The criteria are based upon generally accepted standards of practice, review of the medical literature, federal and state policies, as well as laws applicable to the Massachusetts Medicaid Program. The clinical information included in the criteria is not intended to serve as a source of comprehensive prescribing information. Prescribers and pharmacists should review the List and its applicable therapeutic class tables when prescribing a drug or filling a prescription for a MassHealth member.

As part of the state's efforts to promote clinically appropriate alternatives that are the most cost-effective in each class, MassHealth has entered into supplemental rebate agreements with drug manufacturers for certain drug classes. These drugs are listed on the MassHealth Supplemental Rebate/Preferred Drug List. Please note that MassHealth may still require PA for clinical reasons.

In general, MassHealth strongly advocates the use of generic drugs. However, in some circumstances, generic drugs may cost more than their brand-name equivalents. For this reason, MassHealth is implementing a policy allowing MassHealth to prefer selected brand-name drugs over generic drugs when the net cost of the brand-name drug adjusted for rebates is lower than the net cost of the generic equivalent. These preferred brand-name drugs are listed on the MassHealth Brand Name Preferred Over Generic Drug List.

MassHealth does not pay for immunizing biologicals (i.e., vaccines) and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health without PA (130 CMR 406.413(C)). In cases where free vaccines are available to providers for specific populations (e.g., children, high risk, etc.), MassHealth will reimburse the provider only for individuals not eligible for the free vaccines. Notwithstanding the above, MassHealth will pay pharmacies for seasonal flu vaccine serum without PA, if the vaccine is administered in the pharmacy. Any drug that does not appear on the List requires PA, except for drugs described in 130 CMR 406.413(B) "Limitations on Coverage of Drugs - Drug Exclusions," which are not available to MassHealth adult members. Prescribers may request PA for such drugs for members under 21 years old to determine medical necessity (130 CMR 450.144(A)).

MassHealth members (including those in managed care plans), Health Safety Net patients, and Children's Medical Security Plan members do not have to pay copays for prescription drugs. This comprehensive no cost-sharing policy satisfies and exceeds the requirements of the PACT Act, Chapter 342 of the Acts of 2024, regarding coverage of medications for diabetes, asthma, and heart conditions.

Updates to the List

The updates to the List are effective immediately, unless otherwise specified. For medications that have new PA requirements, MassHealth's policy permits an otherwise valid prescription written before the effective date to be filled for the life of the prescription

without PA. Nevertheless, MassHealth encourages prescribers to reevaluate the medication regimens of their MassHealth patients, and consider either switching their MassHealth patients to a medication regimen that does not require PA or discontinuing the affected medication(s) as soon as possible, if clinically appropriate.

MassHealth encourages the use of specialized PA request forms for certain drugs or classes of drugs. These forms were created to help you provide the information MassHealth needs to evaluate your request. The specialized forms have the name of the drug or drug class in the title. If there is no specialized form, please use the General Drug Prior Authorization Request form. All forms are available at www.mass.gov/druglist.

Future Updates

MassHealth evaluates the prior-authorization status of drugs on an ongoing basis, and updates the MHDL accordingly. To sign up for e-mail alerts that will notify you when the List has been updated, go to the MassHealth Drug List at www.mass.gov/druglist . Click on Introduction to the MassHealth Drug List and then click on Subscribe to E-Mail Alerts in the Introduction section of the MHDL. Send the e-mail that automatically appears on your screen, and you will be subscribed. To get a paper copy of an updated List, submit a written request to the following address, fax number, or e-mail.

MassHealth Publications
P.O. Box 9152
Canton, MA 02021
Fax: 617-988-8973
E-mail: publications@mahealth.net

Include your MassHealth provider number, address, and a contact name with your request. MassHealth Publications will send you the latest version of the List. You will need to submit another written request each time you want a paper copy.

Prior Authorization Status of Drugs

Drugs may require PA for a variety of reasons. MassHealth determines the PA status of drugs on the List on the basis of the following:

- MassHealth program requirements; and
- ongoing evaluation of the drugs' utilization, therapeutic efficacy, safety, and cost.

Drugs are evaluated first on safety and effectiveness, and second on cost. Some drugs require PA because MassHealth and the Drug Utilization Review Board have concluded that there are more cost-effective alternatives. With regard to all such drugs, MassHealth also has concluded that the more costly drugs have no significant clinically meaningful therapeutic advantage in terms of safety, therapeutic efficacy, or clinical outcome compared to those less costly drugs used to treat the same condition. If applicable, the prescriber may submit to MassHealth documentation requesting an exception to step therapy, including written documentation in support of the exception, in accordance with M.G.L. c.118E, § 51A and the applicable PA form. Member stability due to the use of samples does not meet step therapy requirements.

Evaluation of a drug includes a thorough review by physicians and pharmacists using medical literature and consulting with specialists, other physicians, or both. References used may include *AHFS Drug Information; Drug Facts and Comparisons, Micromedex; National Comprehensive Cancer Network (NCCN); literature from peer-reviewed medical journals; Drug Topics Red Book, Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "*Orange Book*"); the *Massachusetts List of Interchangeable Drug Products;* and manufacturers' product information.

MassHealth may impose PA requirements in therapeutic classes in which it has designated a preferred product on the MassHealth Brand Name Preferred Over Generic Drug List or the MassHealth Supplemental Rebate/Preferred Drug List pursuant to the supplemental rebate agreement and preferred brand-name policies described above.

MassHealth may exclude otherwise-covered drugs from a population (including an identified patient sub-population) when it determines a drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome for such population. Any such exclusions will be implemented through the PA clinical criteria specified in the MassHealth Drug List. You may obtain the written basis for any such exclusion by making a request in writing to the MassHealth Pharmacy Program at masshealthdruglist@state.ma.us.

The MassHealth Pharmacy Online Processing System (POPS) uses diagnosis codes from medical claims for some drug classes when processing claims at pharmacies. This means that a prescriber may not need to submit a paper PA form if a member's diagnosis in POPS meets the criteria for that drug. MassHealth uses technical software called Smart PA to link diagnosis codes from medical claims during pharmacy claims adjudication. Smart PA is used in the MHDL to identify drugs for which this process is currently available. For this reason, MassHealth requests pharmacies to submit all claims through POPS, as some drugs that are designated as requiring PA on the MHDL will process at the pharmacy without a paper PA submitted.

In addition, if the limitations on covered drugs specified in 130 CMR 406.412(A) and 406.413(A) and (C) would result in inadequate treatment for a diagnosed medical condition, the prescriber may submit a written request, including written documentation of medical necessity, to MassHealth for PA for an otherwise noncovered drug.

List Conventions

The List uses the following conventions.

- Brand-name products are capitalized. Generic products are in lowercase.

- Formulations of a drug (for example, salt forms, sustained release, or syrups) are not specified on the List, unless a particular formulation requires PA and a different formulation does not.
- Combination products are listed with the individual ingredients separated by a slash mark (/).
- Only the generic and brand names of over-the-counter drugs that are payable by MassHealth appear on the List. Those over-the-counter drugs that are not listed require PA.
- Only the generic names of single and combination vitamins are listed. The brand names of such combinations are not listed, and therefore require PA.

Questions or Comments

Pharmacists and prescribers who have questions or comments about the MassHealth Drug List may contact the Drug Utilization Review Program at (800) 745-7318 or may e-mail the MassHealth Pharmacy Program at masshealthdruglist@state.ma.us. MassHealth does not answer all e-mail inquiries directly, but will use these inquiries to develop frequently asked questions about the MassHealth Drug List for its website.

When e-mailing a question or comment to the above e-mail address, please include your name, title, phone number, and fax number. This electronic mailbox should be used only for submitting questions or comments about the MassHealth Drug List. You will receive an automated response that acknowledges receipt of your e-mail. If you do not receive an automated reply, please resubmit your inquiry.

If a member has questions about the MassHealth Drug List, please refer the member to MassHealth Customer Service at (800) 841-2900 (TDD/TTY:711).

For more information about the MassHealth Pharmacy Program, including regulations, Pharmacy Facts, Publications, and Notices sent to prescribers and pharmacies, go to www.mass.gov/masshealth-pharmacy-program.

Commonwealth of Massachusetts
MassHealth Drug Utilization Review Program
P.O. Box 2586, Worcester, MA 01613-2586
Fax: (877) 208-7428 **Phone:** (800) 745-7318

October 2024 MassHealth Drug List Summary Update

MassHealth evaluates the prior authorization (PA) status for drugs on an ongoing basis and updates the MassHealth Drug List accordingly. This Summary Update document identifies changes to the MassHealth Drug List for the rollout effective October 1, 2024.

Additional information about these agents may be available within the MassHealth Drug List at www.mass.gov/druglist.

Additions

Effective October 1, 2024, the following newly marketed drugs have been added to the MassHealth Drug List.

- Alyglo (immune globulin IV, human-stwk) – **PA**
- Alvaiz (eltrombopag choline) – **PA**
- Cabtreo (clindamycin/adapalene/benzoyl peroxide) – **PA**
- Docivyx (docetaxel); MB
- Fabhalta (iptacopan) – **PA**
- Hepzato (melphalan hepatic delivery system) – **PA**; MB
- Lenmeldy (atidarsagene autotemcel) – **PA**; CO, MB
- leuprolide 22.5 mg vial – **PA**
- Libervant (diazepam buccal film) – **PA ≥ 6 years and PA > 10 units/30 days**
- Mresvia (respiratory syncytial virus vaccine suspension) – **PA < 60 years**
- Omvoh (mirikizumab-mrkz) – **PA**
- Opsynvi (macitentan/tadalafil) – **PA**
- Pemgarda (pemivibart COVID EUA – March 22, 2024) – **PA**; MB
- Rezdiffra (resmetirom) – **PA**
- Voydeya (danicopan) – **PA**
- Winrevair (sotatercept-csrk) – **PA**
- Zilbrysq (zilucoplan) – **PA**

Change in Prior Authorization Status

a. Effective October 1, 2024, the following antiretroviral agent will require PA.
   - Lexiva (fosamprenavir) – **PA**; A90

b. Effective October 1, 2024, the following GABA analog will no longer require PA within newly established dose limits. Pediatric Behavioral Health Medication Initiative criteria will still apply. For additional information, please see the Pediatric Behavioral Health Initiative documents found at www.mass.gov/druglist.
   - Horizant (gabapentin enacarbil) – **PA < 6 years and PA > 1200 mg/day**; BP

c. Effective October 1, 2024, the following GABA analog will no longer require PA within established dose limits. Pediatric Behavioral Health Medication Initiative criteria will still apply. For additional information, please see the Pediatric Behavioral Health Initiative documents found at www.mass.gov/druglist.
   - Lyrica (pregabalin) – **PA < 6 years and PA > 600 mg/day**; #

d. Effective October 1, 2024, the following benzodiazepine agent will require PA for all ages and quantities. Pediatric Behavioral Health Medication Initiative criteria will still apply. For additional information, please see the Pediatric Behavioral Health Initiative documents found at www.mass.gov/druglist.

- flurazepam – **PA**

e. Effective October 1, 2024, the following cardiovascular agent will require PA for members < six years of age and for behavioral medication polypharmacy for members <18 years of age. For additional information, please see the Pediatric Behavioral Health Initiative documents found at www.mass.gov/druglist.
   - Minipress (prazosin) – **PA < 6 years**; #; M90

f. Effective October 1, 2024, the following opioid dependence agent will no longer require PA within established dose limits.
   - buprenorphine/naloxone sublingual tablet ≤ 24 mg/day
   - buprenorphine/naloxone sublingual tablet – **PA > 90 days (>24 mg/day and ≤ 32 mg/day)**
   - buprenorphine/naloxone sublingual tablet – **PA > 32 mg/day**

g. Effective October 1, 2024, the following topical corticosteroid agents will no longer require PA.
   - desonide lotion; A90
   - hydrocortisone valerate ointment; A90
   - Olux-E (clobetasol propionate foam/emollient); BP, A90

h. Effective October 1, 2024, the following dermatologic agents will require PA.
   - Ameluz (aminolevulinic acid) – **PA**; MB
   - Levulan (aminolevulinic acid) – **PA**; MB

i. Effective October 1, 2024, the following topical antibiotic will no longer require PA.
   - Clindagel (clindamycin gel); BP

j. Effective October 1, 2024, the following vaginal antibiotic will require PA.
   - Vandazole (metronidazole 0.75% vaginal gel) – **PA**

k. Effective October 1, 2024, the following oral antibiotic will require PA.
   - tetracycline tablet – **PA**; A90

l. Effective October 1, 2024, the following COVID-19-related medication will require PA.
   - Lagevrio (molnupiravir COVID EUA- December 23, 2021) – **PA**

Change in Coverage Status

Effective October 1, 2024, the following agents will be available through medical billing only and will no longer be available through pharmacy billing.

- Cerebyx (fosphenytoin); MB
- Fensolvi (leuprolide) – **PA**; MB
- Keppra (levetiracetam injection); MB
- phenobarbital 65 mg/mL, 130 mg/mL injection; MB
- Supprelin LA (histrelin) – **PA**; MB
- valproate injection; MB
- Vimpat (lacosamide injection); MB

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- Antipsychotic Prior Authorization Request
- Antiretroviral Agents Prior Authorization Request
- Benzodiazepines and Other Anti-Anxiety Agents Prior Authorization Request
- Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents Prior Authorization Request
- Cerebral Stimulant and ADHD Drugs Prior Authorization Request
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- Thrombocytopenic Agents Prior Authorization Request
- Topical Anesthetics Prior Authorization Request
- Topical Corticosteroids Prior Authorization Request

Updated MassHealth Brand Name Preferred Over Generic Drug List

The MassHealth Brand Name Preferred Over Generic Drug List has been updated to reflect recent changes to the MassHealth Drug List.

a. Effective October 1, 2024, the following agents will be added to the MassHealth Brand Name Preferred Over Generic Drug List.
   - Atralin (tretinoin 0.05% gel) – **PA**; BP, A90
   - Cleocin T (clindamycin lotion); BP, A90
   - Clindagel (clindamycin gel); BP
   - Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate); BP
   - Condylox (podofilox gel); BP, A90
   - Fabior (tazarotene foam) – **PA**; BP
   - Finacea (azelaic acid foam) – **PA**; BP
   - Horizant (gabapentin enacarbil) – **PA < 6 years and PA > 1200 mg/day**; BP
   - Nucynta (tapentadol) – **PA**; BP
   - Nucynta (tapentadol extended-release) – **PA**; BP
   - Olux-E (clobetasol propionate foam/emollient); BP, A90
   - Onexton (clindamycin/benzoyl peroxide gel pump) – **PA;** BP, A90
   - Qudexy XR (topiramate extended-release capsule) – **PA < 6 years**; BP, A90
   - Retin-A Micro (tretinoin microspheres) – **PA**; BP, A90
   - Zyvox (linezolid suspension) – **PA**; BP

b. Effective October 1, 2024, the following agents will be removed from the MassHealth Brand Name Preferred Over Generic Drug List.
   - Bystolic (nebivolol); #, M90
   - Carafate (sucralfate suspension); #, A90
   - Onglyza (saxagliptin); #, M90
   - Selzentry (maraviroc tablet) – **PA**; A90
   - Toviaz (fesoterodine); #, A90
   - Xerese (acyclovir/hydrocortisone)

Updated MassHealth 90-day Initiative

The MassHealth 90-day Initiative has been updated to reflect recent changes to the MassHealth Drug List.

a. Effective October 1, 2024, the following agents may be allowed or mandated to be dispensed in up to a 90-day supply, as indicated below.

- Karbinal ER (carbinoxamine extended-release) – **PA**; A90
- lidocaine 4% patch – **PA > 4 units/day**; A90

b. Effective October 1, 2024, the following agents will no longer be allowed or mandated to be dispensed in up to a 90-day supply, as indicated below.
   - Apexicon-E (diflorasone cream/emollient) – **PA**
   - Ultravate (halobetasol lotion) – **PA**
   - Vandazole (metronidazole 0.75% vaginal gel) – **PA**

Updated MassHealth Over-the-Counter Drug List

The MassHealth Over-the-Counter Drug List has been updated to reflect recent changes to the MassHealth Drug List.

Effective October 1, 2024, the following topical anesthetic agent will be added to the MassHealth Over-the-Counter Drug List.

- lidocaine 4% patch – **PA > 4 units/day**

Updated MassHealth Supplemental Rebate/Preferred Drug List

The MassHealth Supplemental Rebate/Preferred Drug List has been updated to reflect recent changes to the MassHealth Drug List.

Effective October 1, 2024, the following anti-obesity agent will be added to the MassHealth Supplemental Rebate/Preferred Drug List.

- Zepbound (tirzepatide) [PD] – **PA**

Updated MassHealth Quick Reference Guide

The MassHealth Quick Reference Guide has been updated to reflect recent changes to the MassHealth Drug List.

Updated Pharmacy Initiatives

- Pediatric Behavioral Health Medication Initiative

Updated MassHealth Acute Hospital Carve-Out Drugs List

The MassHealth Acute Hospital Carve-Out Drugs list has been updated to reflect recent changes to the MassHealth Drug List.

Long-Acting Injectable Antipsychotic Medications Administered in Inpatient Psychiatry Units List

The Long-Acting Injectable Antipsychotic Medications Administered in Inpatient Psychiatry Units List has been updated to reflect recent changes to MassHealth Subchapter 6.

Deletions

a. The following drugs have been removed from the MassHealth Drug List because they have been discontinued by the manufacturer.
   - Benzaclin (clindamycin/benzoyl peroxide) – **PA**; A90
   - Capastat (capreomycin)
   - Cloderm (clocortolone cream) – **PA**; A90
   - Doryx (doxycycline hyclate delayed-release 50 mg, 120 mg tablet) – **PA**; A90
   - Epivir HBV (lamivudine 5 mg/mL solution) – **PA > 20 mL/day**; A90
   - flutamide; A90
   - Invirase (saquinavir)
   - Impeklo (clobetasol propionate lotion pump) – **PA**
   - Lupaneta Pack (leuprolide/norethindrone) – **PA**
   - Marqibo (vincristine liposome) – **PA**; MB

- Minolira (minocycline extended-release 105 mg, 135 mg tablet) – **PA**; A90
- Monurol (fosfomycin); #, A90
- Norvir (ritonavir solution)
- PegIntron (peginterferon alfa-2b) – **PA**
- Suprax (cefixime) – **PA**; A90
- Sustiva (efavirenz); #, A90
- Synera (lidocaine/tetracaine) – **PA > 4 patches/30 days**
- Taclonex (betamethasone/calcipotriene ointment) – **PA**; A90
- Temixys (lamivudine/tenofovir disoproxil fumarate) – **PA**
- Temovate (clobetasol propionate 0.05% cream)
- Vantas (histrelin) – **PA**
- Vibramycin (doxycycline calcium syrup)
- Vibramycin (doxycycline monohydrate suspension); #, A90
- Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir) – **PA**

b. The following drugs have been removed from the MassHealth Drug List. MassHealth does not pay for drugs that are manufactured by companies that have not signed rebate agreements with the U.S. Secretary of Health and Human Services.
   - Asclera (polidocanol) – **PA**; MB
   - Paser (aminosalicylic acid)
   - SSKI (potassium iodide) – **PA > 1 mL/day**

c. The following drugs have been removed from the MassHealth Drug List because they are not approved by the FDA.
   - clobetasol propionate shampoo kit – **PA**; A90
   - neomycin/fluocinolone cream kit – **PA**; A90
   - Synalar (fluocinolone cream kit) – **PA**
   - Synalar (fluocinolone ointment kit) – **PA**
   - Synalar (fluocinolone solution kit) – **PA**

Corrections / Clarifications

a. The following drugs have been added to the MassHealth Drug List. These changes do not reflect any change in MassHealth policy.
   - Robinul (glycopyrrolate 1 mg tablet); #, A90
   - Robinul Forte (glycopyrrolate 2 mg tablet); #, A90

b. The following drug has been added to the MassHealth Drug List. This change does reflect a change in MassHealth policy.
   - Briviact (brivaracetam injection); MB

c. The following drug has been added to the MassHealth Drug List. It was omitted in error. This change does not reflect any change in MassHealth policy.
   - Thiola EC (tiopronin delayed-release); BP, A90

d. The following listings have been clarified. These changes do reflect a change in MassHealth policy.
   - Abilify (aripiprazole tablet) – **PA < 10 years and PA > 2 units/day**; #, A90
   - Altreno (tretinoin 0.05% lotion) – **PA ≥ 21 years**
   - Arexvy (respiratory syncytial virus vaccine, adjuvanted) – **PA < 50 years**
   - aripiprazole solution – **PA < 10 years or ≥ 18 years and PA > 25 mL/day**; A90
   - Aristada (aripiprazole lauroxil 1,064 mg) [PD] – **PA < 10 years and PA > 1 injection/56 days**
   - Aristada (aripiprazole lauroxil 441 mg, 662 mg, 882 mg) [PD] – **PA < 10 years and PA > 1 injection/28 days**

- Aristada Initio (aripiprazole lauroxil 675 mg) [PD] – **PA < 10 years and PA > 1 injection/28 days**
- Avita (tretinoin) – **PA ≥ 21 years**; #, A90
- chlorpromazine – **PA < 10 years**; A90
- Clozaril (clozapine tablet) – **PA < 10 years**; A90
- fluphenazine – **PA < 10 years**; A90
- Geodon (ziprasidone capsule) – **PA < 10 years and PA > 2 units/day**; #, A90
- Haldol (haloperidol) – **PA < 10 years**; #, A90
- Invega (paliperidone 1.5 mg, 3 mg, 9 mg tablet) – **PA < 10 years and PA > 1 unit/day**; #; A90
- Invega (paliperidone 6 mg tablet) – **PA < 6 years and PA > 2 units/day**; #; A90
- Invega Hafyera (paliperidone extended-release 6-month injection) [PD] – **PA < 10 years and PA > 1 injection/168 days**
- Invega Sustenna (paliperidone extended-release 1-month injection) [PD] – **PA < 10 years and PA > 2 injections/28 days within the first 28 days of therapy and PA > 1 injection/28 days after 28 days of therapy**
- Invega Trinza (paliperidone extended-release 3-month injection) [PD] – **PA < 10 years and PA > 1 injection/84 days**
- isotretinoin – **PA ≥ 21 years;** A90
- Klaron (sulfacetamide 10% lotion) – **PA ≥ 21 years**; #, A90
- Latuda (lurasidone 20 mg, 40 mg, 60 mg, 120 mg) – **PA < 10 years and PA > 1 unit/day**; #, A90
- Latuda (lurasidone 80 mg) – **PA < 10 years and PA > 2 units/day**; #, A90
- Loxitane (loxapine capsule) – **PA < 10 years**; #, A90
- molindone – **PA < 10 years**; A90
- Navane (thiothixene) – **PA < 10 years**; #, A90
- Orap (pimozide) – **PA < 10 years**; #, A90
- Paxlovid (nirmatrelvir/ritonavir 150-100 mg) – **PA < 12 years and PA > 20 units/claim**
- Paxlovid (nirmatrelvir / ritonavir 300-100 mg) – **PA < 12 years and PA > 30 units/claim**
- perphenazine – **PA < 10 years**; A90
- Perseris (risperidone 90 mg, 120 mg extended-release subcutaneous injection) [PD] – **PA < 10 years and PA > 1 injection/28 days**
- Retin-A (tretinoin) – **PA ≥ 21 years;** BP, A90
- Risperdal (risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg tablets) – **PA < 10 years and PA > 3 units/day**; #, A90
- Risperdal (risperidone 4 mg tablet) – **PA < 10 years and PA > 4 units/day**; #, A90
- Risperdal (risperidone solution) – **PA < 10 years and PA > 16 mL/day**; #, A90
- Risperdal Consta (risperidone 12.5 mg, 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection) – **PA < 10 years and PA > 2 injections/28 days**; BP
- Seroquel (quetiapine) – **PA < 10 years and PA > 3 units/day**; #, A90
- Seroquel XR (quetiapine extended-release) – **PA < 10 years and PA > 2 units/day**; #, A90
- thioridazine – **PA < 10 years**; A90
- trifluoperazine – **PA < 10 years**; A90
- Uzedy (risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection) [PD] – **PA < 10 years and PA > 1 injection/56 days**
- Uzedy (risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection) [PD] – **PA < 10 years and PA > 1 injection/28 days**
- Zyprexa (olanzapine 2.5 mg, 5 mg, 7.5 mg, 10 mg tablet) – **PA < 10 years and PA > 3 units/day**; #, A90
- Zyprexa (olanzapine 15 mg and 20 mg tablet) – **PA < 10 years and PA > 2 units/day**; #, A90

- Zyprexa Relprevv (olanzapine 210 mg, 300 mg extended-release injection) – **PA < 10 years and PA > 2 injections/28 days**
- Zyprexa Relprevv (olanzapine 405 mg extended-release injection) – **PA < 10 years and PA > 1 injection/28 days**
- Zyprexa Zydis (olanzapine 15 mg orally disintegrating tablet) – **PA < 10 years and PA > 2 units/day**; #, A90
- Zyprexa Zydis (olanzapine 5 mg, 10 mg, 20 mg orally disintegrating tablet) – **PA < 10 years and PA > 1 unit/day**; #, A90

e. The following listings have been clarified. These changes do not reflect any change in MassHealth policy.
- Abrysvo (respiratory syncytial virus vaccine) – **PA < 60 years**; 1
- brimonidine 0.33% topical gel – **PA**; A90
- clindamycin gel, solution; A90
- clobetasol propionate 0.05% cream; A90
- Comirnaty (COVID-19 Pfizer vaccine, COVID EUA – September 11, 2023 for members ≥ 6 months of age); 1
- desonide; A90
- desoximetasone 0.05% cream – **PA**; A90
- desoximetasone 0.25% ointment, 0.05% gel – **PA**; A90
- doxycycline hyclate delayed-release 50 mg, 75 mg, 100 mg, 150 mg tablet – **PA**; A90
- Flolan (epoprostenol)
- hydrocortisone valerate; A90
- Keppra (levetiracetam solution, tablet); #, A90
- lamivudine 100 mg tablet – **PA > 1 unit/day**; A90
- Luxturna (voretigene neparvovec-rzyl) – **PA**; CO, MB
- Novavax COVID-19 vaccine, adjuvanted (COVID EUA – October 3, 2023 for members ≥ 12 years of age); 1
- Onexton (clindamycin/benzoyl peroxide gel) – **PA**; A90
- phenobarbital tablet, solution
- phenytoin chewable tablet, extended capsule; A90
- podofilox solution; A90
- Promacta (eltrombopag olamine) – **PA**; BP
- Sezaby (phenobarbital 100 mg injection); MB
- Spikevax (COVID-19 Moderna vaccine, COVID EUA – September 11, 2023 for members ≥ 6 months of age); 1
- Taclonex (betamethasone/calcipotriene topical suspension) – **PA**; BP, A90
- Topicort (desoximetasone 0.05% ointment) – **PA**; A90
- Topicort (desoximetasone spray) – **PA**; A90
- valproate oral solution
- Vimpat (lacosamide tablet, solution); #, A90

Abbreviations, Acronyms, and Symbols

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this

drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

PA Prior authorization is required. The prescriber must obtain prior authorization for the drug in order for the provider to receive reimbursement. Note: PA applies to both the brand-name and the FDA "A"-rated generic equivalent of listed product.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

CO Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements.

M90 Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

1 Product may be available through the Massachusetts Department of Public Health (DPH). Please check with DPH for availability. MassHealth does not pay for immunizing biologicals (i.e., vaccines) and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health without PA (130 CMR 406.413(C)). In cases where free vaccines are available to providers for specific populations (e.g. children, high risk, etc.), MassHealth will reimburse the provider only for individuals not eligible for the free vaccines. Notwithstanding the above, MassHealth will pay pharmacies for seasonal flu vaccine serum without prior authorization, if the vaccine is administered in the pharmacy.

Therapeutic Class and Clinical Criteria Tables

Prior Authorization Request Forms

Policy Initiatives

Other Information

The List Uses the Following Symbols:

PA	Prior authorization is required. The prescriber must obtain prior authorization for the drug in order for the pharmacy to receive payment. Note: PA applies to both the brand-name and the FDA "A"-rated generic equivalent of listed product.
#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
CO	Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
o	PA status depends on the drug's formulation.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
1	Product may be available through the Massachusetts Department of Public Health (DPH). Please check with DPH for availability. MassHealth does not pay for immunizing biologicals (i.e., vaccines) and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health without PA (130 CMR 406.413(C)). In cases where free vaccines are available to providers for specific populations (e.g. children, high risk, etc.), MassHealth will reimburse the provider only for individuals not eligible for the free vaccines. Notwithstanding the above, MassHealth will pay pharmacies for seasonal flu vaccine serum without PA, if the vaccine is administered in the pharmacy.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
CP	Compounded pharmaceutical products with a total allowed ingredient cost greater than or equal to $100 require PA. In addition, compounded pharmaceutical products with intradermal, topical, or transdermal route of administration (ROA) require PA. The following ROAs are excluded from the PA requirement for products with a total allowed ingredient cost greater than or equal to $100: infusion, intramuscular, intravenous, intravenous piggyback, intravenous push, subcutaneous. Compounded pharmaceutical products utilizing any PA-requiring agent or not covered ingredient as part of the compound require PA.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.
PND	Preferred Non-Drug Product. This product is a preferred non-drug product for which MassHealth has entered into a rebate agreement with product manufacturer.

Note: Any drug that does not appear on the List requires PA.

Alphabetic List

A

B

C

D

Depakote (divalproex sprinkle capsule) - PA < 6 years; BP, A90; See Table 20, Page 268; See Table 71, Page 706

Depakote ER (divalproex extended-release) - PA < 6 years; #, A90; See Table 20, Page 268; See Table 71, Page 706

Depen (penicillamine tablet); #, A90; See Table 65, Page 661

Depo-estradiol (estradiol-Depo-estradiol)

Depo-Medrol (methylprednisolone acetate); #; See Table 5, Page 117

Depo-Provera (medroxyprogesterone injection); #

Depo-SubQ Provera 104 (medroxyprogesterone injection)

Depo-Testosterone (testosterone cypionate) - PA; See Table 55, Page 506

Derma-Smoothe-FS (fluocinolone body oil, scalp oil); #, A90; See Table 16, Page 225

Dermotic (fluocinolone oil, otic drops); BP, A90; See Table 53, Page 499

Descovy (emtricitabine / tenofovir alafenamide); PD; See Table 38, Page 406

Desferal (deferoxamine); #; See Table 73, Page 775

desipramine - PA; A90; See Table 17, Page 231; See Table 71, Page 706

desloratadine / pseudoephedrine - PA; See Table 12, Page 192

desloratadine orally disintegrating tablet - PA; M90; See Table 12, Page 192

desloratadine tablet - PA; M90; See Table 12, Page 192

desmopressin-DDAVP; A90; See Table 46, Page 457

desmopressin-Nocdurna - PA; See Table 46, Page 457

desonide; A90; See Table 16, Page 225

desoximetasone 0.05% cream - PA; A90; See Table 16, Page 225

desoximetasone 0.05% ointment - PA; A90; See Table 16, Page 225

desoximetasone 0.25% cream; A90; See Table 16, Page 225

desoximetasone 0.25% ointment, 0.05% gel - PA; A90; See Table 16, Page 225

desoximetasone spray - PA; A90; See Table 16, Page 225

Desoxyn (methamphetamine) - PA; See Table 31, Page 358; See Table 71, Page 706

desvenlafaxine extended-release - PA; A90; See Table 17, Page 231; See Table 71, Page 706

desvenlafaxine succinate extended-release - PA < 6 years and PA > 1 unit/day; A90; See Table 17, Page 231; See Table 71, Page 706

Detrol (tolterodine immediate-release); #, A90; See Table 46, Page 457

Detrol LA (tolterodine extended-release); #, A90; See Table 46, Page 457

deucravacitinib - PA; See Table 5, Page 117

deutetrabenazine - PA; See Table 74, Page 779

deutetrabenazine extended-release - PA; See Table 74, Page 779

dexamethasone 20 mg tablet - PA; See Table 5, Page 117

dexamethasone injection; See Table 5, Page 117

dexamethasone intravitreal implant; MB; See Table 29, Page 345

dexamethasone ophthalmic insert; MB; See Table 29, Page 345

dexamethasone ophthalmic suspension; See Table 29, Page 345

dexamethasone sodium phosphate ophthalmic solution; A90; See Table 29, Page 345

dexamethasone solution, tablet; A90; See Table 5, Page 117

dexamethasone tablet pack - PA; A90; See Table 5, Page 117

dexchlorpheniramine solution - PA; A90; See Table 12, Page 192

Dexcom G6 (continuous glucose monitoring system) - PA; PND; See Table 78, Page 800

Dexcom G7 (continuous glucose monitoring system) - PA; PND; See Table 78, Page 800

Dexedrine Spansule (dextroamphetamine 5 mg, 10 mg, 15 mg capsule) - PA < 3 years or ≥ 21 years and PA > 3 units/day; #; See Table 31, Page 358; See Table 71, Page 706

Dexilant (dexlansoprazole); BP, M90; See Table 3, Page 104

dexlansoprazole; BP, M90; See Table 3, Page 104

dexmedetomidine; MB

dexmethylphenidate - PA < 3 years or ≥ 21 years and PA > 3 units/day; See Table 31, Page 358; See Table 71, Page 706

dexmethylphenidate extended-release - PA < 3 years or ≥ 21 years and PA > 2 units/day; BP; See Table 31, Page 358; See Table 71, Page 706

dexrazoxane

Dextenza (dexamethasone ophthalmic insert); MB; See Table 29, Page 345

dextrin; *, A90; See Table 61, Page 629

dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg tablet - PA; See Table 31, Page 358; See Table 71, Page 706

dextroamphetamine 5 mg, 10 mg tablet - PA < 3 years or ≥ 21 years and PA > 3 units/day; See Table 31, Page 358; See Table 71, Page 706

dextroamphetamine 5 mg, 10 mg, 15 mg capsule - PA < 3 years or ≥ 21 years and PA > 3 units/day; See Table 31, Page 358; See Table 71, Page 706

dextroamphetamine solution - PA < 3 years or ≥ 21 years and PA > 40 mL/day; See Table 31, Page 358; See Table 71, Page 706

dextroamphetamine transdermal - PA; See Table 31, Page 358; See Table 71, Page 706

dextromethorphan / bupropion - PA; See Table 17, Page 231; See Table 71, Page 706

dextromethorphan / quinidine - PA; See Table 72, Page 730

dextrose

Diacomit (stiripentol) - PA; See Table 20, Page 268

Diastat (diazepam rectal gel) - PA > 5 kits (10 syringes)/30 days; #; See Table 20, Page 268

diazepam buccal film - PA ≥ 6 years and PA > 10 units/30 days; See Table 20, Page 268

diazepam injection; See Table 69, Page 690

diazepam nasal spray - PA > 10 units/30 days; See Table 20, Page 268

diazepam rectal gel - PA > 5 kits (10 syringes)/30 days; See Table 20, Page 268

diazepam solution, tablet - PA < 6 years; See Table 69, Page 690; See Table 71, Page 706

diazoxide; BP, A90

dichlorphenamide - PA; See Table 72, Page 730
Diclegis (doxylamine / pyridoxine delayed-release) - PA; BP, A90; See Table 27, Page 335
diclofenac / misoprostol - PA < 60 years; A90; See Table 11, Page 185
diclofenac 1% gel; A90; See Table 11, Page 185
diclofenac 18 mg, 35 mg capsule - PA; A90; See Table 11, Page 185
diclofenac 25 mg capsule - PA; A90; See Table 11, Page 185
diclofenac 3% gel; A90; See Table 63, Page 644
diclofenac extended-release; A90; See Table 11, Page 185
diclofenac ophthalmic solution; A90; See Table 29, Page 345
diclofenac potassium 25 mg tablet - PA; A90; See Table 11, Page 185
diclofenac potassium 50 mg tablet; A90; See Table 11, Page 185
diclofenac powder for solution - PA; A90; See Table 11, Page 185
diclofenac sodium tablet; A90; See Table 11, Page 185
diclofenac topical patch-Flector - PA; A90; See Table 11, Page 185
diclofenac topical patch-Licart - PA; See Table 11, Page 185
diclofenac topical solution; A90; See Table 11, Page 185
dicloxacillin; A90; See Table 35, Page 383
dicyclomine; A90; See Table 61, Page 629
didanosine; A90; See Table 38, Page 406
diethylpropion - PA; See Table 81, Page 815
diethylpropion extended-release - PA; See Table 81, Page 815
difelikefalin; MB
difenoxin / atropine - PA; See Table 61, Page 629
Dificid (fidaxomicin) - PA; See Table 35, Page 383
diflorasone cream - PA; A90; See Table 16, Page 225
diflorasone cream / emollient - PA; See Table 16, Page 225
diflorasone ointment - PA; A90; See Table 16, Page 225
Diflucan (fluconazole); #, A90; See Table 47, Page 461
diflunisal; A90; See Table 11, Page 185
difluprednate; A90; See Table 29, Page 345
digoxin; M90; See Table 18, Page 245
dihydrocodeine / acetaminophen / caffeine - PA; See Table 8, Page 157
dihydroergotamine injection - PA; See Table 14, Page 208
dihydroergotamine nasal spray - PA; A90; See Table 14, Page 208
Dilantin (phenytoin extended 30 mg and 100 mg capsule); #, A90; See Table 20, Page 268
Dilantin Infatab (phenytoin chewable tablet); #, A90; See Table 20, Page 268
Dilantin-125 (phenytoin suspension); #, A90; See Table 20, Page 268
Dilaudid (hydromorphone) - PA > 24 mg/day; #; See Table 8, Page 157
diltiazem extended-release capsule; M90; See Table 18, Page 245
diltiazem extended-release tablet; M90; See Table 18, Page 245
diltiazem-Cardizem; M90; See Table 18, Page 245
diltiazem-Tiazac ER; M90; See Table 18, Page 245
dimenhydrinate injection; See Table 12, Page 192
dimercaprol; MB
dimethyl fumarate - PA > 2 units/day; A90; See Table 52, Page 494
dimethyl sulfoxide solution; See Table 72, Page 730
Diovan (valsartan tablet); #, M90; See Table 18, Page 245
Diovan HCT (valsartan / hydrochlorothiazide); #, M90; See Table 18, Page 245
Dipentum (olsalazine); See Table 33, Page 375
diphenhydramine; *, A90; See Table 12, Page 192
diphenoxylate / atropine; See Table 61, Page 629
diphtheria / tetanus / acellular pertussis / poliovirus inactivated / haemophilus B conjugate / hepatitis B vaccine; See Table 32, Page 368
diphtheria / tetanus / acellular pertussis / poliovirus inactivated / haemophilus B conjugate vaccine; 1; See Table 32, Page 368
diphtheria / tetanus toxoids / acellular pertussis / hepatitis B, recombinant / poliovirus, inactivated vaccine; 1; See Table 32, Page 368
diphtheria / tetanus toxoids / acellular pertussis / poliovirus, inactivated vaccine; 1; See Table 32, Page 368
diphtheria / tetanus toxoids / acellular pertussis vaccine; 1; See Table 32, Page 368
diphtheria / tetanus toxoids vaccine; 1; See Table 32, Page 368
Diprolene (betamethasone dipropionate, augmented ointment); #, A90; See Table 16, Page 225
dipyridamole; M90; See Table 58, Page 618
diroximel fumarate - PA; See Table 52, Page 494
disopyramide controlled-release; See Table 18, Page 245
disopyramide immediate-release; A90; See Table 18, Page 245
disulfiram; A90; See Table 36, Page 396
Ditropan XL (oxybutynin extended-release tablet); #, A90; See Table 46, Page 457
Diuril (chlorothiazide); #, M90; See Table 18, Page 245
divalproex extended-release - PA < 6 years; A90; See Table 20, Page 268; See Table 71, Page 706
divalproex immediate-release - PA < 6 years; A90; See Table 20, Page 268; See Table 71, Page 706
divalproex sprinkle capsule - PA < 6 years; BP, A90; See Table 20, Page 268; See Table 71, Page 706
Divigel (estradiol-Divigel); BP, A90
Docefrez (docetaxel); MB; See Table 57, Page 518
docetaxel; MB; See Table 57, Page 518
Docivyx (docetaxel); MB; See Table 57, Page 518
docusate / benzocaine enema; A90; See Table 61, Page 629
docusate sodium capsule, tablet; *, M90; See Table 61, Page 629
docusate sodium enema; A90; See Table 61, Page 629
docusate sodium solution, syrup; *, A90; See Table 61, Page 629
dofetilide; M90; See Table 18, Page 245
Dojolvi (triheptanoin) - PA; See Table 65, Page 661
dolasetron - PA; See Table 27, Page 335

Dolophine (methadone oral-Dolophine) - PA; See Table 8, Page 157

dolutegravir / lamivudine; PD; See Table 38, Page 406

dolutegravir / rilpivirine; PD; See Table 38, Page 406

dolutegravir tablet - PA > 1 unit/day; See Table 38, Page 406

dolutegravir tablet for oral suspension; See Table 38, Page 406

donepezil 10 mg tablet - PA < 6 years and PA > 2 units/day; A90; See Table 56, Page 511; See Table 71, Page 706

donepezil 5 mg, 23 mg tablet - PA < 6 years and PA > 1 unit/day; A90; See Table 56, Page 511; See Table 71, Page 706

donepezil orally disintegrating tablet - PA < 6 years and PA > 1 unit/day; A90; See Table 56, Page 511; See Table 71, Page 706

donepezil patch - PA; See Table 56, Page 511; See Table 71, Page 706

Doptelet (avatrombopag) - PA; See Table 68, Page 684

Doral (quazepam) - PA; See Table 69, Page 690; See Table 71, Page 706

doravirine / lamivudine / tenofovir disoproxil fumarate; PD; See Table 38, Page 406

doravirine; PD; See Table 38, Page 406

dornase alfa; See Table 21, Page 282

Doryx (doxycycline hyclate delayed-release 60 mg, 80 mg, 200 mg tablet) - PA; A90; See Table 35, Page 383

dorzolamide / timolol, preservative free - PA; BP, M90; See Table 51, Page 488

dorzolamide / timolol; M90; See Table 51, Page 488

dorzolamide; M90; See Table 51, Page 488

dostarlimab-gxly - PA; MB; See Table 57, Page 518

double antibiotic ointment (bacitracin / polymyxin B topical ointment); *, A90; See Table 41, Page 422

Dovato (dolutegravir / lamivudine); PD; See Table 38, Page 406

Dovonex (calcipotriene cream) - PA > 60 grams/30 days; #, A90; See Table 5, Page 117

doxazosin extended-release; See Table 19, Page 265

doxazosin immediate-release; M90; See Table 18, Page 245; See Table 19, Page 265

doxepin capsule, oral concentrate - PA < 6 years; A90; See Table 17, Page 231; See Table 71, Page 706

doxepin cream-Prudoxin - PA; See Table 63, Page 644

doxepin cream-Zonalon - PA; See Table 63, Page 644

doxepin tablet - PA; A90; See Table 15, Page 218; See Table 71, Page 706

doxercalciferol capsule - PA; M90; See Table 6, Page 148

doxercalciferol injection; MB; See Table 6, Page 148

Doxil (doxorubicin liposomal injection); MB; See Table 57, Page 518

doxorubicin liposomal injection; MB; See Table 57, Page 518

doxorubicin; MB; See Table 57, Page 518

doxycycline hyclate 100 mg capsule; A90; See Table 35, Page 383

doxycycline hyclate 100 mg tablet pack - PA; See Table 35, Page 383

doxycycline hyclate 20 mg, 100 mg tablet; A90; See Table 35, Page 383

doxycycline hyclate 50 mg capsule; A90; See Table 35, Page 383

doxycycline hyclate 50 mg tablet - PA; A90; See Table 35, Page 383

doxycycline hyclate 75 mg, 150 mg tablet - PA; A90; See Table 35, Page 383

doxycycline hyclate delayed-release 50 mg, 75 mg, 100 mg, 150 mg tablet - PA; A90; See Table 35, Page 383

doxycycline hyclate delayed-release 60 mg, 80 mg, 200 mg tablet - PA; A90; See Table 35, Page 383

doxycycline hyclate injection; See Table 66, Page 673

doxycycline monohydrate 150 mg capsule - PA; A90; See Table 35, Page 383

doxycycline monohydrate 150 mg tablet - PA; A90; See Table 35, Page 383

doxycycline monohydrate 40 mg capsule - PA; A90; See Table 35, Page 383

doxycycline monohydrate 50 mg, 100 mg capsule; A90; See Table 35, Page 383

doxycycline monohydrate 50 mg, 75 mg, 100 mg tablet; A90; See Table 35, Page 383

doxycycline monohydrate 75 mg capsule - PA; A90; See Table 35, Page 383

doxycycline monohydrate suspension; A90; See Table 35, Page 383

doxylamine / pyridoxine delayed-release - PA; BP, A90; See Table 27, Page 335

doxylamine / pyridoxine extended-release - PA; See Table 27, Page 335

doxylamine; *, A90

Drizalma (duloxetine sprinkle capsule) - PA; See Table 17, Page 231; See Table 71, Page 706

dronabinol 2.5 mg - PA > 2 units/day; BP; See Table 27, Page 335

dronabinol 5 mg, 10 mg - PA > 2 units/day; See Table 27, Page 335

dronedarone; A90; See Table 18, Page 245

droperidol

drospirenone

Droxia (hydroxyurea capsule); See Table 45, Page 451

droxidopa - PA; A90; See Table 18, Page 245

Drysol (aluminum chloride) - PA; See Table 63, Page 644

Duaklir (aclidinium / formoterol) - PA; See Table 23, Page 293

Duavee (estrogens, conjugated/bazedoxifene) - PA; See Table 49, Page 475

Duetact (glimepiride / pioglitazone) - PA; BP, M90; See Table 26, Page 320

Duexis (ibuprofen / famotidine) - PA < 60 years; #, A90; See Table 11, Page 185

dulaglutide - PA > 2 mL/28 days; PD; See Table 26, Page 320

Dulera (mometasone / formoterol); BP; See Table 23, Page 293

duloxetine 20 mg, 30 mg, 60 mg capsule - PA < 6 years; A90; See Table 17, Page 231; See Table 71, Page 706

duloxetine 40 mg capsule - PA; A90; See Table 17, Page 231; See Table 71, Page 706

duloxetine sprinkle capsule - PA; See Table 17, Page 231; See Table 71, Page 706

Duobrii (halobetasol / tazarotene lotion) - PA; See Table 16, Page 225

Duopa (carbidopa / levodopa enteral suspension) - PA; See Table 48, Page 468

dupilumab - PA; PD; See Table 64, Page 649

Dupixent (dupilumab) - PA; PD; See Table 64, Page 649

Duraclon (clonidine injection); #; See Table 8, Page 157

E

F

Florastor (saccharomyces boulardii) - PA ≥ 21 years; See Table 61, Page 629

Flowflex (COVID-19 antigen self-test) - PA > 2 tests/28 days; See Table 72, Page 730

floxuridine; MB; See Table 57, Page 518

Fluad (influenza virus vaccine, adjuvanted) - PA < 65 years; 1; See Table 32, Page 368

Fluarix (influenza virus vaccine-Fluarix); 1; See Table 32, Page 368

Flublok (influenza virus vaccine-Flublok); 1; See Table 32, Page 368

Flucelvax (influenza virus vaccine-Flucelvax); 1; See Table 32, Page 368

fluconazole; A90; See Table 47, Page 461

flucytosine; BP, A90; See Table 47, Page 461

fludarabine; See Table 57, Page 518

fludrocortisone; A90; See Table 5, Page 117

Flulaval (influenza virus vaccine-Flulaval); 1; See Table 32, Page 368

Flumist (influenza virus vaccine-Flumist); 1; See Table 32, Page 368

flunisolide nasal spray - PA; M90; See Table 25, Page 316

fluocinolone 0.01% cream; A90; See Table 16, Page 225

fluocinolone 0.025% cream; A90; See Table 16, Page 225

fluocinolone body oil, scalp oil; A90; See Table 16, Page 225

fluocinolone oil, otic drops; BP, A90; See Table 53, Page 499

fluocinolone ointment; A90; See Table 16, Page 225

fluocinolone ophthalmic implant-Iluvien; MB

fluocinolone ophthalmic implant-Retisert; MB

fluocinolone ophthalmic implant-Yutiq; MB

fluocinolone solution; A90; See Table 16, Page 225

fluocinonide / emollient; A90; See Table 16, Page 225

fluocinonide 0.1% cream; A90; See Table 16, Page 225

fluocinonide cream, gel, ointment, solution; A90; See Table 16, Page 225

fluorescein / benoxinate; A90; See Table 59, Page 622

fluorometholone acetate; See Table 29, Page 345

fluorometholone; A90; See Table 29, Page 345

fluorouracil 0.5% cream; BP, A90; See Table 63, Page 644

fluorouracil 5% cream; BP, A90; See Table 63, Page 644

fluorouracil injection; MB; See Table 57, Page 518

fluorouracil solution; A90; See Table 63, Page 644

fluoxetine 10 mg, 20 mg tablet for premenstrual dysphoric disorder - PA < 6 years; A90; See Table 17, Page 231; See Table 71, Page 706

fluoxetine 10 mg, 20 mg, 40 mg capsule, solution - PA < 6 years; A90; See Table 17, Page 231; See Table 71, Page 706

fluoxetine 60 mg tablet - PA; A90; See Table 17, Page 231; See Table 71, Page 706

fluoxetine 90 mg delayed-release capsule - PA; A90; See Table 17, Page 231; See Table 71, Page 706

fluphenazine - PA < 10 years; A90; See Table 24, Page 301; See Table 71, Page 706

flurandrenolide cream, lotion - PA; A90; See Table 16, Page 225

flurandrenolide ointment - PA; A90; See Table 16, Page 225

flurazepam - PA; See Table 69, Page 690; See Table 71, Page 706

flurbiprofen ophthalmic solution; A90; See Table 29, Page 345

flurbiprofen; A90; See Table 11, Page 185

fluticasone / salmeterol inhalation powder-Airduo Digihaler - PA; See Table 23, Page 293

fluticasone / salmeterol inhalation powder-Airduo Respiclick - PA; BP, A90; See Table 23, Page 293

fluticasone / salmeterol inhalation-Advair; BP, A90; See Table 23, Page 293

fluticasone / vilanterol; BP, A90; See Table 23, Page 293

fluticasone cream; A90; See Table 16, Page 225

fluticasone furoate / umeclidinium / vilanterol - PA; See Table 23, Page 293

fluticasone furoate inhalation powder; See Table 23, Page 293

fluticasone lotion - PA; A90; See Table 16, Page 225

fluticasone ointment; A90; See Table 16, Page 225

fluticasone propionate 50 mcg nasal spray - PA > 1 inhaler/30 days; M90; See Table 25, Page 316

fluticasone propionate 93 mcg nasal spray - PA; See Table 25, Page 316

fluticasone propionate inhalation aerosol - PA ≥ 12 years; A90; See Table 23, Page 293

fluticasone propionate inhalation powder - PA; A90; See Table 23, Page 293

fluticasone propionate inhalation powder-Armonair Digihaler - PA; See Table 23, Page 293

fluvastatin - PA; M90; See Table 13, Page 197

fluvastatin extended-release - PA; M90; See Table 13, Page 197

fluvoxamine extended-release - PA; A90; See Table 17, Page 231; See Table 71, Page 706

fluvoxamine immediate-release - PA < 6 years; A90; See Table 17, Page 231; See Table 71, Page 706

Fluzone (influenza virus vaccine, high dose) - PA < 65 years ; 1; See Table 32, Page 368

Fluzone (influenza virus vaccine-Fluzone); 1; See Table 32, Page 368

FML (fluorometholone); #, A90; See Table 29, Page 345

Focalin (dexmethylphenidate) - PA < 3 years or ≥ 21 years and PA > 3 units/day; #; See Table 31, Page 358; See Table 71, Page 706

Focalin XR (dexmethylphenidate extended-release) - PA < 3 years or ≥ 21 years and PA > 2 units/day; BP; See Table 31, Page 358; See Table 71, Page 706

folic acid; *, M90; See Table 6, Page 148

Folotyn (pralatrexate); MB; See Table 57, Page 518

fondaparinux; See Table 58, Page 618

Forfivo XL (bupropion hydrochloride extended-release 450 mg tablet) - PA; A90; See Table 17, Page 231; See Table 71, Page 706

formoterol - PA; See Table 23, Page 293

Forteo (teriparatide 600 mcg/2.4 mL) - PA; BP; See Table 49, Page 475

G

gefitinib - PA; A90; See Table 57, Page 518

Gel-One (hyaluronate, crossed-linked) - PA; MB; See Table 77, Page 798

gelatin capsule, empty; *; See Table 79, Page 806

Gelnique (oxybutynin gel); BP; See Table 46, Page 457

Gelsyn (hyaluronate-Gelsyn) - PA; MB; See Table 77, Page 798

gemcitabine premixed infusion - PA; MB; See Table 57, Page 518

gemcitabine vial; MB; See Table 57, Page 518

gemfibrozil; M90; See Table 13, Page 197

Gemtesa (vibegron) - PA; See Table 46, Page 457

gemtuzumab ozogamicin - PA; MB; See Table 57, Page 518

Genabio (COVID-19 antigen self-test) - PA > 2 tests/28 days; See Table 72, Page 730

Generess Fe (ethinyl estradiol / norethindrone / ferrous fumarate chewable 0.8 mg / 25 mcg); #, M90

Genotropin (somatropin-Genotropin) - PA; PD; See Table 9, Page 170

gentamicin / prednisolone ophthalmic ointment - PA; See Table 34, Page 379

gentamicin / prednisolone ophthalmic suspension; See Table 34, Page 379

gentamicin injection; See Table 66, Page 673

gentamicin ophthalmic ointment, solution; A90; See Table 34, Page 379

gentamicin topical cream, ointment; A90; See Table 41, Page 422

Genvisc (hyaluronate-Genvisc) - PA; MB; See Table 77, Page 798

Genvoya (elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide); PD; See Table 38, Page 406

Geodon (ziprasidone capsule) - PA < 10 years and PA > 2 units/day; #, A90; See Table 24, Page 301; See Table 71, Page 706

Geodon (ziprasidone injection); #; See Table 24, Page 301

Gilenya (fingolimod capsule) - PA > 1 unit/day; #, A90; See Table 52, Page 494

Gilotrif (afatinib) - PA; See Table 57, Page 518

gilteritinib - PA; See Table 57, Page 518

Gimoti (metoclopramide nasal spray) - PA; See Table 3, Page 104

Givlaari (givosiran) - PA; PD, MB; See Table 72, Page 730

givosiran - PA; PD, MB; See Table 72, Page 730

glasdegib - PA; See Table 57, Page 518

Glassia (alpha-1-proteinase inhibitor, human-Glassia); MB

glatiramer; BP; See Table 52, Page 494

glecaprevir / pibrentasvir - PA; PD; See Table 44, Page 436

Gleevec (imatinib); #, A90; See Table 57, Page 518

Gleostine (lomustine) - PA; See Table 57, Page 518

glimepiride / pioglitazone - PA; BP, M90; See Table 26, Page 320

glimepiride; M90; See Table 26, Page 320

glipizide / metformin; M90; See Table 26, Page 320

glipizide extended-release; M90; See Table 26, Page 320

glipizide; M90; See Table 26, Page 320

glofitamab-gxbm - PA; MB; See Table 75, Page 783

Gloperba (colchicine solution) - PA; See Table 62, Page 640

Glucagen (glucagon vial-Glucagen); See Table 78, Page 800

glucagon auto-injection, prefilled syringe, vial-Gvoke; See Table 78, Page 800

glucagon nasal powder; PD; See Table 78, Page 800

glucagon vial-Glucagen; See Table 78, Page 800

glucagon vial; See Table 78, Page 800

glucose products - PA ≥ 19 years; A90; See Table 6, Page 148

Glucotrol XL (glipizide extended-release); #, M90; See Table 26, Page 320

Glumetza (metformin extended-release, gastric tablet) - PA; M90; See Table 26, Page 320

glyburide / metformin; M90; See Table 26, Page 320

glyburide, micronized; M90; See Table 26, Page 320

glyburide; M90; See Table 26, Page 320

glycerin; *; See Table 79, Page 806

glycerol phenylbutyrate - PA; See Table 65, Page 661

glycopyrrolate / formoterol - PA; See Table 23, Page 293

glycopyrrolate 1 mg tablet; A90; See Table 72, Page 730

glycopyrrolate 1.5 mg tablet - PA; A90; See Table 72, Page 730

glycopyrrolate 2 mg tablet; A90; See Table 72, Page 730

glycopyrrolate inhalation solution - PA; See Table 23, Page 293

glycopyrrolate injection - PA; See Table 72, Page 730

glycopyrrolate oral solution - PA; A90; See Table 72, Page 730

glycopyrrolate orally disintegrating tablet - PA; See Table 72, Page 730

glycopyrronium cloth - PA; See Table 63, Page 644

Glynase (glyburide, micronized); #, M90; See Table 26, Page 320

Glyxambi (empagliflozin / linagliptin) - PA; See Table 26, Page 320

Gocovri (amantadine extended-release capsule) - PA; See Table 48, Page 468

Gohibic (vilobelimab COVID EUA - April 4, 2023); MB; See Table 72, Page 730

gold sodium thiomalate

golimumab - PA; See Table 5, Page 117

golimumab for infusion - PA; See Table 5, Page 117

golodirsen - PA; See Table 76, Page 790

Golytely (polyethylene glycol-electrolyte solution-Golytely); #, A90; See Table 61, Page 629

Gonitro (nitroglycerin sublingual powder) - PA; See Table 18, Page 245

Gralise (gabapentin extended-release) - PA; See Table 71, Page 706; See Table 72, Page 730

granisetron extended-release injection - PA > 2 units/28 days; See Table 27, Page 335

granisetron injection; See Table 27, Page 335

granisetron tablet - PA > 2 units/28 days; A90; See Table 27, Page 335

granisetron transdermal system - PA; See Table 27, Page 335

Granix (TBO-filgrastim); See Table 4, Page 112

grass pollen allergen extract - PA; See Table 72, Page 730

Grastek (timothy grass pollen allergen extract) - PA; See Table 72, Page 730

griseofulvin suspension, tablet; A90; See Table 47, Page 461

H

hyaluronate, crossed-linked - PA; MB; See Table 77, Page 798
hyaluronate, modified - PA; MB; See Table 77, Page 798
hyaluronate, stabilized - PA; MB; See Table 77, Page 798
hyaluronate-Euflexxa - PA; MB; See Table 77, Page 798
hyaluronate-Gelsyn - PA; MB; See Table 77, Page 798
hyaluronate-Genvisc - PA; MB; See Table 77, Page 798
hyaluronate-Hyalgan - PA; MB; See Table 77, Page 798
hyaluronate-Monovisc - PA; MB; See Table 77, Page 798
hyaluronate-Supartz - PA; MB; See Table 77, Page 798
hyaluronate-Synojoynt - PA; MB; See Table 77, Page 798
hyaluronate-Triluron - PA; MB; See Table 77, Page 798
hyaluronate-Trivisc - PA; MB; See Table 77, Page 798
hyaluronate-Visco-3 - PA; MB; See Table 77, Page 798
hyaluronidase, human recombinant; MB
hyaluronidase, ovine; MB
hyaluronidase; MB
Hycamtin (topotecan capsule); See Table 57, Page 518
Hycamtin (topotecan injection); MB; See Table 57, Page 518
hydralazine; M90; See Table 18, Page 245
Hydrea (hydroxyurea capsule); #, A90; See Table 57, Page 518
hydrochlorothiazide / triamterene; M90; See Table 18, Page 245
hydrochlorothiazide; M90; See Table 18, Page 245
hydrocodone / acetaminophen - PA > 80 mg/day hydrocodone and PA > 4 g/day acetaminophen; See Table 8, Page 157
hydrocodone / acetaminophen 300 mg - PA; See Table 8, Page 157
hydrocodone 5 mg, 10 mg / ibuprofen - PA; See Table 8, Page 157
hydrocodone 7.5 mg / ibuprofen - PA > 80 mg/day hydrocodone and PA > 3.2 g/day ibuprofen; See Table 8, Page 157
hydrocodone extended-release capsule - PA; See Table 8, Page 157
hydrocodone extended-release tablet - PA; See Table 8, Page 157
hydrocortisone / pramoxine foam; A90; See Table 16, Page 225
hydrocortisone butyrate / emollient - PA; A90; See Table 16, Page 225
hydrocortisone butyrate cream, ointment, solution; A90; See Table 16, Page 225
hydrocortisone butyrate lotion - PA; A90; See Table 16, Page 225
hydrocortisone cream, lotion, ointment; *, A90; See Table 16, Page 225
hydrocortisone enema; A90; See Table 33, Page 375
hydrocortisone foam; See Table 33, Page 375
hydrocortisone hemorrhoidal cream; A90; See Table 33, Page 375
hydrocortisone injection; See Table 5, Page 117
hydrocortisone probutate cream; See Table 16, Page 225
hydrocortisone solution - PA; A90; See Table 16, Page 225
hydrocortisone sprinkle capsule - PA; See Table 5, Page 117
hydrocortisone tablet; A90; See Table 5, Page 117
hydrocortisone valerate; A90; See Table 16, Page 225
hydrogen peroxide; *, A90; See Table 41, Page 422
hydromorphone - PA > 24 mg/day; See Table 8, Page 157
hydromorphone extended-release - PA; See Table 8, Page 157
hydrophilic ointment; *, A90; See Table 79, Page 806
hydroxocobalamin
hydroxychloroquine; A90
hydroxyprogesterone caproate injection - PA; See Table 70, Page 702
hydroxypropyl cellulose ophthalmic insert; See Table 29, Page 345
hydroxyurea capsule; A90; See Table 57, Page 518
hydroxyurea capsule; See Table 45, Page 451
hydroxyurea tablet - PA; See Table 45, Page 451
hydroxyzine hydrochloride; A90; See Table 12, Page 192
hydroxyzine pamoate; A90; See Table 12, Page 192
Hyftor (sirolimus gel) - PA; See Table 57, Page 518
hylan G-F20-Synvisc - PA; MB; See Table 77, Page 798
hylan G-F20-Synvisc-One - PA; MB; See Table 77, Page 798
Hylenex (hyaluronidase, human recombinant); MB
Hymovis (hyaluronate, modified) - PA; MB; See Table 77, Page 798
hyoscyamine oral; A90; See Table 61, Page 629
Hyper-Sal (sodium chloride 3.5%, 7% for inhalation)
Hyperhep B (hepatitis B immune globulin IM, human-Hyperhep B); See Table 1, Page 89
Hyperrab (rabies immune globulin IM, human-Hyperrab); See Table 1, Page 89
Hyperrho (rho(d) immune globulin IM, human-Hyperrho); See Table 1, Page 89
Hypertet (tetanus immune globulin IM, human); See Table 1, Page 89
Hyqvia (immune globulin subcutaneous injection, human / hyaluronidase human recombinant) - PA; See Table 1, Page 89
Hyrimoz (adalimumab-adaz) - PA; See Table 5, Page 117
Hysingla ER (hydrocodone extended-release tablet) - PA; See Table 8, Page 157
Hyzaar (losartan / hydrochlorothiazide); #, M90; See Table 18, Page 245

I

ibalizumab-uiyk - PA; See Table 38, Page 406
ibandronate injection - PA; MB; See Table 49, Page 475
ibandronate tablet; M90; See Table 49, Page 475
Ibrance (palbociclib) - PA; PD; See Table 57, Page 518
ibrexafungerp - PA; See Table 47, Page 461
ibrutinib - PA; See Table 57, Page 518
Ibsrela (tenapanor 50 mg tablet) - PA; See Table 61, Page 629
ibuprofen / famotidine - PA < 60 years; A90; See Table 11, Page 185
ibuprofen; *, A90; See Table 11, Page 185
icatibant - PA; See Table 60, Page 626
Iclusig (ponatinib) - PA; See Table 57, Page 518
icosapent ethyl - PA; BP, M90; See Table 13, Page 197
Idacio (adalimumab-aacf) - PA; See Table 5, Page 117
Idamycin PFS (idarubicin); MB; See Table 57, Page 518

J

K

L

M

Mekinist (trametinib) - PA; See Table 57, Page 518

Mektovi (binimetinib) - PA; See Table 57, Page 518

melatonin gummy, solution, tablet; *, A90; See Table 72, Page 730

meloxicam capsule - PA; A90; See Table 11, Page 185

meloxicam tablet; A90; See Table 11, Page 185

melphalan hepatic delivery system - PA; MB; See Table 57, Page 518

melphalan hydrochloride injection; MB; See Table 57, Page 518

melphalan injection; MB; See Table 57, Page 518

melphalan tablet; A90; See Table 57, Page 518

memantine / donepezil extended-release - PA; See Table 56, Page 511; See Table 71, Page 706

memantine extended-release - PA < 6 years and PA > 1 unit/day; A90; See Table 56, Page 511; See Table 71, Page 706

memantine solution - PA; A90; See Table 56, Page 511; See Table 71, Page 706

memantine tablet - PA < 6 years and PA > 2 units/day; A90; See Table 56, Page 511; See Table 71, Page 706

memantine titration pack - PA < 6 years and PA > 49 units/28 days; A90; See Table 56, Page 511; See Table 71, Page 706

Menactra (quadrivalent meningococcal conjugate vaccine-Menactra); 1; See Table 32, Page 368

Menest (estrogens,esterified); A90

meningococcal group B vaccine-Bexsero; 1; See Table 32, Page 368

meningococcal group B vaccine-Trumenba; 1; See Table 32, Page 368

Menostar (estradiol-menostar)

Menquadfi (quadrivalent meningococcal conjugate vaccine-Menquadfi); 1; See Table 32, Page 368

Mentax (butenafine); See Table 28, Page 341

Menveo (quadrivalent meningococcal conjugate vaccine-Menveo); 1; See Table 32, Page 368

meperidine - PA; See Table 8, Page 157

Mephyton (phytonadione); #, A90

mepivacaine; MB

mepolizumab - PA; See Table 64, Page 649

meprobamate - PA; See Table 69, Page 690; See Table 71, Page 706

Mepron (atovaquone); #, A90; See Table 35, Page 383

Mepsevii (vestronidase alfa-vjbk) - PA; MB; See Table 65, Page 661

mercaptopurine oral suspension - PA; See Table 57, Page 518

mercaptopurine tablet; A90; See Table 57, Page 518

meropenem / vaborbactam - PA; See Table 66, Page 673

meropenem; See Table 66, Page 673

mesalamine 0.375 gram extended-release capsule; BP, A90; See Table 33, Page 375

mesalamine 1.2 gram delayed-release tablet; BP, A90; See Table 33, Page 375

mesalamine 250 mg, 500 mg controlled-release capsule; BP, A90; See Table 33, Page 375

mesalamine 400 mg delayed-release capsule - PA; A90; See Table 33, Page 375

mesalamine 800 mg delayed-release tablet - PA; A90; See Table 33, Page 375

mesalamine enema; A90; See Table 33, Page 375

mesalamine kit - PA; A90; See Table 33, Page 375

mesalamine suppository; A90; See Table 33, Page 375

mesna injection; MB

mesna tablet

Mesnex (mesna injection); MB

Mesnex (mesna tablet)

Mestinon (pyridostigmine bromide 60 mg tablet, 180 mg extended-release tablet); #, A90; See Table 72, Page 730

Mestinon (pyridostigmine bromide solution); BP, A90; See Table 72, Page 730

metaxalone - PA; A90; See Table 7, Page 153

metformin extended-release suspension - PA; See Table 26, Page 320

metformin extended-release, gastric tablet - PA; M90; See Table 26, Page 320

metformin extended-release, osmotic tablet - PA; M90; See Table 26, Page 320

metformin extended-release, XR tablet; M90; See Table 26, Page 320

metformin immediate-release 500 mg, 850 mg, 1,000 mg tablet; M90; See Table 26, Page 320

metformin immediate-release 625 mg tablet - PA; M90; See Table 26, Page 320

metformin immediate-release solution - PA ≥ 13 years; M90; See Table 26, Page 320

methadone injection - PA; See Table 8, Page 157

methadone oral-Dolophine - PA; See Table 8, Page 157

methadone oral-Methadose - PA; See Table 8, Page 157

Methadose (methadone oral-Methadose) - PA; See Table 8, Page 157

methamphetamine - PA; See Table 31, Page 358; See Table 71, Page 706

methazolamide; A90

methenamine; A90; See Table 35, Page 383

methimazole; M90

methocarbamol - PA < 16 years; A90; See Table 7, Page 153

methotrexate 2 mg/mL oral solution - PA; See Table 5, Page 117

methotrexate 2.5 mg/mL oral solution - PA; See Table 5, Page 117

methotrexate injection; See Table 57, Page 518

methotrexate subcutaneous injection-Otrexup - PA; See Table 5, Page 117

methotrexate subcutaneous injection-Rasuvo - PA; See Table 5, Page 117

methotrexate subcutaneous injection-Reditrex - PA; See Table 5, Page 117

methotrexate tablet; A90; See Table 5, Page 117; See Table 57, Page 518

methoxsalen capsules; A90

methoxsalen topical; A90

methoxy polyethylene glycol / epoetin beta; MB; See Table 4, Page 112

methsuximide; A90; See Table 20, Page 268

methylcellulose; *, A90; See Table 61, Page 629

methyldopa / hydrochlorothiazide; M90; See Table 18, Page 245

methyldopa; M90; See Table 18, Page 245

N

O

Oxlumo (lumasiran) - PA; [PD], MB; See Table 72, Page 730

Oxsoralen (methoxsalen topical); A90

Oxsoralen-Ultra (methoxsalen capsules); #, A90

Oxtellar XR (oxcarbazepine extended-release) - PA; BP; See Table 20, Page 268; See Table 71, Page 706

oxybutynin extended-release tablet; A90; See Table 46, Page 457

oxybutynin gel; BP; See Table 46, Page 457

oxybutynin immediate-release 2.5 mg tablet - PA; A90; See Table 46, Page 457

oxybutynin immediate-release 5 mg tablet, syrup; A90; See Table 46, Page 457

oxybutynin solution - PA; A90; See Table 46, Page 457

oxybutynin transdermal system; See Table 46, Page 457

oxycodone / acetaminophen - PA > 80 mg/day oxycodone and PA > 4 g/day acetaminophen; See Table 8, Page 157

oxycodone / acetaminophen 300 mg - PA; See Table 8, Page 157

oxycodone / acetaminophen-Percocet - PA > 80 mg/day oxycodone and PA > 4 g/day acetaminophen; See Table 8, Page 157

oxycodone / aspirin - PA > 80 mg/day oxycodone and PA > 4 g/day aspirin; See Table 8, Page 157

oxycodone extended-release capsule - PA; See Table 8, Page 157

oxycodone extended-release tablet - PA; BP; See Table 8, Page 157

oxycodone immediate-release - PA > 80 mg/day; See Table 8, Page 157

Oxycontin (oxycodone extended-release tablet) - PA; BP; See Table 8, Page 157

oxymetazoline cream - PA; See Table 10, Page 177

oxymorphone extended-release, oral - PA; See Table 8, Page 157

oxymorphone immediate-release, oral - PA; See Table 8, Page 157

Oxytrol (oxybutynin transdermal system); See Table 46, Page 457

ozanimod for multiple sclerosis - PA; See Table 52, Page 494

ozanimod for ulcerative colitis - PA; See Table 5, Page 117

Ozempic (semaglutide injection-Ozempic) - PA; See Table 26, Page 320

ozenoxacin - PA; See Table 41, Page 422

Ozurdex (dexamethasone intravitreal implant); MB; See Table 29, Page 345

P

paclitaxel injectable suspension; MB; See Table 57, Page 518

paclitaxel injection; See Table 57, Page 518

pacritinib - PA; See Table 57, Page 518

Padcev (enfortumab vedotin-ejfv) - PA; MB; See Table 57, Page 518

palbociclib - PA; [PD]; See Table 57, Page 518

Palforzia (peanut allergen powder-dnfp) - PA; See Table 72, Page 730

palifermin; MB

paliperidone 1.5 mg, 3 mg, 9 mg tablet - PA < 10 years and PA > 1 unit/day; A90; See Table 24, Page 301; See Table 71, Page 706

paliperidone 6 mg tablet - PA < 10 years and PA > 2 units/day; A90; See Table 24, Page 301; See Table 71, Page 706

paliperidone extended-release 1-month injection - PA < 10 years, PA > 2 injections/28 days within the first 28 days of therapy and PA > 1 injection/28 days after 28 days of therapy; [PD]; See Table 24, Page 301; See Table 71, Page 706

paliperidone extended-release 3-month injection - PA < 10 years and PA > 1 injection/84 days; [PD]; See Table 24, Page 301; See Table 71, Page 706

paliperidone extended-release 6-month injection - PA < 10 years and PA > 1 injection/168 days; [PD]; See Table 24, Page 301; See Table 71, Page 706

palivizumab - PA; See Table 37, Page 403

palonosetron 0.25 mg/2 mL injection - PA > 2 units/28 days; A90; See Table 27, Page 335

palonosetron 0.25 mg/5 mL injection - PA > 2 units/28 days; See Table 27, Page 335

palovarotene - PA; See Table 72, Page 730

Palynziq (pegvaliase-pqpz) - PA; See Table 65, Page 661

Pamelor (nortriptyline) - PA < 6 years; #, A90; See Table 17, Page 231; See Table 71, Page 706

pamidronate; MB; See Table 49, Page 475

pancrelipase-Creon DR; See Table 65, Page 661

pancrelipase-Pertzye DR; See Table 65, Page 661

pancrelipase-Viokace; See Table 65, Page 661

pancrelipase-Zenpep DR; See Table 65, Page 661

Pandel (hydrocortisone probutate cream); See Table 16, Page 225

panitumumab; MB; See Table 57, Page 518

Panretin (alitretinoin) - PA; See Table 72, Page 730

pantoprazole 40 mg suspension - PA; BP, M90; See Table 3, Page 104

pantoprazole IV; See Table 3, Page 104

pantoprazole tablet - PA > 4 units/day; M90; See Table 3, Page 104

Panzyga (immune globulin IV, human-ifas) - PA; See Table 1, Page 89

Paragard (copper IUD)

paricalcitol capsule - PA; M90; See Table 6, Page 148

paricalcitol injection; MB; See Table 6, Page 148

Parlodel (bromocriptine 2.5 mg, 5 mg); #, A90; See Table 48, Page 468

paromomycin; A90; See Table 35, Page 383

paroxetine controlled-release - PA; A90; See Table 17, Page 231; See Table 71, Page 706

paroxetine hydrochloride - PA < 6 years; A90; See Table 17, Page 231; See Table 71, Page 706

paroxetine mesylate capsule - PA; A90; See Table 72, Page 730

Parsabiv (etelcalcetide); MB

pasireotide - PA; See Table 22, Page 288

pasireotide injectable suspension - PA; MB; See Table 22, Page 288

Patanase (olopatadine nasal spray) - PA; A90; See Table 12, Page 192

patiromer - PA > 1 unit/day; See Table 72, Page 730

patisiran - PA; [PD], MB; See Table 72, Page 730

Paxil (paroxetine hydrochloride) - PA < 6 years; #, A90; See Table 17, Page 231;

Procysbi (cysteamine delayed-release capsule) - PA; See Table 72, Page 730

Procysbi (cysteamine delayed-release granule) - PA; See Table 72, Page 730

Profilnine SD (factor IX complex human-Profilnine SD); See Table 80, Page 809

progesterone capsule; A90

progesterone gel - PA; See Table 70, Page 702

progesterone injection

progesterone vaginal insert - PA; See Table 70, Page 702

Proglycem (diazoxide); BP, A90

Prograf (tacrolimus granules) - PA; See Table 5, Page 117

Prograf (tacrolimus immediate-release capsule); #, A90; See Table 5, Page 117

Prograf (tacrolimus injection); MB; See Table 5, Page 117

Prolastin-C (alpha-1-proteinase inhibitor, human-Prolastin-C); MB

Prolensa (bromfenac 0.07%); BP, A90; See Table 29, Page 345

Proleukin (aldesleukin) - PA; See Table 57, Page 518

Prolia (denosumab-Prolia) - PA; See Table 49, Page 475

Promacta (eltrombopag olamine) - PA; BP; See Table 68, Page 684

promethazine; A90; See Table 12, Page 192

Prometrium (progesterone capsule); #, A90

propafenone extended-release; M90; See Table 18, Page 245

propafenone immediate-release; M90; See Table 18, Page 245

proparacaine; A90; See Table 59, Page 622

propranolol / hydrochlorothiazide; M90; See Table 18, Page 245

propranolol extended-release; M90; See Table 18, Page 245

propranolol immediate-release; M90; See Table 18, Page 245

propranolol long-acting capsule - PA; See Table 18, Page 245

propranolol solution - PA; M90; See Table 18, Page 245

propylthiouracil; M90

Proquad (measles / mumps / rubella / varicella virus vaccine); 1; See Table 32, Page 368

Proscar (finasteride); #, M90; See Table 19, Page 265

protein C concentrate - PA; MB; See Table 72, Page 730

prothrombin complex concentrate, human

Protonix (pantoprazole 40 mg suspension) - PA; BP, M90; See Table 3, Page 104

Protonix (pantoprazole tablet) - PA > 4 units/day; #, M90; See Table 3, Page 104

Protonix IV (pantoprazole IV); #; See Table 3, Page 104

protriptyline - PA; A90; See Table 17, Page 231; See Table 71, Page 706

Provenge (sipuleucel-T) - PA; MB; See Table 57, Page 518

Provera (medroxyprogesterone tablet); #, A90

Provigil (modafinil 100 mg) - PA < 6 years and PA > 1.5 units/day; #; See Table 50, Page 482; See Table 71, Page 706

Provigil (modafinil 200 mg) - PA < 6 years and PA > 2 units/day; #; See Table 50, Page 482; See Table 71, Page 706

Prozac (fluoxetine 10 mg, 20 mg, 40 mg capsule, solution) - PA < 6 years; #, A90; See Table 17, Page 231; See Table 71, Page 706

prucalopride - PA; See Table 61, Page 629

Prudoxin (doxepin cream-Prudoxin) - PA; See Table 63, Page 644

pseudoephedrine - PA > 240 mg/day;*; See Table 72, Page 730

psyllium capsule; *, M90; See Table 61, Page 629

psyllium powder; *, A90; See Table 61, Page 629

Pulmicort (budesonide inhalation powder); See Table 23, Page 293

Pulmicort (budesonide inhalation suspension) - PA ≥ 13 years; #, A90; See Table 23, Page 293

Pulmosal (sodium chloride 7% for inhalation)

Pulmozyme (dornase alfa); See Table 21, Page 282

Purixan (mercaptopurine oral suspension) - PA; See Table 57, Page 518

Pylera (bismuth subcitrate / metronidazole / tetracycline); BP, A90; See Table 3, Page 104

pyrantel pamoate; See Table 35, Page 383

pyrazinamide; A90; See Table 35, Page 383

pyridostigmine bromide 30 mg tablet - PA; A90; See Table 72, Page 730

pyridostigmine bromide 60 mg tablet, 180 mg extended-release tablet; A90; See Table 72, Page 730

pyridostigmine bromide solution; BP, A90; See Table 72, Page 730

pyridoxine; *, M90; See Table 6, Page 148

pyrimethamine - PA; BP, A90; See Table 35, Page 383

Pyrukynd (mitapivat) - PA; See Table 65, Page 661

Q

Qalsody (tofersen) - PA; MB; See Table 72, Page 730

Qbrelis (lisinopril solution) - PA; See Table 18, Page 245

Qbrexza (glycopyrronium cloth) - PA; See Table 63, Page 644

Qdolo (tramadol solution) - PA; See Table 8, Page 157

Qelbree (viloxazine) - PA; See Table 31, Page 358; See Table 71, Page 706

Qinlock (ripretinib) - PA; See Table 57, Page 518

Qnasl (beclomethasone nasal aerosol) - PA; See Table 25, Page 316

Qtern (dapagliflozin / saxagliptin) - PA; See Table 26, Page 320

Quadracel (tetanus toxoids / diphtheria / acellular pertussis / inactivated poliovirus vaccine); See Table 32, Page 368

Quadramet (samarium Sm 153 lexidronam); MB

quadrivalent meningococcal conjugate vaccine-Menactra; 1; See Table 32, Page 368

quadrivalent meningococcal conjugate vaccine-Menquadfi; 1; See Table 32, Page 368

quadrivalent meningococcal conjugate vaccine-Menveo; 1; See Table 32, Page 368

Qualaquin (quinine); #, A90; See Table 35, Page 383

Quartette (levonorgestrel / ethinyl estradiol-Quartette); #, M90

quazepam - PA; See Table 69, Page 690; See Table 71, Page 706

Qudexy XR (topiramate extended-release capsule-Qudexy XR) - PA < 6 years; BP, A90; See Table 20, Page 268; See Table 71, Page 706

quetiapine - PA < 10 years and PA > 3 units/day; A90; See Table 24, Page 301; See Table 71, Page 706

quetiapine extended-release - PA < 10 years and PA > 2 units/day; A90; See Table 24, Page 301; See Table 71, Page 706

Quickvue (COVID-19 antigen self-test) - PA > 2 tests/28 days; See Table 72, Page 730

Quillichew ER (methylphenidate extended-release chewable tablet) - PA; See Table 31, Page 358; See Table 71, Page 706

Quillivant XR (methylphenidate extended-release oral suspension) - PA; See Table 31, Page 358; See Table 71, Page 706

quinapril / hydrochlorothiazide; M90; See Table 18, Page 245

quinapril; M90; See Table 18, Page 245

quinidine gluconate extended-release - PA; A90; See Table 18, Page 245

quinidine sulfate; M90; See Table 18, Page 245

quinine; A90; See Table 35, Page 383

quizartinib - PA; See Table 57, Page 518

Qulipta (atogepant) - PA; [PD]; See Table 14, Page 208

Qutenza (capsaicin high dose patch) - PA; MB; See Table 59, Page 622

Quviviq (daridorexant) - PA; See Table 15, Page 218; See Table 71, Page 706

Qvar Redihaler (beclomethasone inhaler) - PA; See Table 23, Page 293

R

Rabavert (rabies virus vaccine-Rabavert); See Table 32, Page 368

rabeprazole delayed-release capsule - PA; See Table 3, Page 104

rabeprazole delayed-release tablet - PA > 1 unit/day; M90; See Table 3, Page 104

rabies immune globulin IM, human-Hyperrab; See Table 1, Page 89

rabies immune globulin IM, human-Kedrab; See Table 1, Page 89

rabies virus vaccine-Imovax Rabies; See Table 32, Page 368

rabies virus vaccine-Rabavert; See Table 32, Page 368

Radicava (edaravone injection) - PA; See Table 72, Page 730

Radicava ORS (edaravone suspension) - PA; See Table 72, Page 730

Ragwitek (short ragweed pollen allergen extract) - PA; See Table 72, Page 730

raloxifene; M90; See Table 49, Page 475

raltegravir; BP; See Table 38, Page 406

ramelteon - PA > 1 unit/day; BP, A90; See Table 15, Page 218

ramipril; M90; See Table 18, Page 245

ramucirumab - PA; MB; See Table 57, Page 518

ranibizumab-eqrn; MB

ranibizumab-nuna; MB

ranibizumab; MB

ranolazine extended-release granules - PA; See Table 18, Page 245

ranolazine extended-release tablet; A90; See Table 18, Page 245

Rapaflo (silodosin) - PA; M90; See Table 19, Page 265

Rapamune (sirolimus solution, tablet); #, A90; See Table 5, Page 117

rasagiline - PA > 1 unit/day; A90; See Table 48, Page 468

rasburicase; MB

Rasuvo (methotrexate subcutaneous injection-Rasuvo) - PA; See Table 5, Page 117

Ravicti (glycerol phenylbutyrate) - PA; See Table 65, Page 661

ravulizumab-cwvz - PA; MB; See Table 72, Page 730

Rayaldee (calcifediol) - PA; See Table 6, Page 148

Rayos (prednisone delayed-release) - PA; See Table 5, Page 117

Razadyne ER (galantamine extended-release capsule) - PA > 1 unit/day; #, A90; See Table 56, Page 511

Rebif (interferon beta-1a-Rebif); See Table 52, Page 494

Rebinyn (coagulation factor IX recombinant, glycopegylated-Rebinyn); See Table 80, Page 809

Reblozyl (luspatercept-aamt) - PA; MB; See Table 45, Page 451

Rebyota (fecal microbiota, live-jslm) - PA; See Table 61, Page 629

Recarbrio (imipenem / cilastatin / relebactam) - PA; See Table 66, Page 673

Reclast (zoledronic acid 5 mg); MB; See Table 49, Page 475

Recombinate (antihemophilic factor, recombinant-Recombinate); See Table 80, Page 809

Recombivax HB (hepatitis B recombinant vaccine); 1; See Table 32, Page 368

Recorlev (levoketoconazole) - PA; See Table 22, Page 288

Rectiv (nitroglycerin 0.4% ointment)

Reditrex (methotrexate subcutaneous injection-Reditrex) - PA; See Table 5, Page 117

Reese's Pinworm (pyrantel pamoate); See Table 35, Page 383

Reglan (metoclopramide); #, A90

regorafenib - PA; See Table 57, Page 518

Regranex (becaplermin) - PA; See Table 72, Page 730

Relafen DS (nabumetone 1000 mg) - PA; See Table 11, Page 185

Relenza (zanamivir) - PA < 5 years and PA > 20 inhalations/ claim and PA > 40 inhalations/ 365 days; See Table 39, Page 414

Releuko (filgrastim-ayow); See Table 4, Page 112

Relexxii (methylphenidate extended-release-Relexxii) - PA; See Table 31, Page 358; See Table 71, Page 706

Relistor (methylnaltrexone) - PA; See Table 61, Page 629

Relpax (eletriptan) - PA; A90; See Table 14, Page 208

relugolix - PA; See Table 2, Page 97

relugolix / estradiol / norethindrone - PA; See Table 2, Page 97

remdesivir; MB; See Table 72, Page 730

Remeron (mirtazapine) - PA < 6 years; #, A90; See Table 17, Page 231; See Table 71, Page 706

Remeron Sol Tab (mirtazapine orally disintegrating tablet) - PA; A90; See Table 17, Page 231; See Table 71, Page 706

Remicade (infliximab-Remicade) - PA; See Table 5, Page 117

remimazolam - PA; MB; See Table 69, Page 690

Remodulin (treprostinil injection) - PA; BP; See Table 43, Page 429

risedronate - PA; M90; See Table 49, Page 475

risedronate delayed-release - PA; BP, M90; See Table 49, Page 475

Risperdal (risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg tablets) - PA < 10 years and PA > 3 units/day; #, A90; See Table 24, Page 301; See Table 71, Page 706

Risperdal (risperidone 4 mg tablet) - PA < 10 years and PA > 4 units/day; #, A90; See Table 24, Page 301; See Table 71, Page 706

Risperdal (risperidone solution) - PA < 10 years and PA > 16 mL/day; #, A90; See Table 24, Page 301; See Table 71, Page 706

Risperdal Consta (risperidone 12.5 mg, 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection-Risperdal Consta) - PA < 10 years and PA > 2 injections/28 days; BP; See Table 24, Page 301; See Table 71, Page 706

risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg orally disintegrating tablet - PA < 10 years and PA > 2 units/day; A90; See Table 24, Page 301; See Table 71, Page 706

risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg tablets - PA < 10 years and PA > 3 units/day; A90; See Table 24, Page 301; See Table 71, Page 706

risperidone 12.5 mg, 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection-Risperdal Consta - PA < 10 years and PA > 2 injections/28 days; BP; See Table 24, Page 301; See Table 71, Page 706

risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection - PA < 10 years and PA > 1 injection/56 days; PD; See Table 24, Page 301; See Table 71, Page 706

risperidone 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection-Rykindo - PA; See Table 24, Page 301; See Table 71, Page 706

risperidone 3 mg, 4 mg orally disintegrating tablet - PA; A90; See Table 24, Page 301; See Table 71, Page 706

risperidone 4 mg tablet - PA < 10 years and PA > 4 units/day; A90; See Table 24, Page 301; See Table 71, Page 706

risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection - PA < 10 years and PA > 1 injection/28 days; PD; See Table 24, Page 301; See Table 71, Page 706

risperidone 90 mg, 120 mg extended-release subcutaneous injection - PA < 10 years and > 1 injection/28 days; PD; See Table 24, Page 301; See Table 71, Page 706

risperidone solution - PA < 10 years and PA > 16 mL/day; A90; See Table 24, Page 301; See Table 71, Page 706

Ritalin (methylphenidate-Ritalin) - PA < 3 years or ≥ 21 years and PA > 3 units/day; #; See Table 31, Page 358; See Table 71, Page 706

Ritalin LA (methylphenidate-Ritalin LA) - PA; See Table 31, Page 358; See Table 71, Page 706

ritlecitinib - PA; See Table 5, Page 117

ritonavir packet; See Table 38, Page 406

ritonavir tablet; BP, PD, A90; See Table 38, Page 406

Rituxan (rituximab) - PA; MB; See Table 57, Page 518

Rituxan Hycela (rituximab / hyaluronidase human) - PA; MB; See Table 57, Page 518

rituximab - PA; MB; See Table 57, Page 518

rituximab / hyaluronidase human - PA; MB; See Table 57, Page 518

rituximab-abbs - PA; MB; See Table 57, Page 518

rituximab-arrx - PA; MB; See Table 57, Page 518

rituximab-pvvr - PA; MB; See Table 57, Page 518

rivaroxaban 10 mg, 15 mg, 20 mg tablet, starter pack; See Table 58, Page 618

rivaroxaban 2.5 mg tablet - PA > 2 units/day; See Table 58, Page 618

rivaroxaban suspension - PA ≥ 18 years; See Table 58, Page 618

rivastigmine capsule - PA > 2 units/day; A90; See Table 56, Page 511

rivastigmine patch - PA > 1 unit/day; BP, A90; See Table 56, Page 511

Rivive (naloxone 3 mg nasal spray); See Table 36, Page 396

Rixubis (coagulation factor IX, recombinant); See Table 80, Page 809

rizatriptan orally disintegrating tablet - PA > 18 units/30 days; A90; See Table 14, Page 208

rizatriptan tablet - PA > 18 units/30 days; A90; See Table 14, Page 208

Robaxin (methocarbamol) - PA < 16 years; #, A90; See Table 7, Page 153

Robinul (glycopyrrolate 1 mg tablet); #, A90; See Table 72, Page 730

Robinul Forte (glycopyrrolate 2 mg tablet); #, A90; See Table 72, Page 730

Rocaltrol (calcitriol capsule); #, M90; See Table 6, Page 148

Rocaltrol (calcitriol solution) - PA; M90; See Table 6, Page 148

Rocklatan (netarsudil / latanoprost) - PA; See Table 51, Page 488

Roctavian (valoctocogene roxaparvovec-rvox) - PA; CO, MB; See Table 80, Page 809

roflumilast cream, foam - PA; See Table 42, Page 425

roflumilast tablet - PA; M90; See Table 40, Page 417

Rolvedon (eflapegrastim-xnst); MB; See Table 4, Page 112

romidepsin lyophilized - PA; MB; See Table 57, Page 518

romidepsin non-lyophilized - PA; MB; See Table 57, Page 518

romiplostim - PA; MB; See Table 68, Page 684

romosozumab-aqqg - PA; See Table 49, Page 475

ropeginterferon alfa-2b-njft - PA; See Table 57, Page 518

ropinirole extended-release; A90; See Table 48, Page 468

ropinirole; A90; See Table 48, Page 468

ropivacaine; MB

rosuvastatin 40 mg - PA > 1 unit/day; M90; See Table 13, Page 197

rosuvastatin 5 mg, 10 mg, 20 mg - PA > 1.5 units/day; M90; See Table 13, Page 197

rosuvastatin sprinkle capsule - PA; See Table 13, Page 197

Rotarix (rotavirus vaccine, live, oral); 1; See Table 32, Page 368

Rotateq (rotavirus vaccine, live, oral, pentavalent); 1; See Table 32, Page 368

rotavirus vaccine, live, oral, pentavalent; 1; See Table 32, Page 368

rotavirus vaccine, live, oral; 1; See Table 32, Page 368

rotigotine transdermal system - PA > 1 unit/day; BP; See Table 48, Page 468

Rowasa (mesalamine enema); #, A90; See Table 33, Page 375

S

Stribild (elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil fumarate); See Table 38, Page 406

Striverdi (olodaterol) - PA; See Table 23, Page 293

Stromectol (ivermectin tablet); #; See Table 35, Page 383

Sublocade (buprenorphine extended-release injection-Sublocade); PD; See Table 36, Page 396

Suboxone (buprenorphine / naloxone film ≤ 24 mg/day); BP, PD; See Table 36, Page 396

Suboxone (buprenorphine / naloxone film) - PA > 32 mg/day; BP, PD; See Table 36, Page 396

Suboxone (buprenorphine / naloxone film) - PA > 90 days (> 24 mg/day and ≤ 32 mg/day); BP, PD; See Table 36, Page 396

succimer

Sucraid (sacrosidase) - PA; See Table 65, Page 661

sucralfate; A90

sucroferric oxyhydroxide

sufentanil injection; See Table 8, Page 157

Suflave (polyethylene glycol / sodium sulfate / potassium chloride / magnesium sulfate / sodium chloride) - PA; See Table 61, Page 629

Sular (nisoldipine) - PA; M90; See Table 18, Page 245

sulfacetamide / prednisolone sodium phosphate ophthalmic solution; A90; See Table 34, Page 379

sulfacetamide 10% lotion - PA ≥ 21 years; A90; See Table 10, Page 177

sulfacetamide ophthalmic ointment, solution; A90; See Table 34, Page 379

sulfadiazine; A90; See Table 35, Page 383

sulfamethoxazole / trimethoprim injection; See Table 66, Page 673

sulfamethoxazole / trimethoprim suspension; A90; See Table 35, Page 383

sulfamethoxazole / trimethoprim tablet; See Table 35, Page 383

Sulfamylon (mafenide); #, A90; See Table 41, Page 422

sulfasalazine delayed-release; A90; See Table 33, Page 375

sulfasalazine; A90; See Table 33, Page 375

Sulfatrim (sulfamethoxazole / trimethoprim suspension); #, A90; See Table 35, Page 383

sulindac; A90; See Table 11, Page 185

sumatriptan / naproxen - PA; A90; See Table 14, Page 208

sumatriptan 10 mg nasal spray - PA; See Table 14, Page 208

sumatriptan 5 mg, 20 mg nasal spray - PA > 18 units/30 days; A90; See Table 14, Page 208

sumatriptan injection-Imitrex - PA; See Table 14, Page 208

sumatriptan injection-Zembrace - PA; See Table 14, Page 208

sumatriptan tablet - PA > 18 units/30 days; A90; See Table 14, Page 208

sunitinib - PA; BP, A90; See Table 57, Page 518

Sunlenca (lenacapavir) - PA; See Table 38, Page 406

Sunosi (solriamfetol) - PA; See Table 50, Page 482

Supartz (hyaluronate-Supartz) - PA; MB; See Table 77, Page 798

Supprelin LA (histrelin) - PA; MB; See Table 2, Page 97

Suprep (sodium sulfate / potassium sulfate / magnesium sulfate); BP, A90; See Table 61, Page 629

Sustol (granisetron extended-release injection) - PA > 2 units/28 days; See Table 27, Page 335

Susvimo (ranibizumab); MB

Sutab (sodium sulfate / magnesium sulfate / potassium chloride) - PA; See Table 61, Page 629

Sutent (sunitinib) - PA; BP, A90; See Table 57, Page 518

sutimlimab-jome - PA; MB; See Table 72, Page 730

suvorexant - PA; See Table 15, Page 218; See Table 71, Page 706

Syfovre (pegcetacoplan 150 mg/mL vial) - PA; MB; See Table 72, Page 730

Sylvant (siltuximab) - PA; MB; See Table 5, Page 117

Symbicort (budesonide / formoterol); BP, A90; See Table 23, Page 293

Symbyax (olanzapine / fluoxetine) - PA; A90; See Table 17, Page 231; See Table 24, Page 301; See Table 71, Page 706

Symdeko (tezacaftor / ivacaftor) - PA; PD; See Table 21, Page 282

Symfi (efavirenz 600 mg / lamivudine 300 mg / tenofovir disoproxil fumarate 300 mg) - PA; A90; See Table 38, Page 406

Symfi Lo (efavirenz 400 mg / lamivudine 300 mg / tenofovir disoproxil fumarate 300 mg) - PA; A90; See Table 38, Page 406

Symjepi (epinephrine injection); See Table 72, Page 730

Symlinpen (pramlintide); See Table 26, Page 320

Sympazan (clobazam film) - PA; See Table 20, Page 268

Symproic (naldemedine) - PA; See Table 61, Page 629

Symtuza (darunavir / cobicistat / emtricitabine / tenofovir alafenamide); PD; See Table 38, Page 406

Synagis (palivizumab) - PA; See Table 37, Page 403

Synalar (fluocinolone 0.025% cream); #, A90; See Table 16, Page 225

Synalar (fluocinolone ointment); #, A90; See Table 16, Page 225

Synalar (fluocinolone solution); #, A90; See Table 16, Page 225

Synarel (nafarelin) - PA; See Table 2, Page 97

Synjardy (empagliflozin / metformin); See Table 26, Page 320

Synjardy XR (empagliflozin / metformin extended-release); See Table 26, Page 320

Synojoynt (hyaluronate-Synojoynt) - PA; MB; See Table 77, Page 798

Synribo (omacetaxine mepesuccinate) - PA; See Table 57, Page 518

Synthroid (levothyroxine-Synthroid); #, M90

Synvisc (hylan G-F20-Synvisc) - PA; MB; See Table 77, Page 798

Synvisc-One (hylan G-F20-Synvisc-One) - PA; MB; See Table 77, Page 798

Syprine (trientine 250 mg capsule); BP, A90; See Table 65, Page 661

T

Tabrecta (capmatinib) - PA; See Table 57, Page 518

Taclonex (betamethasone / calcipotriene topical suspension) - PA; BP, A90; See

U

V

Vowst (fecal microbiota spores, live-brpk) - PA; See Table 61, Page 629

voxelotor - PA; See Table 45, Page 451

Voxzogo (vosoritide) - PA; See Table 72, Page 730

Voydeya (danicopan) - PA; See Table 72, Page 730

Vpriv (velaglucerase alfa) - PA; MB; See Table 65, Page 661

Vraylar (cariprazine) - PA; PD; See Table 24, Page 301; See Table 71, Page 706

Vtama (tapinarof) - PA; See Table 42, Page 425

Vuity (pilocarpine 1.25% ophthalmic solution) - PA; See Table 72, Page 730

Vumerity (diroximel fumarate) - PA; See Table 52, Page 494

Vusion (miconazole / zinc oxide ointment); BP, A90; See Table 28, Page 341

vutrisiran - PA; PD, MB; See Table 72, Page 730

Vyepti (eptinezumab-jjmr) - PA; MB; See Table 14, Page 208

Vyjuvek (beremagene geperpavec-svdt) - PA; See Table 72, Page 730

Vyndamax (tafamidis) - PA; See Table 72, Page 730

Vyndaqel (tafamidis) - PA; See Table 72, Page 730

Vyondys 53 (golodirsen) - PA; See Table 76, Page 790

Vytorin (ezetimibe / simvastatin) - PA > 1 unit/day; #, M90; See Table 13, Page 197

Vyvanse (lisdexamfetamine capsule) - PA < 3 years or ≥ 21 years and PA > 2 units/day; BP; See Table 31, Page 358; See Table 71, Page 706

Vyvanse (lisdexamfetamine chewable tablet) - PA; BP; See Table 31, Page 358; See Table 71, Page 706

Vyvgart (efgartigimod alfa-fcab) - PA; MB; See Table 72, Page 730

Vyvgart Hytrulo (efgartigimod alfa-fcab and hyaluronidase-qvfc) - PA; MB; See Table 72, Page 730

Vyxeos (daunorubicin / cytarabine) - PA; MB; See Table 57, Page 518

Vyzulta (latanoprostene) - PA; See Table 51, Page 488

W

Wainua (eplontersen) - PA; See Table 72, Page 730

Wakix (pitolisant) - PA; See Table 50, Page 482

warfarin; A90; See Table 58, Page 618

Wegovy (semaglutide injection-Wegovy) - PA; PD; See Table 81, Page 815

Welchol (colesevelam); #, M90; See Table 13, Page 197; See Table 26, Page 320

Welireg (belzutifan) - PA; See Table 57, Page 518

Wellbutrin SR (bupropion hydrochloride sustained-release-Wellbutrin SR) - PA < 6 years; #, A90; See Table 17, Page 231; See Table 71, Page 706

Wellbutrin XL (bupropion hydrochloride extended-release 150 mg, 300 mg tablet) - PA < 6 years and PA > 1 unit/day; #, A90; See Table 17, Page 231; See Table 71, Page 706

Wilate (von willebrand factor / coagulation factor VIII complex); See Table 80, Page 809

Winlevi (clascoterone) - PA; See Table 10, Page 177

Winrevair (sotatercept-csrk) - PA; See Table 43, Page 429

Winrho SDF (rho(d) immune globulin IV, human-Winrho SDF); MB; See Table 1, Page 89

witch hazel; *, A90

X

Xaciato (clindamycin vaginal gel) - PA; See Table 41, Page 422

Xadago (safinamide) - PA; See Table 48, Page 468

Xalatan (latanoprost solution - Xalatan); #, M90; See Table 51, Page 488

Xalkori (crizotinib) - PA; See Table 57, Page 518

Xanax (alprazolam) - PA < 6 years; #; See Table 69, Page 690; See Table 71, Page 706

Xanax XR (alprazolam extended-release) - PA < 6 years and PA > 2 units/day; #; See Table 69, Page 690; See Table 71, Page 706

Xarelto (rivaroxaban 10 mg, 15 mg, 20 mg tablet, starter pack); See Table 58, Page 618

Xarelto (rivaroxaban 2.5 mg tablet) - PA > 2 units/day; See Table 58, Page 618

Xarelto (rivaroxaban suspension) - PA ≥ 18 years; See Table 58, Page 618

Xatmep (methotrexate 2.5 mg/mL oral solution) - PA; See Table 5, Page 117

Xcopri (cenobamate) - PA; See Table 20, Page 268

Xdemvy (lotilaner) - PA; See Table 29, Page 345

Xeljanz (tofacitinib) - PA; See Table 5, Page 117

Xeljanz XR (tofacitinib extended-release) - PA; See Table 5, Page 117

Xeloda (capecitabine); #, A90; See Table 57, Page 518

Xelpros (latanoprost emulsion) - PA; See Table 51, Page 488

Xelstrym (dextroamphetamine transdermal) - PA; See Table 31, Page 358; See Table 71, Page 706

Xembify (immune globulin subcutaneous injection, human-klhw) - PA; See Table 1, Page 89

Xenazine (tetrabenazine) - PA; M90; See Table 74, Page 779

Xenical (orlistat) - PA; BP, A90; See Table 81, Page 815

Xenpozyme (olipudase alfa-rpcp) - PA; MB; See Table 65, Page 661

Xeomin (incobotulinumtoxinA) - PA; See Table 30, Page 352

Xepi (ozenoxacin) - PA; See Table 41, Page 422

Xerava (eravacycline) - PA; See Table 66, Page 673

Xerese (acyclovir / hydrocortisone); See Table 67, Page 681

Xermelo (telotristat ethyl) - PA; See Table 22, Page 288

Xgeva (denosumab-Xgeva) - PA; See Table 49, Page 475

Xhance (fluticasone propionate 93 mcg nasal spray) - PA; See Table 25, Page 316

Xiaflex (collagenase clostridium histolyticum) - PA; See Table 72, Page 730

Xifaxan (rifaximin 200 mg); See Table 35, Page 383

Xifaxan (rifaximin 550 mg) - PA; See Table 35, Page 383

Xigduo XR (dapagliflozin / metformin extended-release); BP, M90; See Table 26, Page 320

Xiidra (lifitegrast) - PA; See Table 29, Page 345

Xipere (triamcinolone ophthalmic suspension-Xipere); MB

Xofluza (baloxavir) - PA; See Table 39, Page 414

Y

Z

Zytiga (abiraterone 250 mg, 500 mg) - PA; A90; See Table 57, Page 518

Zyvox (linezolid injection) - PA; See Table 66, Page 673

Zyvox (linezolid suspension) - PA; BP, A90; See Table 35, Page 383

Zyvox (linezolid tablet); #, A90; See Table 35, Page 383

MassHealth Evaluation Criteria
Table 1 - Immune Globulins

Drug Category: Vaccines and Immune Serums

Medication Class/Individual Agents: Immune Serums

I. Prior-Authorization Requirements

Immune Globulins				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
antithymocyte globulin, equine	Atgam			**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** ***Please note: Gammagard, Gammaked, and Gamunex-C can be administered subcutaneously for primary immunodeficiency disorders (PID), or intravenously for PID as well as other indications.*** *Rate and Route of Administration:* • Administer only at rate, route, and concentration indicated for product; an IV administration rate that is too rapid may lead to a precipitous drop in blood pressure, fluid overload, and a possible thrombotic event. Cautious use in patients with history of cardiovascular disease or thrombotic episodes. *Renal Risk:* • IGIV (human) products have been associated with renal dysfunction, acute renal failure, and osmotic nephrosis. Risk factors include age >/= 66 years, pre-existing renal dysfunction, volume depletion, concurrent use of nephrotoxic drugs, diabetes, and sepsis. *Hypersensitivity Reactions:* • Reportedly rare, however incidence may increase with use of large IM doses or repeated injections of immune
antithymocyte globulin, rabbit	Thymoglobulin			
cytomegalovirus immune globulin IV, human	Cytogam		MB	
hepatitis B immune globulin IM, human-Hyperhep B	Hyperhep B			
hepatitis B immune globulin IM, human-Nabi-HB	Nabi-HB			
hepatitis B immune globulin IV, human-Hepagam B	Hepagam B			
immune globluin IV, human-stwk	Alyglo	PA		
immune globulin IM, human-Gamastan S/D	Gamastan S/D	PA		
immune globulin injection, human-Gammagard	Gammagard	PA		
immune globulin injection, human-Gammaked	Gammaked	PA		
immune globulin injection, human-Gamunex-C	Gamunex-C	PA		
immune globulin IV, human-Bivigam	Bivigam	PA		
immune globulin IV, human-Flebogamma	Flebogamma	PA		
immune globulin IV, human-Gammagard S/D	Gammagard S/D	PA		
immune globulin	Gammaplex	PA		

Immune Globulins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
IV, human-Gammaplex			
immune globulin IV, human-ifas	Panzyga	PA	
immune globulin IV, human-Octagam	Octagam	PA	
immune globulin IV, human-Privigen	Privigen	PA	
immune globulin IV, human-slra	Asceniv	PA	
immune globulin subcutaneous injection, human / hyaluronidase human recombinant	Hyqvia	PA	
immune globulin subcutaneous injection, human-Cuvitru	Cuvitru	PA	
immune globulin subcutaneous injection, human-hipp	Cutaquig	PA	
immune globulin subcutaneous injection, human-Hizentra	Hizentra	PA	
immune globulin subcutaneous injection, human-klhw	Xembify	PA	
rabies immune globulin IM, human-Hyperrab	Hyperrab		
rabies immune globulin IM, human-Kedrab	Kedrab		
rho(d) immune globulin IM, human-Hyperrho	Hyperrho		
rho(d) immune globulin IM, human-Micrhogam	Micrhogam		
rho(d) immune globulin IM, human-Rhogam	Rhogam		
rho(d) immune globulin IV, human-Rhophylac	Rhophylac		MB
rho(d) immune globulin IV, human-Winrho SDF	Winrho SDF		MB

Clinical Notes

globulins.

Live Virus Vaccines (measles, mumps, rubella, varicella):

- Antibodies present in immune globulin preparations may interfere with the immune response of live virus vaccines, especially when large doses of immunoglobulins are given. For many immune globulins, a live virus vaccine should not be administered within 3 months of immune globulin administration. A few immune globulins require an even longer period (5-11 months) before a live virus vaccine should be given. Check individual manufacturer's recommendations for each product.

Immune Globulins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tetanus immune globulin IM, human	Hypertet		

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Chronic inflammatory demyelinating polyneuropathy (CIDP)
- Dermatomyositis in adults (DM)
- Immune thrombocytopenia (ITP)
- Kawasaki disease (mucocutaneous lymph node syndrome)
- Multifocal Motor Neuropathy (MMN)
- Prevention of recurrent infection in B-cell chronic lymphocytic leukemia (CLL)
- Primary immunodeficiency disorder (e.g., primary/congenital agammaglobulinemia, severe combined immunodeficiency (SCID), Wiskott-Aldrich Syndrome, common variable immunodeficiency (CVID), hypogammaglobulinemia, X-linked agammaglobulinemia)

non-FDA-approved, for example:

- Antibody mediated rejection (AMR)
- Autoimmune autonomic ganglionopathy (AAG)
- Autoimmune encephalitis, including anti-NMDA receptor encephalitis
- Autoimmune small fiber neuropathy
- CMV-solid organ transplant
- Guillain-Barré Syndrome
- Immune-mediated necrotizing myopathy (IMNM)
- Immune neutropenia [Autoimmune neutropenia (AIN), Chronic benign neutropenia]
- Interstitial lung disease (ILD)
- Multiple myeloma
- Myasthenia gravis
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS)
- Pemphigus vulgaris (PV)
- Polymyositis (PM)
- Prevention of recurrent infection in pediatric HIV members
- Specific antibody deficiency (SAD)
- Stiff person syndrome (SPS)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Antibody mediated rejection (AMR)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Autoimmune encephalitis, anti-NMDA receptor encephalitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested dose is 2 g/kg/day divided over two to five days, followed by 1 g/kg once monthly; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Autoimmune small fiber neuropathy and autoimmune autonomic ganglionopathy (AAG)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested dose is 1 g/kg/monthly, administered in weekly divided doses, up to a maximum of 2 g/kg monthly; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Chronic inflammatory demyelinating polyneuropathy

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing for member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

CMV-Solid organ transplant

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- member will also receive antiviral therapy with ganciclovir, foscarnet, or cidofovir; **and**
- for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Dermatomyositis in adults
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - one of the following:
    - member has severe disease; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, chloroquine, hydroxychloroquine, methotrexate, mycophenolate mofetil, rituximab; **and**
  - appropriate dosing for member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Gamastan S/D
- Documentation of the following is required:
  - one of the following:
    - use for protection against Hepatitis A virus in unvaccinated member who has been exposed to the virus in the previous 2 weeks **OR** cannot receive hepatitis A vaccine (i.e., hypersensitivity or child less than one year of age); **or**
    - use to prevent or modify symptoms of measles if exposed within the last 6 days; **or**
    - use for passive immunization against varicella in immunosuppressed member when Varicella-Zoster Immune Globulin (human) is not available; **or**
    - use for post-exposure prophylaxis of rubella in a pregnant member; **and**
  - appropriate dosing for member and diagnosis.

Guillain-Barré Syndrome
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested dose is ≤ 2 g/kg; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Immune-mediated necrotizing myopathy (IMNM)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - one of the following:
    - member has severe disease; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, chloroquine, cyclophosphamide, cyclosporin, hydroxychloroquine, methotrexate, mycophenolate mofetil, plasma exchange, rituximab, tacrolimus; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Immune neutropenia (AIN, Chronic benign neutropenia)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - recurrent infections despite prophylactic antibiotics and colony-stimulating factors; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Immune thrombocytopenia

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - platelets < 30,000 /μL; **or**
    - clinically significant bleeding; **or**
    - history of significant bleeding; **or**
    - risk of significant bleeding; **or**
    - medical necessity to raise platelet count within 12 to 24 hours; **and**
  - appropriate dosing for member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Interstitial lung disease (ILD)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: azathioprine, mycophenolate mofetil; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Kawasaki disease

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - onset of illness occurred within previous 10 days; **or**
    - member has unexplained persistent fever; **or**
    - member has evidence of aneurysm; **or**
    - member exhibits signs of persistent inflammation; **and**
  - appropriate drug and dosing for the member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Multifocal motor neuropathy

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing for the member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Multiple myeloma

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - recurrent infections despite prophylactic antibiotics; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Myasthenia gravis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:

- member has severe or rapidly worsening disease, and requested agent will be used as initial therapy followed by longer-acting immunomodulating agents; **or**
- inadequate response, adverse reaction, or contraindication to all of the following: pyridostigmine, systemic corticosteroids, one immunomodulating agent (e.g., azathioprine, cyclosporine, mycophenolate); **and**

- for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one antibiotic or contraindication to all antibiotics; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Pemphigus vulgaris (PV)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - inadequate response, adverse reaction, or contraindication to rituximab; **and**
  - requested dose is ≤ 2 g/kg; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Polymyositis (PM)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one systemic corticosteroid or contraindication to all systemic corticosteroids; **and**
  - one of the following:
    - member has severe disease; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, chloroquine, cyclophosphamide, cyclosporin, hydroxychloroquine, methotrexate, mycophenolate mofetil, plasma exchange, rituximab, tacrolimus; **and**
  - requested dose is 1 g/kg per day on 2 consecutive days every 4 weeks (total monthly dose: 2 g/kg); **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Prevention of recurrent infection in B-cell chronic lymphocytic leukemia

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing for member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Prevention of recurrent infection in pediatric HIV members

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is < 18 years of age; **and**
  - CD4 count is ≥ 200 cells/microliter (within the last three months); **and**
  - requested dose is 400 mg/kg every 28 days; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Primary immunodeficiency disorders

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - laboratory documentation supporting diagnosis (e.g., deficient serum IgG [or subclasses IgG1, IgG2, IgG3, and IgG4], IgM, and/or IgA levels, assessment of functional antibody production, immunophenotype of B cells [flow cytometry] or genetic testing); **and**
  - serum IgG (or subclasses IgG1, IgG2, IgG3, and IgG4), IgM, and/or IgA levels are provided via medical records or written on PA with dates drawn and reference ranges; **and**
  - appropriate dosing for the member and treatment course; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Specific antibody deficiency (SAD)

- Documentation of the following is required:
  - appropriate diagnosis with moderate or severe polysaccharide non-responsiveness; **and**
  - evidence of recurrent infections requiring antibiotic therapy; **and**
  - requested dose is 400 to 600 mg/kg IV every four weeks or a corresponding subcutaneous dose; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

Stiff Person Syndrome (SPS)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one benzodiazepine or contraindication to all benzodiazepines; **and**
  - inadequate response, adverse reaction, or contraindication to baclofen; **and**
  - requested dose is 2 g/kg, divided over two to three infusions; **and**
  - for Asceniv, clinical rationale for use instead of other available intravenous immune globulin products.

MassHealth Evaluation Criteria

Table 2 - Hormones - Gonadotropin-Releasing Hormone Analogs

Drug Category: Hormones

Medication Class/Individual Agents: Gonadotropin-Releasing Hormone Analogs

I. Prior-Authorization Requirements

Hormones – Gonadotropin-Releasing Hormone Analogs			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
degarelix	Firmagon	PA	
elagolix	Orilissa	PA	
elagolix / estradiol / norethindrone	Oriahnn	PA	
histrelin	Supprelin LA	PA	MB
leuprolide - Fensolvi	Fensolvi	PA	MB
leuprolide 22.5 mg vial		PA	
leuprolide-Camcevi	Camcevi	PA	
leuprolide-Eligard	Eligard	PA	
leuprolide-Lupron	Lupron	PA	
nafarelin	Synarel	PA	
relugolix	Orgovyx	PA	
relugolix / estradiol / norethindrone	Myfembree	PA	
triptorelin-Trelstar	Trelstar	PA	MB
triptorelin-Triptodur	Triptodur	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Class Contraindication:

- pregnancy category X

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- central precocious puberty (CPP) – Fensolvi, Lupron Ped, Supprelin LA, Synarel, Triptodur
- endometriosis – Lupron, Myfembree, Orilissa, Synarel
- prostatic cancer (advanced) – Camcevi, Eligard, Firmagon, leuprolide 22.5 mg vial, Lupron, Trelstar
- prostatic cancer (castration-sensitive, metastatic) – Orgovyx
- uterine leiomyomata – Lupron, Myfembree, Oriahnn

Non-FDA-approved, for example:

- abnormal uterine bleeding – Eligard, Fensolvi, leuprolide 22.5 mg vial, Lupron, Myfembree, Orilissa, Synarel, Triptodur
- catamenial epilepsy – Trelstar
- endometriosis - extended duration of therapy – Lupron, Myfembree, Orilissa, Synarel
- Gender Dysphoria – Eligard, Fensolvi, leuprolide 22.5 mg vial, Lupron, Lupron Ped, Supprelin LA, Triptodur
- GnRH stimulation test for CPP diagnosis – Fensolvi, Lupron Ped, Supprelin LA, Synarel, Triptodur
- ovarian suppression/preservation – Eligard, Fensolvi, Lupron
- paraphilia – Camcevi, Eligard, Fensolvi, Firmagon, leuprolide 22.5 mg vial, Lupron, Myfembree, Oriahnn, Orgovyx, Orilissa, Supprelin LA, Synarel, Trelstar, Triptodur
- premenstrual dysphoric disorder (PMDD) – Eligard, leuprolide 22.5 mg vial, Lupron, Myfembree, Orilissa, Synarel
- uterine leiomyomata - extended duration of therapy – Lupron, Myfembree, Oriahnn

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Abnormal uterine bleeding (Eligard, Fensolvi, leuprolide 22.5 mg vial, Lupron, Myfembree, Orilissa, Synarel, Triptodur)

- Documentation of the following is required:
  - severity of menstrual bleeding (e.g., anemia, hemoglobin levels, abdominal pain, interference with daily activities); **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: hormonal contraceptives, non-contraceptive estrogen-progestin formulations; **and**
  - inadequate response, adverse reaction, or contraindication to tranexamic acid; **and**
  - for Fensolvi, Myfembree, Orilissa, and Triptodur, inadequate response, adverse reaction, or contraindication to one of the following: Eligard, leuprolide 22.5 mg vial, Lupron; **and**
  - for Lupron Depot 7.5 mg, Lupron Depot 22.5 mg every three months, Lupron Depot 30 mg, and Lupron Depot 45 mg every six months, clinical rationale for use instead of the equivalent dose of Eligard; **and**
  - one of the following:
    - if member is a surgical candidate, expected date of surgery; **or**

- if member is not a surgical candidate, one of the following:
  - requested agent is Myfembree; **or**
  - member is being treated with add-back therapy for bone loss; **or**
  - yearly BMD scan has been performed to indicate that the member does not need to be treated for osteoporosis.

Advanced prostate cancer (Camcevi, Eligard, Firmagon, leuprolide 22.5 mg vial, Trelstar)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an oncologist or urologist; **and**
  - appropriate dose and frequency of the requested agent.

SmartPA: Claims for Camcevi, Eligard, and Firmagon will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for prostate cancer.†

Advanced prostate cancer (Lupron)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an oncologist or urologist; **and**
  - appropriate dose and frequency; **and**
  - for Lupron Depot 7.5 mg, Lupron Depot 22.5 mg, Lupron Depot 30 mg, and Lupron Depot 45 mg, clinical rationale for use instead of the equivalent dose of Eligard.

Advanced prostate cancer (Orgovyx)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an oncologist or urologist; **and**
  - appropriate dose and frequency; **and**
  - inadequate response, adverse reaction, or contraindication to Firmagon; **and**
  - inadequate response, adverse reaction, or contraindication to Eligard, leuprolide 22.5 mg vial, or Lupron.

Catamenial epilepsy (Trelstar)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or endocrinologist or consult notes from a neurologist or endocrinologist are provided; **and**
  - inadequate response or adverse reaction to two anticonvulsants; **and**
  - inadequate response or adverse reaction to one or contraindication to all progesterone therapy or synthetic progestin therapy; **and**
  - requested dose is 3.75 mg every four weeks.

Endometriosis (Lupron, Synarel)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dose and frequency of the requested agent; **and**
  - inadequate response or adverse reaction to one or contraindication to all non-steroidal anti-inflammatory drugs (NSAIDs); **and**
  - inadequate response or adverse reaction to one or contraindication to all hormonal contraceptives.

Endometriosis (Myfembree, Orilissa)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dose and frequency of the requested agent; **and**

- inadequate response or adverse reaction to one or contraindication to all non-steroidal anti-inflammatory drugs (NSAIDs); **and**
- inadequate response or adverse reaction to one or contraindication to all hormonal contraceptives; **and**
- inadequate response, adverse reaction, or contraindication to Lupron; **and**
- for Myfembree, requested quantity is ≤ one unit/day.

Endometriosis - extended duration of therapy (Lupron, Myfembree, Orilissa, Synarel)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - anticipated duration of therapy; **and**
  - for Lupron, Orilissa, and Synarel one of the following:
    - member is being treated with add-back therapy for bone loss; **or**
    - yearly bone mineral density (BMD) scan has been performed to indicate that the member does not need to be treated for osteoporosis.

Gender dysphoria (Eligard)
- Documentation of the following is required:
  - diagnosis of one of the following:
    - gender dysphoria; **or**
    - transgenderism; **or**
    - therapy after gender reassignment surgery; **and**
  - one of the following:
    - for the 7.5 mg syringe, requested quantity is ≤ one unit/28 days (one month); **or**
    - for the 22.5 mg syringe, requested quantity is ≤ one unit/84 days (three months); **or**
    - for the 30 mg syringe, requested quantity is ≤ one unit/112 days (four months); **or**
    - for the 45 mg syringe, requested quantity is ≤ one unit/168 days (six months).

SmartPA: Claims for Eligard 7.5 mg, 22.5 mg, 30 mg, and 45 mg syringe within quantity limits will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender dysphoria or personal history of gender reassignment surgery.†

Gender dysphoria (Fensolvi, Triptodur)
- Documentation of the following is required:
  - diagnosis of one of the following:
    - gender dysphoria; **or**
    - transgenderism; **or**
    - therapy after gender reassignment surgery; **and**
  - requested quantity is ≤ one unit/112 days (four months).

SmartPA: Claims for Fensolvi and Triptodur within quantity limits will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender dysphoria or personal history of gender reassignment surgery.†

Gender dysphoria (leuprolide 22.5 mg vial, Lupron, Lupron Ped)
- Documentation of the following is required:
  - diagnosis of one of the following:
    - gender dysphoria; **or**
    - transgenderism; **or**
    - therapy after gender reassignment surgery; **and**
  - for Lupron 7.5 mg, 22.5 mg, 30 mg, and 45 mg adult kit, clinical rationale for use instead of the equivalent dose of Eligard; **and**
  - one of the following:
    - for leuprolide 14 mg 2-week kit, and 14 mg 2-week vial, requested quantity is ≤ two units/28 days (one month); **or**

- for the 3.75 mg kit, 7.5 mg kit, 11.25 mg pediatric 1-month kit, and 15 mg pediatric kit, requested quantity is ≤ one unit/28 days (one month); **or**
- for the 11.25 mg 3-month kit, 22.5 mg kit, 30 mg pediatric kit, and leuprolide 22.5 mg vial, requested quantity is ≤ one unit/84 days (three months); **or**
- for the 30 mg adult kit, requested quantity is ≤ one unit/112 days (four months); **or**
- for the 45 mg kit, requested quantity is ≤ one unit/168 days (six months).

SmartPA: Claims for leuprolide 14 mg 2-week kit, 14 mg 2-week vial, leuprolide 22.5 mg vial, Lupron 3.75 mg kit, 7.5 mg pediatric kit, 11.25 mg kit, 15 mg kit, 22.5 mg pediatric kit, 30 mg pediatric kit, and 45 mg pediatric kit within quantity limits will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender dysphoria or personal history of gender reassignment surgery.†

Gender dysphoria (Supprelin LA)

- Documentation of the following is required:
  - diagnosis of one of the following:
    - gender dysphoria; **or**
    - transgenderism; **or**
    - therapy after gender reassignment surgery; **and**
  - requested quantity is ≤ one unit/365 days (one year).

SmartPA: Claims for Supprelin LA within quantity limits will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender dysphoria or personal history of gender reassignment surgery.†

GnRH stimulation test for CPP diagnosis (Fensolvi, Lupron Ped, Supprelin LA, Synarel, Triptodur)

- Documentation of the following is required:
  - product will be used for a stimulation test to diagnose CPP.

Idiopathic or neurogenic central precocious puberty (CPP) (Fensolvi, Lupron Ped, Supprelin LA, Synarel, Triptodur)

- Documentation of the following is required:
  - diagnosis of CPP with onset of secondary sex characteristics before age eight years (female sex assigned at birth/biologic females) or nine years (male sex assigned at birth/biologic males); **and**
  - prescriber is a pediatric endocrinologist or consult notes from a pediatric endocrinologist are provided; **and**
  - appropriate dose and frequency; **and**
  - one of the following:
    - member is currently less than 11 years of age (female sex assigned at birth/biologic females) or 12 years of age (male sex assigned at birth/biologic males); **or**
    - member is ≥ 11 years of age and less than 12 years of age (female sex assigned at birth/biologic females) or ≥ 12 years of age and less than 13 years of age (male sex assigned at birth/biologic males) and requires one additional year of prolonged therapy due to developmental delay; **and**
  - for Fensolvi and Triptodur, inadequate response, adverse reaction, or contraindication to Lupron Ped.
- For recertification, member must be less than 11 years of age (female sex assigned at birth/biologic females) or less than 12 years of age (male sex assigned at birth/biologic males), or for member with developmental disability that requires extended treatment, member must be less than 12 years of age (female sex assigned at birth/biologic females) or less than 13 years of age (male sex assigned at birth/biologic males).

Ovarian suppression/preservation (Eligard, Fensolvi, Lupron)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is currently being treated with a chemotherapeutic agent; **and**
  - appropriate dose and frequency; **and**

- for Lupron Depot 7.5 mg, Lupron Depot 22.5 mg every three months, Lupron Depot 30 mg, and Lupron Depot 45 mg every six months, clinical rationale for use instead of the equivalent dose of Eligard.

Paraphilia (Camcevi, Eligard, Fensolvi, Firmagon, leuprolide 22.5 mg vial, Lupron, Myfembree, Oriahnn, Orgovyx, Orilissa, Supprelin LA, Synarel, Trelstar, Triptodur)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is under the care of a specialist (or being prescribed by specialist) to treat the disorder.

Premenstrual Dysphoric Disorder (PMDD) (Eligard, leuprolide 22.5 mg vial, Lupron, Myfembree, Orilissa, Synarel)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dose and frequency; **and**
  - inadequate response or adverse reaction to two or contraindication to all SSRIs; **and**
  - inadequate response or adverse reaction to one or contraindication to all hormonal contraceptives; **and**
  - for Lupron Depot 7.5 mg, Lupron Depot 22.5 mg, Lupron Depot 30 mg, and Lupron Depot 45 mg, clinical rationale for use instead of the equivalent dose of Eligard; **and**
  - for Myfembree and Orilissa, inadequate response or adverse reaction to one or contraindication to all of the following: Eligard, leuprolide 22.5 mg vial, Lupron; **and**
  - for Myfembree, requested quantity is ≤ one unit/day.

Uterine leiomyomata (Lupron, Myfembree, Oriahnn)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - anticipated surgery date or clinical rationale why surgical intervention is not appropriate; **and**
  - inadequate response or adverse reaction to one or contraindication to all hormonal contraceptives; **and**
  - for Oriahnn, both of the following:
    - inadequate response, adverse reaction, or contraindication to Lupron; **and**
    - requested quantity is ≤ two units/day; **and**
  - for Myfembree, both of the following:
    - inadequate response, adverse reaction, or contraindication to both of the following: Lupron, Oriahnn; **and**
    - requested quantity is ≤ one unit/day; **and**
  - appropriate dose and frequency.

Uterine leiomyomata - extended duration of therapy (Lupron, Myfembree, Oriahnn)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Myfembree and Oriahnn, one of the following:
    - updated surgery date; **or**
    - clinical rationale why surgery is not an option; **or**
  - for Lupron, one of the following:
    - updated surgery date; **or**
    - all of the following:
      - clinical rationale why surgery is not an option; **and**
      - one of the following:
        - member is being treated with add-back therapy for bone loss; **or**
        - yearly bone mineral density (BMD) scan has been performed to indicate that the member does not need to be treated for osteoporosis.

†**Note**: The decision on whether PA is required is based on information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria

Table 3 - Gastrointestinal Drugs - Histamine H2 Antagonists, Proton Pump Inhibitors, and Miscellaneous Gastroesophageal Reflux Agents

Drug Category: Gastrointestinal Drugs

Medication Class/Individual Agents: Histamine H2 Antagonists, Proton Pump Inhibitors, Miscellaneous Gastroesophageal Reflux Agents

I. Prior-Authorization Requirements

Gastrointestinal Drugs – Proton Pump Inhibitors (PPIs)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
dexlansoprazole	Dexilant		BP, M90	**Optimize Dosing Regimen:** • For maximum efficacy, a PPI must be taken in a fasting state, just before or with breakfast. In general for members on PPIs, it is not necessary to prescribe other antisecretory agents (e.g., H_2 antagonists, prostaglandins). If an antisecretory agent is prescribed with a PPI, the PPI should not be taken within six hours of the H_2 antagonist or prostaglandin. **Once Daily (QD) Dosing versus Twice Daily (BID) Dosing:** • QD dosing is adequate for most individuals except for H. pylori treatment (PPI is BID for the first two weeks of therapy). For pathological hypersecretory conditions, such as Zollinger-Ellison syndrome, a BID PPI regimen may be needed for high total daily doses. When/if a second dose is prescribed, it should be taken just before the evening meal. **Apparent PPI Non-responder:** • Careful history should be obtained to ensure appropriate timing of drug administration and no significant drug interactions before prescribing a second dose or switching to another PPI. **Duration of Therapy:** • DU – four weeks (QD dosing) • GU – eight weeks (QD dosing) • H. pylori – two weeks (BID dosing) + two more weeks if DU using QD dosing and six more weeks if GU using QD dosing • acute symptomatic gastroesophageal reflux disease (GERD) – four to eight weeks (QD dosing) **Nasogastric (NG) Tube Administration:**
esomeprazole magnesium 10 mg, 20 mg, 40 mg suspension	Nexium		BP, M90	
esomeprazole magnesium 2.5 mg, 5 mg suspension	Nexium	PA	M90	
esomeprazole magnesium capsule	Nexium	PA - > 1 unit/day	# , M90	
esomeprazole sodium IV	Nexium IV	PA		
lansoprazole capsule	Prevacid	PA - > 1 unit/day	# , M90	
lansoprazole orally disintegrating tablet	Prevacid Solutab	PA - ≥ 2 years	BP, M90	
omeprazole / sodium bicarbonate capsule	Zegerid		# , M90	
omeprazole / sodium bicarbonate powder for oral suspension	Zegerid	PA	M90	
omeprazole / sodium bicarbonate suspension	Konvomep	PA		
omeprazole 10 mg		PA - > 1 unit/day	M90	
omeprazole 20 mg capsule		PA - > 4 units/day	M90	
omeprazole 40 mg		PA - > 2 units/day	M90	
omeprazole suspension	Prilosec	PA		
omeprazole suspension compounding kit	First-Omeprazole	PA		
pantoprazole 40	Protonix	PA	BP, M90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
mg suspension				Omeprazole capsules, lansoprazole capsules, and esomeprazole capsules may be opened and mixed in a small amount of liquid (see specific product information for further information on liquids compatible with capsule contents and the recommended techniques for NG tube administration). **Tablet/Capsule Administration:** PPI tablets or the contents of PPI capsules should not be chewed, split, or crushed. For members who have difficulty swallowing PPI capsules, the capsule can be opened and the intact granules can be sprinkled on applesauce. See specific product information for further information on liquids and foods compatible with capsule contents.
pantoprazole IV	Protonix IV		#	
pantoprazole tablet	Protonix	PA - > 4 units/day	# , M90	
rabeprazole delayed-release capsule	Aciphex Sprinkle	PA		
rabeprazole delayed-release tablet	Aciphex	PA - > 1 unit/day	# , M90	

Gastrointestinal Drugs – Miscellaneous Gastroesophageal Reflux Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
metoclopramide nasal spray	Gimoti	PA		

Gastrointestinal Drugs – Combination H. Pylori Medication

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
bismuth subcitrate / metronidazole / tetracycline	Pylera		BP, A90	The separate ingredients of the combination products are available without prior authorization (PA). **Please note: lansoprazole, omeprazole, and pantoprazole are available without PA (within quantity limits).**
lansoprazole / amoxicillin / clarithromycin		PA	A90	
omeprazole / amoxicillin / rifabutin	Talicia	PA		
omeprazole / clarithromycin / amoxicillin	Omeclamox-Pak	PA		
vonoprazan / amoxicillin	Voquezna Dual Pak	PA		
vonoprazan / amoxicillin / clarithromycin	Voquezna Triple Pak	PA		

Gastrointestinal Drugs – Histamine H2 Antagonists

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
cimetidine			*, M90	**Optimize Dosing Regimen:** • For duodenal ulcer (DU) or gastric ulcer (GU) treatment,
famotidine injection				

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
famotidine suspension			A90	administer total daily dose between evening meal and bedtime; ulcer healing is directly proportional to degree of nocturnal acid reduction. **Duration of Therapy:** • DU – four weeks • GU – eight weeks
famotidine tablet	Pepcid		# , *, M90	
nizatidine 150 mg capsule		PA - > 2 units/day	M90	
nizatidine 300 mg capsule		PA - > 1 unit/day	M90	

Gastrointestinal Drugs – Potassium-Competitive Acid Blockers (PCABs)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
vonoprazan	Voquezna	PA		

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- active benign gastric ulcer
- diabetic gastroparesis
- extraesophageal symptoms/conditions secondary to gastric reflux (e.g., asthma, non-cardiac chest pain, etc.)
- GERD
- healing of erosive esophagitis, ulcerative GERD, DUs, GUs
- H. pylori eradication
- non-ulcer or functional dyspepsia
- pathological hypersecretory syndromes (e.g., Zollinger-Ellison, Barrett's esophagus)
- reduction of risk of upper GI bleeding in critically ill patients

Non-FDA-approved, for example:

- extraesophageal symptoms/conditions secondary to gastric reflux (e.g., asthma, non-cardiac chest pain, etc.)
- GERD
- healing of erosive esophagitis, ulcerative GERD, DUs, GUs
- H. pylori eradication
- pathological hypersecretory syndromes (e.g., Zollinger-Ellison)
- non-ulcer or functional dyspepsia

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Gimoti

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following:
    - metoclopramide tablets; **and**
    - metoclopramide solution.

lansoprazole/amoxicillin/clarithromycin, and Omeclamox-Pak

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the combination product instead of the conventionally packaged formulation.

nizatidine 150 mg capsule > two units/day, nizatidine 300 mg capsule > one unit/day

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a gastrointestinal (GI) specialist or a GI consult is provided; **and**
  - medical records documenting inadequate response (defined as ≥ 14 days of therapy) to the requested agent dosed at 300 mg daily.

Talicia

- Documentation of the following is required:

- appropriate diagnosis; **and**
- one of the following:
  - clinical rationale for use instead of other multi-drug regimens for the treatment of H. pylori; **or**
  - inadequate response or adverse reaction to one or contraindication to all of the following:
    - bismuth quadruple therapy; **or**
    - concomitant therapy consisting of a PPI, clarithromycin, amoxicillin, and metronidazole; **or**
    - clarithromycin triple therapy.

Note: All PPIs have a quantity limit of one unit/day for members ≥ 13 years of age (with the exception of omeprazole 20 mg capsules and pantoprazole tablets where the quantity limit is four units/day, and omeprazole 40 mg capsules where the quantity limit is two units/day).

Aciphex Sprinkle, esomeprazole 2.5 mg, 5 mg suspension, lansoprazole ODT (two years of age or older), pantoprazole suspension, and Prilosec powder for suspension

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - request is for esomeprazole suspension and the member is < one year of age; **or**
    - inadequate response (defined as ≥ 28 days of therapy) or adverse reaction to one or contraindication to all of the following: esomeprazole magnesium capsule 40 mg daily, lansoprazole capsule 30 mg daily, omeprazole 40 mg daily, pantoprazole 40 mg daily, rabeprazole tablet 20 mg daily; **or**
    - both of the following:
      - member has a g-tube/swallowing disorder; **and**
      - inadequate response (defined as ≥ 28 days of therapy), or adverse reaction to one, or contraindication to all of the following: esomeprazole magnesium capsule 40 mg daily, lansoprazole capsule 30 mg daily, omeprazole 40 mg daily.

Aciphex Sprinkle > one unit/day, esomeprazole 2.5 mg, 5 mg suspension > one unit/day, lansoprazole ODT (2 years of age or older) > one unit/day, pantoprazole 40 mg suspension > one unit/day, and Prilosec powder for suspension > one unit/day

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - diagnosis of abnormal secretion of gastrin/Zollinger-Ellison, Barrett's Esophagus, or esophagitis; **or**
    - medical records documenting an inadequate response to once daily dosing of the requested agent (defined as ≥ 14 days of therapy); **and**
  - one of the following:
    - request is for esomeprazole suspension and the member is < one year of age; **or**
    - inadequate response (defined as ≥ 28 days of therapy) or adverse reaction to one or contraindication to all of the following: esomeprazole magnesium capsule 40 mg daily, lansoprazole capsule 30 mg daily, omeprazole 40 mg daily, pantoprazole 40 mg daily, rabeprazole tablet 20 mg daily; **or**
    - both of the following:
      - member has a g-tube/swallowing disorder; **and**
      - inadequate response (defined as ≥ 28 days of therapy), or adverse reaction to one, or contraindication to all of the following: esomeprazole magnesium capsule 40 mg daily, lansoprazole capsule 30 mg daily, omeprazole 40 mg daily.

esomeprazole magnesium capsule > one unit/day, lansoprazole capsule > one unit/day, and rabeprazole delayed-release tablet > one unit/day for uncomplicated GERD, extraesophageal symptoms/conditions secondary to gastric reflux, healing/maintenance of healed duodenal ulcers, H. pylori eradication, non-ulcer or functional dyspepsia, risk reduction/healing of drug-induced gastric ulcer

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to both of the following:
    - omeprazole 40 mg daily; **and**
    - pantoprazole 40 mg daily; **and**
  - medical records documenting an inadequate response (defined as ≥ 14 days of therapy) to once daily dosing of the requested agent.

SmartPA: Claims for esomeprazole magnesium capsule > one unit/day, lansoprazole capsule > one unit/day, and rabeprazole delayed-release tablet > one unit/day will usually process at the pharmacy without a PA request if the member is < 13 years of age.†

esomeprazole magnesium capsule > one unit/day, lansoprazole capsule > one unit/day, omeprazole 20 mg capsule > four units/day, omeprazole 40 mg > two units/day, pantoprazole tablet > four units/day, and rabeprazole delayed-release tablet > one unit/day for abnormal secretion of gastrin/Zollinger-Ellison, Barrett's Esophagus, esophagitis

- Documentation of the diagnosis is required for approval.

SmartPA: Claims for esomeprazole magnesium capsule > one unit/day, lansoprazole capsule > one unit/day, omeprazole 20 mg capsule > four units/day, omeprazole 40 mg > two units/day, pantoprazole tablet > four units/day, and rabeprazole delayed-release tablet > one unit/day will usually process at the pharmacy without a PA request if the member is < 13 years of age or there is a history of MassHealth medical claims for abnormal secretion of gastrin/Zollinger-Ellison, Barrett's esophagus, or erosive esophagitis.†

esomeprazole magnesium OTC

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to both of the following:
    - omeprazole 40 mg daily; **and**
    - pantoprazole 40 mg daily; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one, or contraindication to both of the following: lansoprazole 30 mg capsule daily, rabeprazole 20 mg tablet daily; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to prescription esomeprazole capsules to an equivalent dose to the requested dose.

esomeprazole sodium IV

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for intravenous route of administration; **and**
  - inadequate response, adverse reaction, or contraindication to pantoprazole IV.

First-Omeprazole

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow.

Konvomep, omprazole/sodium bicarbonate powder for oral suspension

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**

- medical necessity for the requested formulation as noted by one of the following:
  - member utilizes tube feeding (G-tube/J-tube); **or**
  - member has a swallowing disorder or condition affecting ability to swallow; **and**
- inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to three or contraindication to all of the following: esomeprazole suspension, lansoprazole orally disintegrating tablet, omeprazole capsule, pantoprazole suspension.

lansoprazole OTC
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to both of the following:
    - omeprazole 40 mg daily; **and**
    - pantoprazole 40 mg daily; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to prescription lansoprazole capsules to an equivalent dose to the requested dose.

omeprazole 10 mg > one unit/day
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for omeprazole 10 mg above quantity limits when omeprazole 20 mg capsules are available up to four capsules/day without PA.

omeprazole 20 mg capsule > four units/day, omeprazole 40 mg > two units/day, and pantoprazole tablet > four units/day for uncomplicated GERD, extraesophageal symptoms/conditions secondary to gastric reflux, healing/maintenance of healed duodenal ulcers, H. pylori eradication, non-ulcer or functional dyspepsia, risk reduction/healing of drug-induced gastric ulcer
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response (defined as ≥ 14 days of therapy) to the agent dosed at 80 mg daily; **and**
  - prescriber is a GI specialist or a GI consult is provided.

SmartPA: Claims for omeprazole 20 mg capsule > four units/day, omeprazole 40 mg > two units/day, and pantoprazole tablet > four units/day will usually process at the pharmacy without a PA request if the member is < 13 years of age.†

omeprazole OTC
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to pantoprazole 40 mg daily; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to one of the following: esomeprazole magnesium 40 mg capsule daily, lansoprazole 30 mg capsule daily, rabeprazole 20 mg tablet daily; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to prescription omeprazole to an equivalent dose to the requested dose.

omeprazole/sodium bicarbonate OTC
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to both of the following:
    - omeprazole 40 mg daily; **and**
    - pantoprazole 40 mg daily; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one, or contraindication to all of the following:
    - esomeprazole magnesium 40 mg capsule daily; **or**

- lansoprazole 30 mg capsule daily; **or**
- rabeprazole 20 mg tablet daily; **and**

- medical records documenting an inadequate response, adverse reaction, or contraindication to prescription omeprazole to an equivalent dose to the requested dose.

Brand-name Protonix

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ four units/day; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to omeprazole 40 mg daily; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to one of the following:
    - esomeprazole magnesium 40 mg capsule daily; **or**
    - lansoprazole 30 mg capsule daily; **or**
    - rabeprazole 20 mg tablet daily; **and**
  - medical records documenting an adverse reaction or inadequate response to a generic equivalent of the requested product.
- For requested quantity > four units/day will be evaluated on a case-by-case basis taking into account the member's diagnosis, documentation of GI consult, and medical records of prior trials of the requested agent.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

Voquezna

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age: **and**
  - prescriber is a gastroenterologist, or consult notes from a gastroenterologist are provided; **and**
  - requested quantity is ≤ one tablet/day; **and**
  - one of the following:
    - both of the following:
      - diagnosis of LA grade C or D erosive esophagitis; **and**
      - inadequate response (defined as ≥ 28 days of therapy) or adverse reaction to one or contraindication to all of the following: dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole or rabeprazole; **or**
    - inadequate response (defined as ≥ 28 days of therapy) or adverse reaction to three or contraindication to all of the following: dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole or rabeprazole.

Voquezna Dualpak and Voquezna Triplepak

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age: **and**
  - requested quantity is ≤ eight tablet/day; **and**
  - medical necessity for the requested agent instead of other multi-drug regimens available without PA; **and**
  - one of the following:
    - for Voquezna Dualpak, member has not utilized an amoxicillin-containing regimen for the current infection; **or**
    - for Voquezna Triplepak, member has not utilized an amoxicillin or a clarithromycin containing regimen for the current infection.

MassHealth Evaluation Criteria

Table 4 - Hematologic Agents - Hematopoietic and Miscellaneous Hematologic Agents

Drug Category: Blood and Circulation Agents

Medication Class/Individual Agents: Hematopoietic Agents

I. Prior-Authorization Requirements

Hematologic Agents – Chemokine receptor type 4 (CXCR4) inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
motixafortide	Aphexda	PA	MB

Hematopoietic Agents – Erythropoiesis-Stimulating Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
darbepoetin alfa	Aranesp	PA	
epoetin alfa-epbx	Retacrit	PA	
epoetin alfa-Epogen	Epogen	PA	
epoetin alfa-Procrit	Procrit	PA	
methoxy polyethylene glycol / epoetin beta	Mircera		MB

Hematopoietic Agents – Colony-Stimulating Factors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
eflapegrastim-xnst	Rolvedon		MB
filgrastim	Neupogen		
filgrastim-aafi	Nivestym		
filgrastim-ayow	Releuko		
filgrastim-sndz	Zarxio		
pegfilgrastim	Neulasta		
pegfilgrastim-apgf	Nyvepria		
pegfilgrastim-bmez	Ziextenzo		
pegfilgrastim-cbqv	Udenyca		
pegfilgrastim-fpgk	Stimufend		
pegfilgrastim-jmdb	Fulphila		
pegfilgrastim-pbbk	Fylnetra		
sargramostim	Leukine		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

For PA drugs, an FDA-approved indication must be met. For unlabeled uses, approval will be considered based on current medical evidence.

Monitoring:

- colony-stimulating factors (G-CSF, GM-CSF) – Certain drugs, such as corticosteroids and lithium, may potentiate the myeloproliferative effects of colony-stimulating factors; GM-CSF: fluid retention, occasional transient supraventricular arrhythmias, and dyspnea may occur. Use cautiously in members with cardiac or pulmonary disease.
- erythropoietin – Evaluate iron status before and during therapy. Transferrin saturation should be at least 20% and serum ferritin at least 100 ng/mL. Most members will eventually require supplemental iron.
- oprelvekin – Fluid retention will occur. Use cautiously in members with congestive heart failure (CHF) or preexisting fluid collections (e.g., ascites, pericardial, or pleural effusions).

Please note for evaluation criteria of inadequate response to

Hematopoietic Agents – Colony-Stimulating Factors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
TBO-filgrastim	Granix		
Hematopoietic Agents – Hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
daprodustat	Jesduvroq	PA	
Hematopoietic Agents – Interleukins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
oprelvekin	Neumega		

Clinical Notes
erythropoiesis-stimulating agent (ESA) treatment, hyporesponsiveness is defined as the need for > 300 units per week of epoetin alfa or > 1.5 mcg/kg per week of darbepoetin alfa, no increase in hemoglobin (Hb) concentration from baseline after the first month of ESA treament with appropriate weight-based dosing, or two ESA dose increases up to 50% beyond the dose previously stabilized on to maintain a stable Hb concentration.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Anemia due to chemotherapy treatment for cancer (Aranesp, Epogen, Procrit, Retacrit)
- Anemia due to chronic renal failure (Aranesp, Epogen, Procrit, Retacrit)
- Anemia due to a myelosuppressive medication regimen for HIV (Aranesp, Epogen, Procrit, Retacrit)
- Decrease the need for blood transfusions during surgery (Aranesp, Epogen, Procrit, Retacrit)
- Dialysis dependent anemia of chronic kidney disease (Jesduvroq)
- Multiple myeloma requiring autologous hematopoietic cell transplantation (Aphexda)

non-FDA approved, for example:

- Anemia due to a myelosuppressive medication regimen for Hepatitis C (Aranesp, Epogen, Procrit, Retacrit).
- Anemia due to myelodysplastic syndrome (MDS)
- Anemia post-renal transplant
- Idiopathic sideroblastic anemia

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available)

require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may result in additional restrictions.

Aphexda

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an oncologist or hematologist or consult notes from an oncologist or hematologist are provided; **and**
  - requested agent will be used in combination with a granulocyte colony stimulating factor (G-CSF); **and**
  - clinical rationale for use of the requested agent instead of plerixafor; **and**
  - appropriate dosing.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to chronic renal failure

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hemoglobin (Hb) < 10 g/dL (dated within the last 60 days); **and**
  - member is not receiving hemodialysis; **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit; **and**
  - glomerular filtration rate (GFR) ≤ 60 mL/min.
- For recertification, documentation of the following is required:
  - Hb level ≤ 12 g/dL (dated within the last 60 days); **or**
  - Hb level > 12 g/dL (dated within the last 60 days) and the request addresses if the erythropoietin dose is to be held or reduced to remain with the appropriate target.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to chemotherapy treatment for cancer

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hb < 10 g/dL (dated within the last 60 days); **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit.
- For recertification, documentation of the following is required:
  - Hb level ≤ 12 g/dL (dated within the last 60 days); **and**
  - member continues to receive the causative agent.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to a myelosuppressive medication regimen for HIV

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hb < 10 g/dL (dated within the last 60 days); **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit; **and**
  - member is on myelosuppressive medication for the treatment of HIV that includes zidovudine or zidovudine-containing products.
- For recertification, documentation of the following is required:
  - Hb level ≤ 12 g/dL (dated within the last 60 days); **and**
  - member continues to receive the causative agent.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to idiopathic sideroblastic anemia/myelodysplastic syndrome

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hb < 10 g/dL (dated within the last 60 days); **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit.
- For recertification, documentation of the following is required:
  - Hb level ≤ 12 g/dL (dated within the last 60 days); **or**
  - Hb level > 12 g/dL (dated within the last 60 days) and the request addresses if the erythropoietin dose is to be held or reduced to remain with the appropriate target.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to a myelosuppressive medication regimen for Hepatitis C

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit; **and**
  - one of the following:
    - Hb < 10 g/dL (dated within the last 60 days) and member is currently being treated with a hepatitis C regimen containing an interferon product, with or without ribavirin; **or**
    - Hb < 10 g/dL (dated within the last 60 days) and member is currently being treated with a hepatitis C regimen containing ribavirin without interferon, and ribavirin dose reduction to 600 mg per day has been attempted; **or**
    - member is currently being treated with a hepatitis C regimen containing ribavirin without interferon and ribavirin dose reduction to 600 mg per day is not indicated by one of the following:
      - Hb < 8.5 g/dL (dated within the last 60 days); **or**
      - Hb < 12 g/dL (dated within the last 60 days) and member has a history of cardiac disease.
- For recertification, documentation that the member continues to receive the causative agent is required.

Aranesp, Epogen, Procrit, and Retacrit for anemia due to renal transplant

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hb < 10 g/dL (dated within the last 60 days); **and**
  - member is not receiving hemodialysis; **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit.
- For recertification, documentation of the following is required:
  - Hb level ≤ 12 g/dL (dated within the last 60 days); **or**

- Hb level > 12 g/dL (dated within the last 60 days) and the request addresses if the erythropoietin dose is to be held or reduced to remain with the appropriate target.

Aranesp, Epogen, Procrit, and Retacrit to decrease the need for blood transfusions due to surgery

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - Hb ≤ 13 g/dL (dated within the last 30 days); **and**
  - surgery is planned within the next 3 months and date is provided; **and**
  - requested strength is the minimum strength necessary to administer the requested dose; **and**
  - for Procrit, adverse reaction or contraindication to both of the following: Epogen, Retacrit.

Jesduvroq

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a nephrologist or consult notes from a nephrologist are provided; **and**
  - member has been receiving hemodialysis or peritoneal dialysis for ≥ four months; **and**
  - appropriate dosing; **and**
  - inadequate response (defined as indicated by hyporesponsiveness) or adverse reaction to one or contraindication to all of the following: Aranesp, Epogen or Procrit, Mircera, Retacrit.

MassHealth Evaluation Criteria
Table 5 - Immunological Agents

Drug Category: Immunological Agents

Medication Class/Individual Agents: Anti-TNF-Alpha, Corticosteroid, Immunosuppressant, Interleukin Antagonist, Miscellaneous, Topical

I. Prior-Authorization Requirements

Immunological Agents – Anti-TNF-Alpha			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
adalimumab	Humira PD	PA	BP
adalimumab-aacf	Idacio	PA	
adalimumab-aacf, unbranded		PA	
adalimumab-aaty	Yuflyma	PA	
adalimumab-aaty, unbranded		PA	
adalimumab-adaz	Hyrimoz	PA	
adalimumab-adaz, unbranded		PA	
adalimumab-adbm	Cyltezo	PA	
adalimumab-adbm, unbranded		PA	
adalimumab-afzb	Abrilada	PA	
adalimumab-aqvh	Yusimry	PA	
adalimumab-atto	Amjevita	PA	
adalimumab-bwwd	Hadlima	PA	
adalimumab-fkjp	Hulio	PA	
adalimumab-fkjp, unbranded		PA	
adalimumab-ryvk	Simlandi	PA	
adalimumab-ryvk, unbranded		PA	
certolizumab	Cimzia	PA	
etanercept	Enbrel PD	PA	
golimumab	Simponi	PA	
golimumab for infusion	Simponi Aria	PA	
infliximab, unbranded		PA	
infliximab-abda	Renflexis	PA	
infliximab-axxq	Avsola	PA	
infliximab-dyyb	Inflectra	PA	
infliximab-dyyb	Zymfentra	PA	
infliximab-Remicade	Remicade	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

For PA drugs, one of the following FDA-approved indications must be met. For unlabeled uses, approval is considered based on current medical evidence.

Immunological agents warnings and precautions:

- Chronic obstructive pulmonary disease, concomitant use of biologic therapy, use of live vaccines in previous three months, viral hepatitis, hypersensitivity reactions, tuberculosis, injection site reactions, infusion reactions, infections, demyelinating disease, heart failure, malignancy, induction of autoimmunity. See manufacturers' information for full details on each agent.

Monoclonal antibodies warning and precautions:

- History of malignancy, members with human immunodeficiency virus (HIV) infection, lymphopenia, malignancy, serious infections, immunosuppression, allergic reactions, hepatic injury, immune-mediated thrombocytopenia or hemolytic anemia, psoriasis worsening and variants; see manufacturers' information for full details.

Immunological Agents – Interleukin (IL)-6 Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
sarilumab	Kevzara	PA	
tocilizumab auto-injection, prefilled syringe	Actemra	PA	
tocilizumab vial	Actemra	PA	MB

Immunological Agents – Interleukin (IL)-13 Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tralokinumab-ldrm	Adbry	PA	

Immunological Agents – Corticosteroids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betamethasone injection	Celestone		#
budesonide 4 mg delayed-release capsule	Tarpeyo	PA	
budesonide oral suspension	Eohilia	PA	
deflazacort	Emflaza	PA	BP
dexamethasone 20 mg tablet	Hemady	PA	
dexamethasone injection			
dexamethasone solution, tablet	Decadron		# , A90
dexamethasone tablet pack		PA	A90
fludrocortisone			A90
hydrocortisone injection	Solu-Cortef		
hydrocortisone sprinkle capsule	Alkindi	PA	
hydrocortisone tablet	Cortef		# , A90
methylprednisolone	Medrol		# , A90
methylprednisolone acetate	Depo-Medrol		#
methylprednisolone sodium succinate	Solu-Medrol		#
prednisolone 10 mg/5 mL oral solution		PA	A90
prednisolone 15 mg/5 mL, 25 mg/5 mL oral			A90

Immunological Agents – Corticosteroids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
solution			
prednisolone 20 mg/5 mL oral solution		PA	A90
prednisolone 5 mg/5 mL oral solution	Pediapred		# , A90
prednisolone orally disintegrating tablet		PA	A90
prednisolone tablet		PA	A90
prednisone			A90
prednisone delayed-release	Rayos	PA	
triamcinolone extended-release injectable suspension	Zilretta	PA	MB
triamcinolone injection	Kenalog		#
vamorolone	Agamree	PA	

Immunological Agents – Miscellaneous Interleukin Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
basiliximab	Simulect		MB
canakinumab	Ilaris	PA	
rilonacept	Arcalyst	PA	
siltuximab	Sylvant	PA	MB

Immunological Agents – Immunosuppressants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
azathioprine 50 mg tablet	Imuran		# , A90
azathioprine 75 mg, 100 mg tablet		PA	A90
azathioprine injection			MB
belatacept	Nulojix	PA	
cyclosporine capsule	Sandimmune		# , A90
cyclosporine injection	Sandimmune		MB
cyclosporine modified	Neoral		# , A90
cyclosporine solution	Sandimmune	PA	

Immunological Agents – Immunosuppressants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
everolimus 0.25 mg, 0.5 mg, 0.75 mg, 1 mg	Zortress		# , A90
mycophenolate mofetil	Cellcept		# , A90
mycophenolic acid	Myfortic		# , A90
sirolimus solution, tablet	Rapamune		# , A90
tacrolimus extended-release capsule	Astagraf XL		
tacrolimus extended-release tablet	Envarsus XR	PA	
tacrolimus granules	Prograf	PA	
tacrolimus immediate-release capsule	Prograf		# , A90
tacrolimus injection	Prograf		MB
voclosporin	Lupkynis	PA	

Immunological Agents – Interleukin (IL)-17A and IL-17F Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bimekizumab-bkzx	Bimzelx	PA	

Immunological Agents – Janus Kinase (JAK) Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
abrocitinib	Cibinqo	PA	
baricitinib	Olumiant	PA	
ritlecitinib	Litfulo	PA	
tofacitinib	Xeljanz	PA	
tofacitinib extended-release	Xeljanz XR	PA	
upadacitinib	Rinvoq	PA	

Immunological Agents – Interleukin (IL)-17A Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
brodalumab	Siliq	PA	
ixekizumab	Taltz [PD]	PA	

Immunological Agents – Interleukin (IL)-17A Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
secukinumab auto-injection, prefilled syringe	Cosentyx	PA	
secukinumab vial	Cosentyx	PA	MB

Immunological Agents – Topical Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
calcipotriene cream	Dovonex	PA - > 60 grams/30 days	# , A90
calcipotriene foam	Sorilux	PA	A90
calcipotriene ointment		PA - > 60 grams/30 days	A90
calcipotriene scalp solution			A90
calcitriol ointment		PA	A90

Immunological Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
apremilast	Otezla	PA	
etrasimod	Velsipity	PA	
methotrexate 2 mg/mL oral solution	Jylamvo	PA	
methotrexate 2.5 mg/mL oral solution	Xatmep	PA	
methotrexate subcutaneous injection-Otrexup	Otrexup	PA	
methotrexate subcutaneous injection-Rasuvo	Rasuvo	PA	
methotrexate subcutaneous injection-Reditrex	Reditrex	PA	
methotrexate tablet			A90
ozanimod for ulcerative colitis	Zeposia	PA	
vedolizumab	Entyvio	PA	

Immunological Agents – Interleukin (IL)-23 Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
guselkumab	Tremfya	PA	

Immunological Agents – Interleukin (IL)-23 Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
mirikizumab-mrkz	Omvoh	PA	
risankizumab-rzaa	Skyrizi	PA	
tildrakizumab-asmn	Ilumya	PA	

Immunological Agents – Interleukin (IL)-1 Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
anakinra	Kineret	PA	

Immunological Agents – Selective T-Cell Costimulation Blocker			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
abatacept auto-injection, prefilled syringe	Orencia	PA	
abatacept vial	Orencia	PA	MB

Immunological Agents – Tyrosine Kinase 2 (TYK2) Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
deucravacitinib	Sotyktu	PA	

Immunological Agents – Interleukin (IL)-36 Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
spesolimab-sbzo	Spevigo	PA	

Immunological Agents – Interleukin (IL)-12/23 Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ustekinumab 130 mg/26 mL vial	Stelara	PA	MB
ustekinumab 45 mg/0.5 mL prefilled syringe, 90 mg/mL prefilled syringe, 45 mg/0.5 mL vial	Stelara PD	PA	

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acute Graft Versus Host Disease Prophylaxis – Orencia
- Acute lymphoblastic leukemia – Jylamvo, Xatmep
- Adult Onset Still's Disease (AOSD) – Ilaris
- Adrenocortical Insufficiency – Alkindi
- Alopecia Areata, severe – Litfulo, Olumiant
- Ankylosing spondylitis – Abrilada, Amjevita, Avsola, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Rinvoq, Simlandi, Simponi, Simponi Aria, Taltz, unbranded adalimumab generics, unbranded infliximab, Xeljanz, Yuflyma, Yusimry
- Atopic Dermatitis, moderate-to-severe – Adbry, Cibinqo, Rinvoq
- Crohn’s disease, moderate-to-severe – Abrilada, Amjevita, Avsola, Cimzia, Cyltezo, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Rinvoq, Simlandi, Skyrizi, Stelara, unbranded adalimumab generics, unbranded infliximab, Yuflyma, Yusimry
- Crohn’s disease (including fistulizing disease), moderate-to-severe – Avsola, Inflectra, Remicade, Renflexis, unbranded infliximab
- Cytokine release syndrome – Actemra
- Deficiency of Interleukin-1 Receptor Antagonist (DIRA) – Arcalyst, Kineret
- Duchenne muscular dystrophy (DMD) – Agamree, deflazacort
- Enthesitis-related arthritis – Cosentyx
- Eosinophilic esophagitis – Eohilia
- Familial cold autoinflammatory syndrome – Arcalyst, Ilaris
- Familial Mediterranean fever (FMF) – Ilaris
- Generalized Pustular Psoriasis – Spevigo
- Giant cell arteritis – Actemra
- Gout Flares – Ilaris
- Hidradenitis Suppurativa, moderate-to-severe – Abrilada, Amjevita, Cosentyx auto-injection, prefilled syringe, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, unbranded adalimumab generics, Yuflyma, Yusimry
- Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD)– Ilaris
- Immunoglobulin A nephropathy (IgAN) – Tarpeyo
- Inflammatory, allergic, or immunological disorders – dexamethasone tablet pack, prednisolone ODT, prednisolone oral solution, Rayos
- Lupus Nephritis – Lupkynis

- Muckle-Wells syndrome – Arcalyst, Ilaris
- Multicentric Castleman's Disease – Sylvant
- Multiple myeloma – Hemady
- Mycosis fungoides – Jylamvo
- Neonatal-onset multisystem inflammatory disease – Kineret
- Non-infectious uveitis – Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, unbranded adalimumab generics, Yuflyma, Yusimry
- Non-radiographic axial spondyloarthritis – Cimzia, Cosentyx, Rinvoq, Taltz
- Oral ulcers associated with Behçet's Disease – Otezla
- Osteoarthritis pain of the knee – Zilretta
- Plaque psoriasis – calcipotriene cream, ointment, calcipotriene foam, calcitriol ointment, Otezla
- Plaque psoriasis, moderate-to-severe – Abrilada, Amjevita, Avsola, Bimzelx, Cimzia, Cosentyx auto-injection, prefilled syringe, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Inflectra, Otrexup, Rasuvo, Reditrex, Remicade, Renflexis, Siliq, Simlandi, Skyrizi, Sotyktu, Stelara, Taltz, Tremfya, unbranded adalimumab generics, unbranded infliximab, Yuflyma, Yusimry
- Polyarticular juvenile idiopathic arthritis – Otrexup, Rasuvo, Reditrex, Xatmep
- Polyarticular juvenile idiopathic arthritis, moderate-to-severe – Abrilada, Amjevita, Actemra, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Orencia, Simlandi, Simponi Aria, unbranded adalimumab generics, Xeljanz, Yuflyma, Yusimry
- Polymyalgia rheumatica – Kevzara
- Prevention of rejection of heart transplant – Prograf granules, Sandimmune solution
- Prevention of rejection of kidney transplant – azathioprine 75 mg and 100 mg tablets, Envarsus XR, Nulojix, Prograf granules, Sandimmune solution
- Prevention of rejection of liver transplant – Prograf granules, Sandimmune solution
- Prevention of rejection of lung transplant – Prograf granules
- Psoriasis, severe – Jylamvo
- Psoriatic arthritis – Abrilada, Amjevita, Avsola, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Orencia, Otezla, Remicade, Renflexis, Rinvoq, Simlandi, Simponi, Simponi Aria, Skyrizi, Stelara, Taltz, Tremfya, unbranded adalimumab generics, unbranded infliximab, Xeljanz, Xeljanz XR, Yuflyma, Yusimry
- Recurrent pericarditis – Arcalyst
- Relapsed or refractory non-Hodgkin lymphoma – Jylamvo
- Rheumatoid arthritis – azathioprine 75 mg and 100 mg tablets, Jylamvo, Otrexup, Rasuvo, Reditrex
- Rheumatoid arthritis, moderate-to-severe – Abrilada, Amjevita, Actemra, Avsola, Cimzia, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Remicade, Renflexis, Rinvoq, Simlandi, Simponi, Simponi Aria, unbranded adalimumab generics, unbranded infliximab, Xeljanz, Xeljanz XR, Yuflyma, Yusimry
- Systemic juvenile idiopathic arthritis (sJIA) – Actemra, Ilaris
- Systemic sclerosis-associated interstitial lung disease – Actemra
- Tumor necrosis factor receptor associated periodic syndrome – Ilaris
- Ulcerative colitis, moderate-to-severe – Abrilada, Amjevita, Avsola, Cyltezo, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Omvoh, Remicade, Renflexis, Rinvoq, Simlandi, Simponi, Stelara, unbranded adalimumab generics, unbranded infliximab, Xeljanz, Xeljanz XR, Yuflyma, Yusimry, Velsipity, Zeposia

Non-FDA-approved, for example:

- Acute gout – Kineret
- Acute lymphoblastic leukemia in adult members – Xatmep
- Adult Onset Still's Disease (AOSD) – Kineret
- Alopecia Areata – Xeljanz, Xeljanz XR
- Behçet's Disease (BD) – Avsola, Enbrel, Humira, Inflectra, Remicade, Renflexis, unbranded adalimumab generics, unbranded infliximab

- Familial cold autoinflammatory syndrome – Kineret
- Fistulizing Crohn's disease – Stelara
- Hidradenitis Suppurativa – Xeljanz, Xeljanz XR
- Hidradenitis Suppurativa, moderate-to-severe – Avsola, Inflectra, Kineret, Remicade, Renflexis, Stelara, unbranded infliximab
- Hyperimmunoglobulin D syndrome (HIDS) – Kineret
- Lichen Planus – Otezla
- Muckle-Wells syndrome – Kineret
- Mycosis fungoides – Xatmep
- Neurologic Sarcoidosis – Avsola, Inflectra, Remicade, Renflexis, unbranded infliximab
- Pityriasis rubra pilaris (PRP) – Cosentyx auto-injection, prefilled syringe, Ilumya, Siliq, Skyrizi, Stelara, Taltz, Tremfya
- Plaque psoriasis, moderate-to-severe – Xatmep, Xeljanz, Xeljanz XR
- Polymyalgia Rheumatica (PMR) – Actemra, Kevzara
- Pulmonary Sarcoidosis – Avsola, Humira, Inflectra, Remicade, Renflexis, unbranded adalimumab generics, unbranded infliximab
- Recurrent Pericarditis – Kineret
- Relapsed or refractory non-Hodgkin lymphoma – Xatmep
- Rheumatoid arthritis – Xatmep
- Synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome – Avsola, Cosentyx, Enbrel, Humira, Inflectra, Kineret, Remicade, Renflexis, Stelara, unbranded adalimumab generics, unbranded infliximab
- Scleritis – Actemra, Avsola, Humira, Inflectra, Remicade, Renflexis, unbranded adalimumab generics, unbranded infliximab
- Systemic juvenile idiopathic arthritis (sJIA) – Kineret
- Takayasu Arteritis – Avsola, Enbrel, Humira, Inflectra, Remicade, Renflexis, unbranded adalimumab generics, unbranded infliximab
- Uveitis – Actemra, Avsola, Inflectra, Remicade, Renflexis, unbranded infliximab

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Abrilada, Amjevita, Avsola, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, Simponi, Simponi Aria, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for ankylosing spondylitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to two or contraindication to all NSAIDs; **and**
  - for Avsola, Cimzia, Inflectra, Remicade, Renflexis, Simponi, Simponi Aria, and unbranded infliximab, both of the following:
    - clinical rationale for the use of the requested agent instead of Enbrel; **and**
    - clinical rationale for the use of the requested agent instead of Humira; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Avsola, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for Behçet's Disease (BD)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, colchicine, cyclophosphamide, cyclosporine, methotrexate, Otezla; **and**
  - for infliximab agents, clinical rationale for use of the requested agent instead of Enbrel and Humira; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Avsola, Cyltezo, Enbrel, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, Skyrizi, Stelara, unbranded adalimumab generics, unbranded infliximab, Yuflyma, Yusimry, and Zymfentra for Crohn's disease

- Documentation of the following is required for moderate-to-severe Crohn's disease (see below for fistulizing Crohn's disease):
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**

- for Avsola, Cimzia, Inflectra, Remicade, Renflexis, and unbranded infliximab, clinical rationale for the use of the requested agent instead of Humira; **and**
- for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
- for Entyvio, inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for Crohn's disease; **and**
- for Skyrizi, both of the following:
  - inadequate response, adverse reaction, or contraindication to Stelara; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for Crohn's disease; **and**
- for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
  - clinical rationale for use of the requested agent instead of Humira; **or**
  - medical records documenting an inadequate response or adverse reaction to Humira; **and**
- for Zymfentra, both of the following:
  - medical necessity for subcutaneous formulation instead of intravenous infliximab formulation; **and**
  - documentation of current stability (at least 10 weeks of treatment) with an intravenous infliximab product; **and**
- for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
- for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

- For Avsola, Inflectra, Remicade, Renflexis, and unbranded infliximab for fistulizing Crohn's disease, documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Cosentyx auto-injection, prefilled syringe, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics for moderate-to-severe hidradenitis suppurativa

- Documentation of the following is required:
  - diagnosis of moderate-to-severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III disease); **and**
  - appropriate dosing; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Cosentyx, inadequate response, adverse reaction, or contraindication to Humira; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.

Abrilada, Amjevita, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Orencia, Simlandi, Simponi Aria, unbranded adalimumab generics, Yuflyma, and Yusimry for moderate-to-severe PJIA

- Documentation of the following is required:

- appropriate diagnosis; **and**
- appropriate dosing; **and**
- one of the following:
  - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **or**
  - inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for PJIA; **and**
- for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
  - clinical rationale for use of the requested agent instead of Humira; **or**
  - medical records documenting an inadequate response or adverse reaction to Humira; **and**
- for Simponi Aria, both of the following:
  - clinical rationale for the use of the requested agent instead of Enbrel; **and**
  - clinical rationale for the use of the requested agent instead of Humira; **and**
- for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.

Abrilada, Amjevita, Avsola, Bimzelx, Cimzia, Cyltezo, Cosentyx auto-injection, prefilled syringe, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Ilumya, Inflectra, Remicade, Renflexis, Siliq, Simlandi, Skyrizi, Stelara, Taltz, Tremfya, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for moderate-to-severe plaque psoriasis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for plaque psoriasis; **or**
    - inadequate response or adverse reaction to one or contraindication to all conventional therapies (topical agents, phototherapy, and systemic agents as defined in appendix below); **and**
  - for Avsola, Cimzia, Inflectra, Remicade, Renflexis, and unbranded infliximab, both of the following:
    - clinical rationale for the use of the requested agent instead of Enbrel; **and**
    - clinical rationale for the use of the requested agent instead of Humira; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Bimzelx, Cosentyx, Iluymya, Siliq, Skyrizi, and Tremfya, clinical rationale for the use of the requested agent instead of Stelara and Taltz; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Actemra, Avsola, Cimzia, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Kevzara, Orencia, Remicade, Renflexis, Simlandi, Simponi, Simponi Aria, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for moderate-to-severe rheumatoid arthritis (RA)

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- appropriate dosing; **and**
- one of the following:
  - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **or**
  - inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for RA; **and**
- for Avsola, Cimzia, Inflectra, Remicade, Renflexis, Simponi, Simponi Aria, and unbranded infliximab, both of the following:
  - clinical rationale for the use of the requested agent instead of Enbrel; **and**
  - clinical rationale for the use of the requested agent instead of Humira; **and**
- for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
  - clinical rationale for use of the requested agent instead of Humira; **or**
  - medical records documenting an inadequate response or adverse reaction to Humira; **and**
- for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
- for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
- for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Avsola, Cyltezo, Entyvio, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Omvoh, Remicade, Renflexis, Simlandi, Simponi, Stelara, unbranded adalimumab generics, unbranded infliximab, Yuflyma, Yusimry, and Zymfentra for moderate-to-severe ulcerative colitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - for Avsola, Inflectra, unbranded infliximab, Remicade, Renflexis, and Simponi, clinical rationale for use of the requested agent instead of Humira; **and**
  - for Entyvio, inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for ulcerative colitis; **and**
  - for Omvoh, inadequate response, adverse reaction or contraindication to Stelara; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for Zymfentra, both of the following:
    - medical necessity for subcutaneous formulation instead of intravenous infliximab formulation; **and**
    - documentation of current stability (at least 10 weeks of treatment) with an intravenous infliximab product; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics for non-infectious uveitis

- Documentation of the following is required:

- appropriate diagnosis; **and**
- appropriate dosing; **and**
- inadequate response or adverse reaction to one topical or systemic glucocorticoid, or contraindication to all topical and systemic glucocorticoids; **and**
- inadequate response or adverse reaction to one or contraindication to all systemic immunosuppressive therapies (e.g., methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, cyclophosphamide); **and**
- for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
  - clinical rationale for use of the requested agent instead of Humira; **or**
  - medical records documenting an inadequate response or adverse reaction to Humira; **and**
- for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.

Abrilada, Amjevita, Avsola, Cimzia, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Orencia, Otezla, Remicade, Renflexis, Simlandi, Simponi, Simponi Aria, Skyrizi, Stelara, Taltz, Tremfya, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for psoriatic arthritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - for Avsola, Cimzia, Inflectra, Remicade, Renflexis, Simponi, Simponi Aria, and unbranded infliximab, both of the following:
    - clinical rationale for the use of the requested agent instead of Enbrel; **and**
    - clinical rationale for the use of the requested agent instead of Humira; **and**
  - for Orencia, an inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for psoriatic arthritis; **and**
  - for Otezla, requested quantity is ≤ two tablets/day; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic.
  - for Cosentyx, Skyrizi, and Tremfya, both of the following:
    - inadequate response, adverse reaction, or contraindication to Stelara and Taltz; **and**
    - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for psoriatic arthritis.

Abrilada, Amjevita, Avsola, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for Pulmonary Sarcoidosis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: systemic glucocorticoids, one traditional

DMARD; **and**

- for Avsola, Inflectra, Remicade, Renflexis, or unbranded infliximab, one of the following:
  - inadequate response, adverse reaction or contraindication to Humira; **or**
  - clinical rationale for use of the requested agent instead of Humira; **and**
- for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
  - clinical rationale for use of the requested agent instead of Humira; **or**
  - medical records documenting an inadequate response or adverse reaction to Humira; **and**
- for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
- for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
- for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Avsola, Cosentyx, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, Stelara, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for Synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all NSAIDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and**
  - for infliximab agents, clinical rationale for use of the requested agent instead of Enbrel and Humira; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab; **and**
  - for Cosentyx, clinical rationale for use of the requested agent instead of Stelara.

Abrilada, Actemra, Amjevita, Avsola, Cyltezo, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for scleritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following:
    - ophthalmic, oral, or injectable glucocorticoids; **and**
    - oral or injectable immunosuppressive therapy; **and**
  - for Actemra, inadequate response, adverse reaction, or contraindication to Rituxan; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**

- medical records documenting an inadequate response or adverse reaction to Humira; **and**
- for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
- for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
- for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Abrilada, Amjevita, Avsola, Cyltezo, Enbrel, Hadlima, Hulio, Humira, Hyrimoz, Idacio, Inflectra, Remicade, Renflexis, Simlandi, unbranded adalimumab generics, unbranded infliximab, Yuflyma, and Yusimry for Takayasu arteritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: systemic glucocorticoids, one traditional DMARD; **and**
  - for Avsola, Inflectra, Remicade, Renflexis, or unbranded infliximab, one of the following:
    - inadequate response, adverse reaction, or contraindication to Humira and Enbrel; **or**
    - clinical rationale for use of the requested agent instead of Humira and Enbrel; **and**
  - for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generics, one of the following:
    - clinical rationale for use of the requested agent instead of Humira; **or**
    - medical records documenting an inadequate response or adverse reaction to Humira; **and**
  - for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Cyltezo, Hulio, Hyrimoz 40 mg/0.4 mL syringe and pen, Idacio, Simlandi, and Yuflyma the prescriber must provide medical records documenting an inadequate response or adverse reaction to the respective therapeutically equivalent generic; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Adbry for moderate-to-severe atopic dermatitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - prescriber is a specialist (i.e., allergist/immunologist or dermatologist) or consult notes from a specialist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all superpotent or potent topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Eucrisa, topical tacrolimus.

Actemra for Polymyalgia Rheumatica (PMR)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and**
    - inadequate response, adverse reaction or contraindication to methotrexate.

Actemra for cytokine release syndrome

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - concurrent therapy with CAR T-cell therapies (request must include anticipated date of administration); **and**
  - appropriate dosing**.**

Actemra for giant cell arteritis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all systemic glucocorticoids.

Actemra for moderate-to-severe polyarticular juvenile idiopathic arthritis (PJIA)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **or**
    - inadequate response, adverse reaction, or contraindication to Humira.

Actemra for systemic juvenile idiopathic arthritis (sJIA)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **or**
    - inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for systemic juvenile idiopathic arthritis.

Actemra for systemic sclerosis-associated interstitial lung disease
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: cyclophosphamide, mycophenolate.

Actemra, Avsola, Inflectra, Remicade, Renflexis, and unbranded infliximab for uveitis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following:
    - ophthalmic, oral, or injectable glucocorticoids; **and**
    - oral or injectable immunosuppressive therapy; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to Humira; **or**
    - clinical rationale for use of the requested agent instead of Humira; **and**
  - for Inflecta, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

Agamree

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - genetically confirmed mutation in the dystrophin gene representative of DMD; **and**
  - member is ≥ two years of age; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - adverse reaction to prednisone that was not alleviated with at least a 25% dose reduction (~0.56 mg/kg/day); **and**
  - adverse reaction to deflazacort that was not alleviated with at least a 25% dose reduction (~0.675 mg/kg/day); **and**
  - requested dose ≤ 6 mg/kg/day or 300 mg/day.
- For recertification, documentation of the following is required:
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - requested dose ≤ 6 mg/kg/day or 300 mg/day; **and**
  - medical records to support improvement from baseline in steroid-specific side effects after treatment with the requested agent.

Alkindi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is < 18 years of age; **and**
  - medical necessity for the requested formulation instead of hydrocortisone tablets.

Arcalyst and Ilaris for familial cold autoinflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate age (for Arcalyst member is ≥ 12 years of age, for Ilaris member is ≥ four years of age); **and**
  - appropriate dosing; **and**
  - one of the following:
    - evidence of symptoms indicative of the disease; **or**
    - confirmation of diagnosis through genetic testing; **and**
  - for Arcalyst, an inadequate response, adverse reaction, or contraindication to Ilaris.

Arcalyst and Kineret for Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - confirmation of diagnosis through genetic testing; **and**
  - appropriate dosing; **and**
  - for Arcalyst, an inadequate response, adverse reaction, or contraindication to Kineret.

Arcalyst for recurrent pericarditis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: aspirin, NSAIDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: colchicine, Kineret.

Avsola, Bimzelx, Inflectra, Kineret, Remicade, Renflexis, Stelara, and unbranded infliximab for moderate-to-severe hidradenitis

suppurativa

- Documentation of the following is required:
  - diagnosis of moderate-to-severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III disease); **and**
  - inadequate response or adverse reaction to one or contraindication to all oral antibiotics; **and**
  - for Avsola, Inflectra, Kineret, Remicade, Renflexis, or unbranded infliximab, inadequate response, adverse reaction, or contraindication to Humira; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for Stelara, inadequate response, adverse reaction, or contraindication to Humira; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab; **and**
  - for Bimzelx, inadequate response, adverse reaction, or contraindication to all of the following:
    - Cosentyx; **and**
    - Humira; **and**
    - one of the following:
      - Kineret; **or**
      - Stelara.

Avsola, Inflectra, Remicade, Renflexis, and unbranded infliximab for Neurologic Sarcoidosis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate mofetil; **and**
  - for Inflectra, Remicade, or Renflexis, clinical rationale for use of the requested agent instead of Avsola and unbranded infliximab; **and**
  - for brand name Remicade, the prescriber must provide medical records documenting an inadequate response or adverse reaction to unbranded infliximab.

azathioprine 75 mg, 100 mg tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the use of the 75 mg or 100 mg tablets instead of the 50 mg tablets.

SmartPA: Claims for azathioprine 75 mg and 100 mg tablets will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent and the member has a history of MassHealth medical claims for organ transplant, complications of transplanted organs, or paid MassHealth pharmacy claims for sirolimus in the past 365 days.†

calcipotriene cream, ointment > 60 grams/30 days

- Documentation of the following is required:
  - diagnosis of plaque psoriasis; **and**
  - member is ≥ 18 years of age; **and**
  - clinical rationale for the use of > 60 grams/30 days.

calcipotriene foam and calcitriol ointment

- Documentation of the following is required:
  - diagnosis of plaque psoriasis; **and**
  - one of the following:
    - for calcitriol ointment, member is ≥ two years of age; **or**

    - for calcipotriene foam, member is ≥ four years of age; **and**
- inadequate response or adverse reaction to one or contraindication to all topical corticosteroids; **and**
- inadequate response or adverse reaction to one or contraindication to all of the following: calcipotriene cream, ointment, and scalp solution; **and**
- for calcipotriene foam, one of the following:
    - requested quantity is 60 grams; **or**
    - clinical rationale for the use of > 60 grams/30 days.

Cibinqo for moderate-to-severe atopic dermatitis

- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - appropriate dosing; **and**
    - prescriber is a specialist (i.e., allergist/immunologist or dermatologist) or consult notes from a specialist are provided; **and**
    - member is ≥ 12 years of age; **and**
    - inadequate response or adverse reaction to one superpotent or potent topical corticosteroid, or contraindication to all superpotent or potent topical corticosteroids; **and**
    - inadequate response or adverse reaction to one or contraindication to both of the following: Eucrisa, topical tacrolimus; **and**
    - inadequate response, adverse reaction, or contraindication to Dupixent; **and**
    - requested quantity is ≤ one tablet/day; **and**
    - for the 200 mg tablet, inadequate response (defined as ≥ 12 weeks of therapy) to the 100 mg dose.

Cimzia and Taltz for ankylosing spondylitis

- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - appropriate dosing; **and**
    - inadequate response or adverse reaction to two or contraindication to all NSAIDs; **and**
    - for Cimzia, both of the following:
        - clinical rationale for the use of the requested agent instead of Enbrel; **and**
        - clinical rationale for the use of the requested agent instead of Humira.

Cimzia and Taltz for non-radiographic axial spondyloarthritis

- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - appropriate dosing; **and**
    - inadequate response or adverse reaction to two or contraindication to all NSAIDs.

Cosentyx, Rinvoq, Xeljanz and Xeljanz XR for ankylosing spondylitis

- Documentation of the following is required:
    - appropriate diagnosis; **and**
    - appropriate dosing; **and**
    - inadequate response or adverse reaction to two or contraindication to all NSAIDs; **and**
    - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for ankylosing spondylitis; **and**
    - for Cosentyx, inadequate response, adverse reaction, or contraindication to Taltz; **and**
    - for Rinvoq, inadequate response or adverse reaction to one or contraindication to both of the following: Xeljanz, Xeljanz XR; **and**
    - one of the following:
        - for Xeljanz, requested quantity is ≤ two tablets/day; **or**
        - for Rinvoq and Xeljanz XR, requested quantity is ≤ one tablet/day.

Cosentyx for Enthesitis-Related Arthritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ four years and < 18 years of age; **and**
  - appropriate dosing.

Cosentyx and Rinvoq for non-radiographic axial spondyloarthritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to two or contraindication to all NSAIDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents; **and**
  - inadequate response, adverse reaction, or contraindication to Taltz; **and**
  - for Rinvoq, requested quantity is ≤ one tablet/day.

Cosentyx auto-injection, prefilled syringe for psoriatic arthritis in pediatric members

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years and < 18 years of age; **and**
  - inadequate response or adverse reaction one or contraindication to both of the following: Enbrel, Humira; **and**
  - appropriate dosing.

Cosentyx auto-injection, prefilled syringe, Ilumya, Siliq, Skyrizi, Stelara, Taltz, and Tremfya for Pityriasis rubra pilaris (PRP)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all topical corticosteroids; **and**
  - for Cosentyx, Ilumya, Siliq, Skyrizi, and Tremfya, clinical rationale for use of the requested agent instead of Stelara and Taltz.

deflazacort

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - genetically confirmed mutation in the dystrophin gene representative of DMD; **and**
  - member is ≥ two years of age; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - trial of prednisone and experienced significant weight gain [e.g., crossing two major percentiles and/or reaching the 98th percentile for body mass index (BMI) for age and gender] that was not alleviated with at least a 25% dose reduction (~0.56 mg/kg/day); **and**
  - appropriate dosing for weight (~0.9 mg/kg/day) (current dose and current weight must be provided); **and**
  - for suspension formulation, one of the following:
    - medical necessity for use of the suspension formulation instead of the tablet formulation; **or**
    - member is not utilizing other solid oral formulations.
- For recertification, documentation of the following is required:
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - appropriate dosing for weight (~0.9 mg/kg/day) (current dose and current weight must be provided); **and**
  - medical records to support improvement from baseline in steroid-specific side effects after treatment with the requested agent; **and**
  - for suspension formulation, one of the following:

- continued medical necessity for use of the suspension formulation instead of the tablet formulation; **or**
- member is not utilizing other solid oral formulations.

dexamethasone tablet pack
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested agent instead of other glucocorticoid formulations available without PA.

Envarsus XR
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to tacrolimus capsules.

SmartPA: Claims for Envarsus XR will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days of therapy out of the last 120 days.†

Eohilia
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (i.e., allergist, hematologist, immunologist, gastroenterologist, etc.) or consult notes from specialist are provided; **and**
  - member is ≥ 11 years of age; **and**
  - inadequate response (defined as ≥ 60 days of therapy) or adverse reaction to one or contraindication to all proton pump inhibitors; **and**
  - inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to fluticasone propionate inhalation aerosol; **and**
  - appropriate dosing; **and**
  - requested duration does not exceed 12 weeks.

Hemady, prednisolone 10 mg/5 mL oral solution, prednisolone 20 mg/5 mL oral solution, prednisolone orally disintegrating tablet, and prednisolone tablet
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested agent instead of other glucocorticoid formulations available without PA.

Ilaris for familial Mediterranean fever (FMF), Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD), or Tumor necrosis factor receptor associated periodic syndrome (TRAPS)
- Documentation of the following is required:
  - an appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - one of the following:
    - evidence of symptoms indicative of the disease; **or**
    - confirmation of diagnosis through genetic testing; **and**
  - for diagnosis of FMF, an inadequate response, adverse reaction, or contraindication to colchicine.

Ilaris for Adult Onset Still's Disease (AOSD) and sJIA
- Documentation of the following is required:

- appropriate diagnosis; **and**
- member is ≥ two years of age; **and**
- inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and**
- inadequate response, adverse reaction, or contraindication to Kineret; **and**
- appropriate dosing.

Ilaris for gout flares

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: colchicine, corticosteroids, NSAIDs; **and**
  - appropriate dosing.

Jylamvo for acute lymphoblastic leukemia, mycosis fungoides, relapsed or refractory non-Hodgkin lymphoma, RA, or severe psoriasis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to methotrexate tablet; **or**
    - medical necessity for methotrexate oral solution as noted by one of the following:
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - use of dose that is not optimal to obtain from tablet formulation; **or**
      - member utilizes tube feeding (G-tube/J-tube).

Kevzara for Polymyalgia Rheumatica (PMR)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and**
  - inadequate response, adverse reaction, or contraindication to methotrexate; **and**
  - appropriate dosing.

Kineret for acute gout

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: colchicine, NSAIDs, oral or intraarticular glucocorticoids.

Kineret for Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA)

- Documentation of the following is required:
  - diagnosis of one of the following:
    - AOSD; **or**
    - SJIA; **and**
  - inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and**
  - requested dose is 1 to 2 mg/kg once daily (maximum initial dose of 100 mg); if no response, dose may be titrated up to 4 mg/kg once daily (maximum dose of 200 mg).

Kineret for familial cold autoinflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS)

- Documentation of the following is required:
  - diagnosis of one of the following:
    - FCAS; **or**
    - MWS; **and**
  - requested dose is 1 mg/kg/day subcutaneously (maximum, 100 mg).

Kineret for Hyperimmunoglobulin D Syndrome (HIDS)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all NSAIDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids.

Kineret for neonatal-onset multisystem inflammatory disease (NOMID)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing.

Kineret for moderate-to-severe RA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all biologic DMARDs that are FDA-approved for RA.

Kineret for recurrent pericarditis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: aspirin, NSAIDs; **and**
  - inadequate response or adverse reaction to one corticosteroid, or contraindication to all corticosteroids; **and**
  - inadequate response, adverse reaction, or contraindication to colchicine; **and**
  - requested dose is 100 mg subcutaneously once daily.

Litfulo and Olumiant for severe alopecia areata

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
  - one of the following:
    - for Litfulo, member is ≥ 12 years of age; **or**
    - for Olumiant, member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all intralesional corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Xeljanz, Xeljanz XR; **and**
  - requested quantity is ≤ one unit/day.

Lupkynis

- Documentation of the following is required:

- appropriate diagnosis; **and**
- member is ≥ 18 years of age; **and**
- member is receiving concurrent immunosuppressive therapy, excluding cyclophosphamide and biologics; **and**
- appropriate dosing.

Nulojix
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age.

Olumiant, Rinvoq, Xeljanz, and Xeljanz XR for moderate-to-severe RA
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for RA; **and**
  - for Olumiant and Rinvoq, inadequate response or adverse reaction to one or contraindication to both of the following: Xeljanz, Xeljanz XR; **and**
  - one of the following:
    - for Xeljanz, requested quantity is ≤ two tablets/day; **or**
    - for Olumiant, Rinvoq, and Xeljanz XR, requested quantity is ≤ one tablet/day.

Orencia for Acute Graft Versus Host Disease (aGVHD) prophylaxis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - requested agent will be used in combination with both a calcineurin inhibitor and methotrexate; **and**
  - appropriate dosing.

Otezla for Lichen Planus
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one high-potency or super-high-potency topical corticosteroid or contraindication to all high-potency or super high potency topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all intralesional corticosteroids; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: phototherapy, acitretin, cyclosporine, dapsone, hydroxychloroquine, hydroxyzine, methotrexate, metronidazole, mycophenolate mofetil, sulfasalazine, systemic glucocorticoids.

Otezla for plaque psoriasis (all severity levels)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all conventional therapies (topical agents, phototherapy, and systemic agents as defined in appendix below); **and**
  - requested quantity is ≤ two tablets/day.

Otezla for oral ulcers associated with Behçet's disease
- Documentation of the following is required:

- appropriate diagnosis; **and**
- appropriate dosing; **and**
- requested quantity is ≤ two tablets/day.

Otrexup, Rasuvo, and Reditrex for moderate-to-severe plaque psoriasis in adults or RA
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to oral methotrexate; **and**
  - for Otrexup, inadequate response or adverse reaction to Rasuvo or Reditrex; **and**
  - medical necessity for prefilled methotrexate injector as noted by one of the following:
    - physical disability; **or**
    - visual impairment; **or**
    - cognitive impairment.

Otrexup, Rasuvo, and Reditrex for moderate-to-severe plaque psoriasis in pediatrics or PJIA
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Otrexup, inadequate response or adverse reaction to Rasuvo or Reditrex; **and**
  - medical necessity for prefilled methotrexate injector as noted by one of the following:
    - physical disability; **or**
    - visual impairment; **or**
    - cognitive impairment.

Prograf granules
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to tacrolimus capsules; **or**
    - medical necessity for tacrolimus granules as noted by one of the following:
      - member is < 13 years of age; **or**
      - requested dose cannot be obtained from capsule formulation; **or**
      - member utilizes tube feeding (J-tube, G-tube); **or**
      - member has a swallowing disorder.
- For recertification, documentation of continued medical necessity for the requested formulation is required.

Rayos
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the delayed-release formulation instead of other glucocorticoid formulations available without PA.

Rinvoq for Crohn's disease
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for Crohn's disease; **and**
  - requested quantity is ≤ one tablet/day.

Rinvoq for moderate-to-severe atopic dermatitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., allergist/immunologist or dermatologist), or consult notes from a specialist office are provided; **and**
  - member is ≥ 12 years of age; **and**
  - for members ≥ 12 years and < 18 years of age, weight is ≥ 40 kg; **and**
  - inadequate response or adverse reaction to one superpotent or potent topical corticosteroid, or contraindication to all superpotent and potent topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Eucrisa, topical tacrolimus; **and**
  - inadequate response, adverse reaction, or contraindication to Dupixent; **and**
  - appropriate dosing; **and**
  - requested quantity is ≤ one tablet/day.

Rinvoq, Xeljanz, and Xeljanz XR for psoriatic arthritis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all traditional DMARDs; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for psoriatic arthritis; **and**
  - for Rinvoq, an inadequate response or adverse reaction to one or contraindication to both of the following: Xeljanz, Xeljanz XR; **and**
  - one of the following:
    - for Xeljanz, requested quantity is ≤ two tablets/day; **or**
    - for Rinvoq or Xeljanz XR, requested quantity is ≤ one tablet/day.

Rinvoq, Xeljanz, and Xeljanz XR for ulcerative colitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for ulcerative colitis; **and**
  - for Rinvoq, inadequate response or adverse reaction to one or contraindication to both of the following: Xeljanz, Xeljanz XR; **and**
  - one of the following:
    - for Xeljanz, requested quantity is ≤ two tablet/day; **or**
    - for Rinvoq or Xeljanz XR, requested quantity is ≤ one tablets/day.

Sandimmune solution

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to cyclosporine capsules; **or**
    - medical necessity for cyclosporine solution as noted by one of the following:
      - member is < 13 years of age; **or**
      - requested dose cannot be obtained from capsule formulation; **or**
      - member utilizes tube feeding (J-tube, G-tube); **or**
      - member has a swallowing disorder.
- For recertification, documentation of continued medical necessity for the requested formulation is required.

Sotyktu for moderate-to-severe plaque psoriasis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - requested quantity is ≤ one tablet/day; **and**
  - inadequate response or adverse reaction to one of the following or contraindication to both of the following: one biologic DMARD that is FDA-approved for plaque psoriasis, Otezla.

Spevigo for generalized pustular psoriasis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - both of the following:
      - member is ≥ 12 years of age; **and**
      - member's current weight is ≥ 40 kg; **or**
    - member is ≥ 18 years of age; **and**
  - for Spevigo prefilled syringe, one of the following:
    - inadequate response or adverse reaction to one, or contraindication all of the following: Enbrel, Humira, infliximab, Stelara, Taltz; **or**
    - documentation of positive response to treatment for an acute pustular psoriasis flare using Spevigo vial; **and**
  - appropriate dosing.

Stelara for fistulizing Crohn's disease

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents; **and**
  - appropriate dosing.

Sylvant

- Documentation of the following is required:
  - diagnosis of multicentric Castleman's disease (MCD); **and**
  - member is ≥ 18 years of age; **and**
  - member is HIV negative and HHV-8 negative; **and**
  - member's current weight; **and**
  - results from hematological laboratory tests at baseline showing all of the following:
    - absolute neutrophil count ≥ $1.0x10^9$/L; **and**
    - platelet count ≥$75x10^9$/L; **and**
    - hemoglobin <17 g/dL.

Tarpeyo

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - prescriber is a nephrologist or consult notes from a nephrologist are provided; **and**
  - one of the following:
    - both of the following:

- inadequate response (defined as ≥ 90 days of therapy) to the maximally tolerated dose of an ACE inhibitor or ARB; **and**
- medical records documenting intolerance to an ACE inhibitor or ARB at a dose above the maximally tolerated dose; **or**
- inadequate response (defined as ≥ 90 days of therapy) to the maximum FDA-approved dose of an ACE inhibitor or ARB; **and**

- medical records documenting one of the following despite treatment with a maximally tolerated dose of an ACE inhibitor or ARB for ≥ 90 days:
  - urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g; **or**
  - proteinuria >1.0 g/day; **and**
- medical necessity for the delayed-release formulation instead of other glucocorticoid formulations available without PA.

Velsipity and Zeposia for moderate-to-severe ulcerative colitis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or consult notes from a gastroenterology office are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to all anti-TNF agents that are FDA-approved for ulcerative colitis; **and**
  - inadequate response, adverse reaction, or contraindication to Entyvio; **and**
  - appropriate dosing; **and**
  - requested quantity is ≤ one capsule/day.

Xatmep for acute lymphoblastic leukemia in members < 18 years or PJIA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is < 18 years of age; **and**
  - appropriate dosing; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to methotrexate tablets; **or**
    - medical necessity for methotrexate oral solution as noted by one of the following:
      - member is < 13 years of age; **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - requested dose cannot be obtained from tablet formulation; **or**
      - member utilizes tube feeding (G-tube/J-tube).

Xatmep for acute lymphoblastic leukemia in members ≥ 18 years, moderate-to-severe plaque psoriasis, relapsed or refractory non-Hodgkin lymphoma, or RA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to methotrexate injection; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to methotrexate tablets; **or**
    - medical necessity for methotrexate oral solution as noted by one of the following:
      - member is < 13 years of age; **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - requested dose cannot be obtained from tablet formulation; **or**
      - member utilizes tube feeding (G-tube/J-tube).

Xeljanz and Xeljanz XR for Alopecia Areata

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
- inadequate response or adverse reaction to one or contraindication to all topical corticosteroids; **and**
- inadequate response or adverse reaction to one or contraindication to all intralesional corticosteroids
- one of the following:
  - for Xeljanz, requested quantity is ≤ two tablets/day; **or**
  - for Xeljanz XR, requested quantity is ≤ one tablet/day; **or**
  - for Xeljanz solution, requested quantity is ≤ 20 mL/day; **and**
- for Xeljanz solution, medical necessity for the use of a solution formulation as noted by one of the following:
  - member utilizes tube feeding (G-tube/J-tube); **or**
  - member has a swallowing disorder or condition affecting ability to swallow; **or**
  - member is < 13 years of age; **or**
  - requested dose is < 5 mg.

Xeljanz and Xeljanz XR for Hidradenitis Suppurativa (HS)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to Humira; **and**
  - for Xeljanz solution, medical necessity for the use of a solution formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **or**
    - requested dose is < 5 mg; **and**
  - one of the following:
    - for Xeljanz, requested quantity is ≤ two tablets/day; **or**
    - for Xeljanz XR, requested quantity is ≤ one tablet/day; **or**
    - for Xeljanz solution, requested quantity is ≤ 20 mL/day.

Xeljanz and Xeljanz XR for moderate-to-severe plaque psoriasis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication all conventional therapies (topical agents, phototherapy, and systemic agents as defined in appendix below); **and**
    - inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for plaque psoriasis; **and**
  - for Xeljanz solution, medical necessity for the use of a solution formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **or**
    - requested dose is < 5 mg; **and**
  - one of the following:
    - for Xeljanz, requested quantity is ≤ two tablets/day; **or**
    - for Xeljanz XR, requested quantity is ≤ one tablet/day; **or**
    - for Xeljanz solution, requested quantity is ≤ 20 mL/day.

Xeljanz for moderate-to-severe PJIA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**

- inadequate response or adverse reaction to one or contraindication to all anti-TNF agents; **and**
- one of the following:
  - for solution, requested quantity is ≤ 20 mL/day; **or**
  - for tablets, requested quantity is ≤ two tablets/day.

Xeljanz solution for off-label indications

- Documentation of the following is required:
  - PA criteria for Xeljanz or Xeljanz XR must be met, depending on indication; **and**
  - medical necessity for the use of a solution formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **or**
    - requested dose is < 5 mg; **and**
  - requested quantity is ≤ 20 mL/day.

Zilretta

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two different intra-articular corticosteroid injection preparations or contraindication to all other intra-articular corticosteroid injection preparations; **and**
  - appropriate dosing.

Appendix:

Conventional Therapies for Plaque Psoriasis		
Phototherapy	**Topical Agents**	**Systemic Agents**
ultraviolet A and topical psoralens (topical PUVA)	emollients	*Traditional DMARDs:*
ultraviolet A and oral psoralens (systemic PUVA)	keratolytics	methotrexate
narrow band UV-B (NUVB)	corticosteroids	sulfasalazine
	calcipotriene	cyclosporine
	tazarotene	tacrolimus
		acitretin
		mycophenolate mofetil
		azathioprine
		hydroxyurea
		leflunomide
		6-thioguanine

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 6 - Nutrients, Vitamins, and Vitamin Analogs

Drug Category: Vitamin supplementation and management

Medication Class/Individual Agents: Vitamins and Nutrients

I. Prior-Authorization Requirements

Nutrients, Vitamins, and Vitamin Analogs – Vitamins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ascorbic acid	vitamin C		*, M90
calcium replacement			*, M90
cyanocobalamin	vitamin B-12		o, M90
cyanocobalamin nasal spray	Nascobal	PA	
ergocalciferol capsule			M90
folic acid			*, M90
multivitamin injection	Infuvite		
multivitamin-Dekas Essential	Dekas Essential	PA	M90
multivitamins			*, M90
multivitamins / minerals / coenzyme Q10-Dekas Plus	Dekas Plus	PA	M90
multivitamins / minerals / folic acid / coenzyme Q10-Dekas Bariatric	Dekas Bariatric	PA	M90
multivitamins / minerals / folic acid / coenzyme Q10-Dekas Plus	Dekas Plus	PA	M90
multivitamins / zinc gummy	Adek Gummies	PA	M90
niacin	vitamin B-3		*, M90
niacinamide			*, M90
pediatric multivitamins			*, M90
prenatal vitamins			*, M90
pyridoxine	vitamin B-6		*, M90
retinol	vitamin A		*, M90
riboflavin	vitamin B-2		*, M90
thiamine	vitamin B-1		*, M90
vitamin A injection	Aquasol A		
vitamin B complex			*, M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Vitamin D and Vitamin D Analogs:

- In patients with stage 3-5 CKD not on dialysis with intact parathyroid hormone (PTH) progressively rising or persistently above the upper normal limit of the assay, it is suggested to evaluate for hyperphosphatemia, hypocalcemia, high phosphate intake, and vitamin D deficiency.[1]
- In adults with stage 3-5 CKD not on dialysis, it is suggested to not routinely use calcitriol and vitamin D analogs. It is reasonable to reserve the use of calcitriol and vitamin D analogs for adults with CKD G4–G5 with severe and progressive hyperparathyroidism. The use in children may be considered to maintain serum calcium levels in the age-appropriate normal range.[1]
- Excessive administration of vitamin D compounds may lead to over suppression of parathyroid hormone (PTH), hypercalcemia, hypercalciuria, hyperphosphatemia, and adynamic bone disease.[4]

calcifediol:

- FDA-approved for the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 CKD and serum total 25-hydoxyvitamin D levels less than 30

Nutrients, Vitamins, and Vitamin Analogs – Vitamins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
vitamin D			*, M90
vitamin E, oral			*, M90
vitamins, multiple			*, M90
vitamins, multiple / minerals			*, M90
vitamins, pediatric			*, M90
vitamins, prenatal			*, M90

Nutrients, Vitamins, and Vitamin Analogs – Vitamin D Analogs			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
calcifediol	Rayaldee	PA	
calcitriol capsule	Rocaltrol		# , M90
calcitriol injection			MB
calcitriol solution	Rocaltrol	PA	M90
doxercalciferol capsule		PA	M90
doxercalciferol injection	Hectorol		MB
paricalcitol capsule	Zemplar	PA	M90
paricalcitol injection	Zemplar		MB

Nutrients, Vitamins, and Vitamin Analogs – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
glucose products		PA - ≥ 19 years	A90
magnesium injection			MB
magnesium salts			*, A90
potassium bicarbonate			A90
potassium chloride extended-release capsule			A90
potassium chloride extended-release tablet	K-Tab		# , A90
potassium chloride injection			
potassium chloride oral solution			A90
potassium chloride powder for oral solution	Pokonza	PA	
potassium chloride	Klor-Con		# , A90

Clinical Notes

ng/mL.

cyanocobalamin (generic Nascobal):

- FDA-approved for the maintenance of normal hematologic status in pernicious anemia in patients in remission following intramuscular vitamin B-12 therapy with no nervous system involvement.
- FDA-approved as a supplement for various other vitamin B-12 deficiencies.

doxercalciferol:

- FDA-approved for the treatment of secondary hyperparathyroidism in adults with stage 3 or 4 CKD or with CKD and on dialysis.

paricalcitol:

- FDA-approved for the treatment of secondary hyperparathyroidism in adults and children 10 years or older with stage 3 or 4 CKD or CKD and on dialysis.

potassium chloride powder for oral solution[2,3]:

- FDA-approved for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient.
- The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance; volume status; electrolytes, including magnesium, sodium, chloride, phosphate, and calcium; electrocardiograms; and the clinical status of the patient. Correct volume status, acid-base balance, and electrolyte deficits as appropriate.
- Administration of oral potassium salts rarely causes serious hyperkalemia in persons with normal potassium excretion. Serious hyperkalemia is characterized by electrocardiographic changes, and potentially muscle paralysis or cardiovascular collapse in the most severe cases.
- For members who have difficulty swallowing capsules or tablets, some potassium chloride capsules may be opened and sprinkled on soft food and some potassium chloride tablets may be split in half or dissolved in water. See specific product information for further information on food and liquids compatible with capsule or tablet contents.

[1] Kidney Disease Improving Global Outcomes. KDIGO Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney

Nutrients, Vitamins, and Vitamin Analogs – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
powder packet, extended-release tablet			

Clinical Notes

Disease-Mineral and Bone Disorder (CKD-MBD) [guideline on the Internet]. Kidney international supplements, 2017 [cited 2018 May 31]. Available from: https://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf.

[2] Lexicomp Online Database [database on the Internet]. Hudson (OH): Lexicomp Inc.; 2024 [cited 2024 Apr 10]. Available from: http://online.lexi.com. Subscription required to view.

[3] Pokonza [package insert]. Hazlet (NJ): Carwin Pharmaceutical Associates, LLC; 2024 Mar.

[4] Zemplar [package insert on the internet]. North Chicago (IL): AbbVie, Inc.; 2016 Oct [cited 2016 Dec 14]. Available from: www.zemplar.com.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
o	PA status depends on the drug's formulation.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Secondary hyperparathyroidism in chronic kidney disease (CKD)
- Short bowel syndrome
- Vitamin deficiency

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available)

require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Adek Gummies, Dekas Bariatric, Dekas Essential, and Dekas Plus

- Documentation of the following is required:
  - appropriate diagnosis (e.g., cystic fibrosis, short gut syndrome, malabsorption syndrome).

SmartPA: Claims for Adek Gummies, Dekas Bariatric, Dekas Essential, and Dekas Plus will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent within the last 90 days, or if the member has a history of MassHealth medical claims for cystic fibrosis, malabsorption syndrome, or short gut syndrome.†

calcitriol solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age.

cyanocobalamin (generic Nascobal)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all other comparable cyanocobalamin and vitamin B12 preparations available without prior authorization.

doxercalciferol capsule and paricalcitol capsule

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate age (for doxercalciferol capsule member is ≥ 18 years of age, for paricalcitol capsule member is ≥ ten years of age); **and**
  - inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to both of the following: Vitamin D, calcitriol; **and**
  - for doxercalciferol, inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to paricalcitol.

glucose products for members ≥ 19 years of age

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested agent above age limit.

Pokonza

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: potassium bicarbonate, potassium chloride oral solution; **and**
  - for members ≥ 13 years of age, inadequate response, adverse reaction, or contraindication to both of the following: potassium chloride extended-release capsule, potassium chloride extended-release tablet; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to potassium chloride 20 mEq powder packet at an equivalent requested dose; **or**
    - requested dose cannot be achieved without using Pokonza.
- For recertification, documentation that the member meets the criteria above is required.

Rayaldee

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - total 25-hydroxyvitamin D level is < 30 ng/mL; **and**
  - inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to all of the following: vitamin D, calcitriol, paricalcitol; **and**
  - appropriate dosing.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 7 - Muscle Relaxants - Skeletal

Drug Category: Musculoskeletal

Medication Class/Individual Agents: Muscle Relaxants - Skeletal

I. Prior-Authorization Requirements

Muscle Relaxants - Skeletal			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
baclofen granules	Lyvispah	PA	
baclofen injection	Gablofen		#
baclofen intrathecal injection	Lioresal		
baclofen oral solution		PA	A90
baclofen suspension	Fleqsuvy	PA	A90
baclofen tablet			A90
carisoprodol	Soma	PA	
carisoprodol / aspirin		PA	
carisoprodol / aspirin / codeine		PA	
chlorzoxazone 250 mg, 375 mg, 750 mg		PA	A90
chlorzoxazone 500 mg		PA - < 18 years	# , A90
cyclobenzaprine 5 mg, 10 mg		PA - < 15 years	A90
cyclobenzaprine 7.5 mg		PA	A90
cyclobenzaprine extended-release	Amrix	PA	A90
dantrolene capsule	Dantrium		# , A90
dantrolene injection solution	Dantrium		MB
dantrolene injection suspension	Ryanodex		MB
metaxalone	Skelaxin	PA	A90
methocarbamol	Robaxin	PA - < 16 years	# , A90
orphenadrine		PA - < 18 years	A90
orphenadrine / aspirin / caffeine		PA	A90
tizanidine capsule	Zanaflex	PA	A90
tizanidine tablet	Zanaflex		# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Precautions:

- All agents within this class may cause drowsiness and dizziness. Members should be advised of this and to avoid alcohol and other CNS depressants.
- anticholinergic effects - baclofen, cyclobenzaprine, orphenadrine, tizanidine
- cyclobenzaprine - structurally related to tricyclic antidepressants (TCAs); consider potential for similar adverse effects and drug interactions as with TCAs.
- tizanidine - an $alpha_2$ agonist structurally related to clonidine; may cause hypotension; hepatocellular injury reported – monitor LFTs.

Urine discoloration

- orange or red-purple: chlorzoxazone
- brown, black, or green: methocarbamol

Carisoprodol and carisoprodol-containing products

Please see the following link to find out more information regarding carisoprodol products (e.g., Letter to Prescribers) https://www.mass.gov/doc/carisoprodol-letter/download

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- spastic conditions
- adjunctive treatment to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal disorders.

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

baclofen oral solution, baclofen suspension, and Lyvispah

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - medical necessity for the requested formulation as noted by one of the following:

- member is < 13 years of age; **or**
- requested dose is not available in the tablet formulation; **or**
- swallowing disorder or condition affecting ability to swallow; **or**
- inadequate response or adverse reaction to baclofen tablets; **and**

- for baclofen suspension or Lyvispah, inadequate response or adverse reaction to baclofen oral solution.

carisoprodol and carisoprodol-containing products

- Documentation of all of the following is required:
  - medical records documenting an inadequate response, adverse reaction, or contraindication to all other centrally acting skeletal muscle relaxants; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - the request is for an acute condition; **or**
    - clinical rationale for the use of carisoprodol for the treatment of a chronic condition.

Spastic Conditions

Brand-name products (Dantrium, Zanaflex tablets) and tizanidine capsules

- Documentation of the following is required:
  - diagnosis of a spastic condition; **and**
  - for brand name Dantrium or Zanaflex, the prescriber must provide documentation of an inadequate response, adverse reaction, or contraindication to dantrolene, baclofen, and tizanidine tablets; **and**
  - for a brand name drug with an A-rated generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to a generic equivalent of the requested product; **and**
  - for tizanidine capsules, both of the following:
    - inadequate response, adverse reaction, or contraindication to both of the following: baclofen, tizanidine tablets; **and**
    - medical necessity for capsule formulation (2 mg and 4 mg) or for dose (6 mg).

Musculoskeletal Conditions

chlorzoxazone 250 mg, 375 mg, 750 mg, cyclobenzaprine 7.5 mg, cyclobenzaprine extended-release, metaxalone, and orphenadrine/aspirin/caffeine

- Documentation of the following is required:
  - diagnosis of musculoskeletal condition; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: cyclobenzaprine, orphenadrine, methocarbamol, chlorzoxazone 500 mg; **and**
  - one of the following:
    - member is ≥ 18 years of age; **or**
    - inadequate response or adverse reaction to acetaminophen and two NSAIDS or contraindication to acetaminophen and all NSAIDS; **and**
  - for orphenadrine/aspirin/caffeine, medical necessity for the combination product instead of the commercially available separate agents; **and**
  - for a brand name drug (with or without an A-rated generic) the prescriber must provide medical records documenting an inadequate response or adverse reaction to a generic equivalent of the requested drug.

Please note: requests for cyclobenzaprine extended-release require medical records of a trial with cyclobenzaprine immediate-release. Chlorzoxazone 250 mg, 375 mg, and 750 mg requests require medical records of a trial with chlorzoxazone 500 mg.

SmartPA: Claims for metaxalone will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a musculoskeletal disorder and paid MassHealth pharmacy claims for the following drugs: cyclobenzaprine immediate-release, orphenadrine, methocarbamol, and chlorzoxazone for members ≥ 18 years of age.†

chlorzoxazone 500 mg < 18 years of age cyclobenzaprine 5 mg, 10 mg < 15 years of age, methocarbamol < 16 years of age, and orphenadrine < 18 years of age:

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to acetaminophen; **and**
  - inadequate response or adverse reaction to two or contraindication to all NSAIDs.

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 8 - Opioids and Analgesics

Drug Category: Pain and Inflammation

Medication Class/Individual Agents: Opioids and Analgesics

I. Prior-Authorization Requirements

Opioids and Analgesics – Short-Acting Opioids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acetaminophen / codeine		PA - < 12 years and PA > 4 g/day acetaminophen and PA > 360 mg/day codeine	
benzhydrocodone / acetaminophen	Apadaz	PA	
buprenorphine injection	Buprenex	PA	
butorphanol nasal spray		PA	
celecoxib / tramadol	Seglentis	PA	
codeine		PA - < 12 years and PA > 360 mg/day	
dihydrocodeine / acetaminophen / caffeine		PA	
fentanyl buccal tablet	Fentora	PA	
fentanyl injection			
fentanyl transmucosal system	Actiq	PA	
hydrocodone / acetaminophen		PA - > 80 mg/day hydrocodone and PA > 4 g/day acetaminophen	
hydrocodone / acetaminophen 300 mg		PA	
hydrocodone 5 mg, 10 mg / ibuprofen		PA	
hydrocodone 7.5 mg / ibuprofen		PA - > 80 mg/day hydrocodone and PA > 3.2 g/day ibuprofen	
hydromorphone	Dilaudid	PA - > 24 mg/day	#
meperidine	Demerol	PA	
morphine immediate-release		PA - > 120 mg/day	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please note: PA will be required if it is determined that the member is stable on opioid dependence therapy (≥ 60 days of therapy within the last 90 days of an oral opioid dependence agent, or ≥ 56 days of Brixadi or Sublocade in the last 84 days) for any long-acting opioid agent, any short-acting opioid agent > 7 days supply, and any short-acting opioid agent if there is ≥ 7 days of a short-acting opioid agent in the last 30 days.

Please note: Opioids and Analgesics that require PA are listed within this therapeutic class table. Managed Care Organizations (MCOs) may have different high dose thresholds and quantity limits.

Acetaminophen Hepatotoxicity:

- Acetaminophen has been associated with severe hepatotoxicity following acute and chronic ingestion.
- Maximum recommended dose of acetaminophen for adults is four grams/day.
- Be sure to consider and ask about all potential sources of acetaminophen (e.g., OTC, combination analgesics) when determining daily acetaminophen dose.

Opioids and Analgesics – Short-Acting Opioids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
morphine infusion	Infumorph		
morphine suppositories			
morphine, injection-Astramorph-PF	Astramorph-PF	PA - > 120 mg/day	
morphine, injection-Duramorph	Duramorph	PA - > 120 mg/day	
oliceridine	Olinvyk	PA	MB
oxycodone / acetaminophen		PA - > 80 mg/day oxycodone and PA > 4 g/day acetaminophen	
oxycodone / acetaminophen 300 mg		PA	
oxycodone / acetaminophen-Percocet	Percocet	PA - > 80 mg/day oxycodone and PA > 4 g/day acetaminophen	#
oxycodone / aspirin		PA - > 80 mg/day oxycodone and PA > 4 g/day aspirin	
oxycodone immediate-release	Roxicodone	PA - > 80 mg/day	#
oxymorphone immediate-release, oral		PA	
sufentanil injection			
tapentadol	Nucynta	PA	BP
tramadol / acetaminophen	Ultracet	PA	
tramadol 100 mg		PA	
tramadol 50 mg	Ultram	PA - < 12 years and PA > 400 mg/day	#
tramadol solution	Qdolo	PA	

Opioids and Analgesics – Long-Acting Opioids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
buprenorphine buccal film	Belbuca	PA	
buprenorphine transdermal	Butrans	PA - > 20 mcg/hr and PA > 4 patches/28 days	BP
fentanyl 12, 25, 50 mcg/hr transdermal system		PA - > 50 mcg/hr and PA > 10 patches/30 days	

Clinical Notes

- Risk may increase with concurrent alcohol use, underlying liver disease, and/or the fasting state.
- **PA is required for any acetaminophen-containing product that exceeds four grams/day.**

Aspirin Dose Limit:

- The maximum recommended dose of aspirin for adults is four grams/day.
- **PA is required for any aspirin-containing product that exceeds four grams/day.**

Ibuprofen Dose Limit:

- The maximum recommended dose of ibuprofen for adults is 3.2 grams/day.
- **PA is required for any ibuprofen-containing product that exceeds 3.2 grams/day.**

Concomitant Opioid and Benzodiazepine Initiative (COBI)

PA is required for members who are newly starting opioid therapy and are stable on benzodiazepine therapy for ≥ 15 days supply within the past 45 days. Members can receive up to a combined total of 14 days supply of one or more opioid(s) within the past 45-day period without PA within dose limits.

High-Dose Opioid and Analgesic Dose Limit:

- **PA is required for certain high-dose opioids and analgesics if used at doses exceeding the established limits. The accumulated high dose threshold is 120 mg of morphine or morphine milligram equivalent (MME) per day for an individual agent, and 180 MME per day for the entire regimen. All buprenorphine formulations are excluded from the opioid accumulator.**
- Please refer to the High-Dose section of this table for individual agents and their respective high-dose thresholds.

Duplicate Opioid Therapy:

- Standard practice in chronic pain management includes a long-acting opioid for chronic pain and a short-acting opioid for acute/breakthrough pain as needed.
- **PA is required for ≥ two long-acting opioids for > two months.**
- **PA is required for ≥ two short-acting opioids for > two months.**

Allergy:

- True systemic opioid allergy, such as a generalized rash, or angioedema, is unusual. A local, itchy wheal

Opioids and Analgesics – Long-Acting Opioids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fentanyl 37.5, 62.5, 87.5 mcg/hr transdermal system		PA	
fentanyl 75, 100 mcg/hr transdermal system		PA	
hydrocodone extended-release capsule		PA	
hydrocodone extended-release tablet	Hysingla ER	PA	
hydromorphone extended-release		PA	
levorphanol tablet		PA	
methadone injection		PA	
methadone oral-Dolophine	Dolophine	PA	
methadone oral-Methadose	Methadose	PA	
morphine controlled-release tablet	MS Contin	PA - > 120 mg/day	#
morphine extended-release capsule		PA	
oxycodone extended-release capsule	Xtampza	PA	
oxycodone extended-release tablet	Oxycontin	PA	BP
oxymorphone extended-release, oral		PA	
tapentadol extended-release	Nucynta ER	PA	BP
tramadol extended -release capsule	Conzip	PA	
tramadol extended -release tablet		PA	

Opioids and Analgesics – Other Analgesics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acetaminophen		PA - > 4 g/day	*, A90
clonidine injection	Duraclon		#
pentazocine / naloxone		PA	

Clinical Notes

formation at the site of narcotic injection, generalized pruritus (no rash), or flushing may occur, and is due to histamine release.

Renal Dysfunction:

- Accumulation of certain opioids in members with significant renal dysfunction can lead to excess sedation, respiratory depression, delirium, myoclonus, or seizures.
  - avoid use: meperidine, tapentadol (severe impairment), tramadol (severe impairment)
  - cautious use: acetaminophen, codeine, hydrocodone, morphine, oxycodone

Constipation:

- Common adverse effect with chronic opioid use; prescribe laxative +/- stool softener with opioid.

Hydrocodone and oxycodone in combination with acetaminophen:

- Generically available solution formulations continue to be available without PA within dose limits.
- Select generic tablet formulations continue to be available without PA within dose limits. These include the following products.

Hydrocodone or Oxycodone Strength	Acetaminophen Strength
2.5 mg	325 mg
5 mg	325 mg
7.5 mg	325 mg
10 mg	325 mg

Opioid First-Fill Seven-Day Supply Restriction:

- In general, members who have not filled an opioid prescription recently (defined as no history of a paid MassHealth pharmacy claim for an opioid in the past 90 days) or who are naïve to opioids will be limited to a seven-day supply for their first fill.
- In general, seven-day supply opioid restrictions do not apply to members who already take opioids.
- Certain exemptions may apply to seven-day supply opioid restrictions.

Please note: In general, members that are residents of nursing homes or chronic care facilities, enrolled in hospice, or with a current diagnosis of cancer or sickle cell disease

	Clinical Notes
	may be considered on a case-by-case basis for an exemption from select opioid-related requirements (e.g., COBI, high dose criteria documentation, opioid first-fill seven-day supply restriction). Please click on the link below to see the Opioid and Pain Initiative. MassHealth Pharmacy Initiatives and Clinical Information For additional information about Opioids (e.g., Letters to Prescribers), go to the following link. https://www.mass.gov/lists/opioids-and-controlled-substances-information

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- acute pain
- chronic pain

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available)

require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, frequency, and formulation.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply, depending upon the member's condition, requested medication, and Duplicate Therapy, High-Dose, High-Dose Short-Acting Monotherapy, and Quantity Limit restrictions (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.
- If MassHealth pharmacy claims history of required trials is not available, medical records documenting such trials may be required.

Please note: PA will be required if it is determined that the member is stable on opioid dependence therapy (≥ 60 days of therapy within the last 90 days of an oral opioid dependence agent, or ≥ 56 days of Sublocade in the last 84 days) for any long-acting opioid agent, any short-acting opioid agent > seven days supply, and any short-acting opioid agent if there is ≥ seven days of a short-acting opioid agent in the last 30 days.

Belbuca

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - adverse reaction or contraindication to morphine sulfate extended-release that cannot be expected or managed as a part of opioid therapy; **or**
    - medical necessity for buccal formulation; **or**
    - prescriber wants to avoid using a full opioid agonist; **and**
  - requested dose is ≤ 1,800 mcg/day.

benzhydrocodone/acetaminophen, dihydrocodeine/acetaminophen/caffeine, hydrocodone/acetaminophen 300mg, hydrocodone 5 mg, 10 mg/ibuprofen, oxycodone/acetaminophen 300 mg

Please refer to table in Section I. Prior-Authorization Requirements: Clinical Notes above for hydrocodone/acetaminophen and oxycodone/acetaminophen strengths available without PA within dose limits.

- For strengths and formulations that require PA, documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to all of the following:
    - codeine/acetaminophen; **and**
    - hydrocodone/acetaminophen; **and**
    - hydrocodone/ibuprofen; **and**
    - oxycodone/acetaminophen.

Buprenex (buprenorphine injection)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale why oral pain medications cannot be used; **and**
  - adverse reaction or contraindication to both of the following: buprenorphine transdermal, fentanyl transdermal

butorphanol nasal spray

- Documentation of the following is required for the diagnosis of acute pain:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ two canisters/30 days; **and**
  - medical records documenting one of the following:
    - adverse reaction or contraindication to all other generic short-acting opioids: codeine, hydromorphone, morphine, and oxycodone; **or**
    - both of the following:
      - medical necessity for nasal spray formulation; **and**
      - adverse reaction or contraindication to both of the following: morphine immediate-release solution, oxycodone immediate-release solution.
- Documentation of the following is required for the treatment of acute migraine:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to two or contraindication to all triptans; **and**
  - one of the following:
    - medical records documenting an inadequate response, adverse reaction to one additional triptan; **or**
    - medical records documenting an inadequate response, adverse reaction, or contraindication to one agent from a different anti-migraine medication class.
- Documentation of the following is required for requests noting the member is tapering off butorphanol nasal spray:
  - indication for the treatment of acute migraine; **and**
  - medical records documenting the member is on chronic butiorphanol; **and**
  - treatment plan including taper period for discontinuation.

codeine products for members < 12 years of age

- Documentation of one of the following is required:
  - CYP2D6 genotyping confirms member is not an ultra-rapid CYP2D6 metabolizer; **or**
  - member has previously utilized a codeine-containing product without adverse effect that prevents repeat use.

fentanyl buccal tablet

- Documentation of the following is required:
  - indication of breakthrough cancer pain; **and**
  - adverse reaction or contraindication to all of the following:
    - hydromorphone immediate-release; **and**
    - morphine immediate-release; **and**
    - oxycodone immediate-release; **and**
    - fentanyl transmucosal system (generic Actiq) (requires PA - see criteria below); **and**
  - member is maintained on a long-acting opioid regimen; **and**
  - prescriber is an oncologist or pain specialist.

fentanyl 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr transdermal system

- Documentation of the following is required:
  - clinical rationale why two patches cannot be combined to obtain the equivalent strength requested.

fentanyl transmucosal system (Actiq)

- Documentation of the following is required:
  - indication of breakthrough cancer pain; **and**
  - adverse reaction or contraindication to all of the following:
    - hydromorphone immediate-release; **and**
    - morphine immediate-release; **and**
    - oxycodone immediate-release; **and**
  - member is maintained on a long-acting opioid regimen; **and**
  - prescriber is an oncologist or pain specialist.

hydrocodone extended-release capsule, hydrocodone extended-release tablet, hydromorphone extended-release, Nucynta ER (tapentadol extended-release), oxymorphone extended-release, Xtampza (oxycodone extended-release capsule)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - adverse reaction or contraindication to all of the following that cannot be expected or managed as a part of opioid therapy:
    - fentanyl transdermal; **and**
    - morphine extended-release; **and**
    - oxycodone extended-release tablet (requires PA - see criteria below).

levorphanol tablet

- Documentation of the following is required:
  - adverse reaction or contraindication to all of the following that cannot be expected or managed as a part of opioid therapy:
    - fentanyl transdermal; **and**
    - morphine extended-release; **and**
    - oxycodone extended-release tablet (requires PA - see criteria below); **and**
  - clinical rationale for use of the requested agent instead of all other long-acting opioids.

meperidine

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - allergy to morphine; **and**
  - member has not used morphine derivatives since documented date of morphine allergy.

methadone injection

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for use instead of oral formulations of methadone.

methadone tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is not opioid naïve; **and**
  - baseline ECG showing normal QTc interval; **and**
  - one of the following:
    - adverse reaction or contraindication to both of the following: morphine sulfate extended-release, fentanyl transdermal; **or**
    - clinical rationale for the use of methadone instead of other long-acting opioids.

morphine extended-release capsules

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to morphine extended-release tablets; **and**
  - medical necessity for once daily dosing.

Nucynta (tapentadol), oxymorphone immediate-release

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - adverse reaction or contraindication to all of the following:
    - hydromorphone immediate-release; **and**
    - morphine immediate-release; **and**
    - oxycodone immediate-release.

Olinvyk (oliceridine)

- Documentation of the following is required:
  - diagnosis of acute moderate to severe pain; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following:
    - fentanyl injection; **and**
    - hydromorphone injection; **and**
    - morphine injection; **and**
  - appropriate dosing; **and**
  - total course of therapy is limited to 48 hours.

oxycodone extended-release tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - adverse reaction or contraindication to one of the following: fentanyl transdermal, morphine sulfate extended-release.

pentazocine/naloxone

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - adverse reaction or contraindication to all of the following:
    - one nonsteroidal anti-inflammatory drug (NSAID); **and**
    - hydromorphone immediate-release; **and**
    - morphine immediate-release; **and**
    - oxycodone immediate-release; **and**
    - tramadol; **and**
  - requested dose is ≤ 600 mg/day of pentazocine.

Seglentis

- Documentation of the following is required:
  - diagnosis of management of acute pain; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents.

tramadol 100 mg

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- medical necessity for the use of the 100 mg tablets instead of the 50 mg tablets; **and**
- medical records documenting an inadequate response or adverse reaction to tramadol 50 mg tablet (two 50 mg tablets).

tramadol/acetaminophen
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents.

tramadol extended-release capsule, tablet
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to tramadol immediate-release; **and**
  - medical necessity for use of an extended-release formulation.

tramadol solution
- Documentation of the following is required:
  - diagnosis of moderate to severe pain; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - medical necessity for the oral solution formulation; **or**
    - medical records documenting inadequate response or adverse reaction to tramadol immediate-release tablets that are available without prior authorization.

tramadol products for members < 12 years of age
- Documentation of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - one of the following:
    - CYP2D6 genotyping confirms member is not an ultra-rapid CYP2D6 metabolizer; **or**
    - member has previously utilized a tramadol-containing product without adverse effect that prevents repeat use.

In addition to individual drug PA criteria above, some opioids are subject to additional concomitant opioid and benzodiazepine polypharmacy, duplicate therapy, concurrent therapy with opioid dependence agents, high-dose, high-dose short-acting monotherapy, and quantity limit restrictions.

Concomitant Opioid and Benzodiazepine Polypharmacy (pharmacy claims for ≥ 15 days supply for one or more opioid(s) [new to therapy] and one or more benzodiazepine(s) [clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations are not included] for ≥ 15 days supply within the past 45-day period.
- If PA is required for concomitant opioid and benzodiazepine polypharmacy, documentation of the following is required
  - individual drug PA criteria must be met first where applicable; **and**
  - appropriate diagnosis for the opioid; **and**
  - appropriate diagnosis for the benzodiazepine; **and**
  - one of the following:
    - member is currently stable on chronic opioid; **or**
    - member's treatment is currently managed by palliative care; **or**
    - member is currently in hospice or is transitioning to hospice; **or**
    - member is currently being treated for sickle cell disease or cancer pain; **or**
    - inadequate response or adverse reaction to three non-opioid therapies (e.g., prescription NSAIDs, topical analgesics, physical therapy); **or**

- clinical rationale for the use of opioids instead of non-opioid alternatives; **or**
- treatment plan to taper off opioid therapy; **or**
- treatment plan to taper off or taper down from benzodiazepine therapy; **or**
- clinical rationale for the concomitant use of opioids and benzodiazepines; **and**

- member will be co-prescribed naloxone.

Duplicate Therapy and Concurrent Therapy with Opioid Dependence Agents

The following opioids require PA if there is concurrent use of two long-acting or two short-acting opioids for at least 60 days out of any 180-day period. In addition, PA will be required if it is determined that the member is stable on opioid dependence therapy, for any long-acting opioid agent, any short-acting opioid agent > seven days supply, and any short-acting opioid agent if there is ≥ seven days of a short-acting opioid agent in the last 30 days.

Long-acting	Short-acting
Belbuca (buprenorphine buccal film)	acetaminophen/codeine
Butrans (buprenorphine transdermal)	Actiq, Fentora
Conzip (tramadol extended-release capsule)	Apadaz (benzhydrocodone/acetaminophen)
Dolophine, Methadose (methadone)	Buprenex (buprenorphine injection)
fentanyl transdermal system	butalbital/aspirin/caffeine/codeine
hydrocodone extended-release capsule	butorphanol nasal spray
hydromorphone extended-release	carisoprodol/aspirin/codeine
Hysingla ER (hydrocodone extended-release tablet)	codeine
levorphanol tablet	Demerol (meperidine)
morphine extended-release capsule	dihydrocodeine/acetaminophen/caffeine
MS Contin (morphine controlled-release)	Dilaudid (hydromorphone)
Nucynta ER (tapentadol extended-release)	hydrocodone/acetaminophen
Oxycontin (oxycodone extended-release tablet)	hydrocodone/ibuprofen
oxymorphone extended-release	MSIR (morphine immediate-release)
tramadol extended-release tablet	Nucynta (tapentadol)
Xtampza (oxycodone extended-release capsule)	oxymorphone immediate-release
	oxycodone/aspirin
	Percocet (oxycodone/acetaminophen)
	pentazocine/naloxone
	Seglentis (celecoxib/tramadol)
	tramadol solution
	Ultracet (tramadol/acetaminophen)
	Ultram (tramadol)

- If PA is required for duplicate therapy, documentation of the following is required:
  - appropriate diagnosis; **and**
  - individual drug PA criteria must be met first where applicable; **and**
  - clinical rationale for not maximizing opioid monotherapy.

- If PA is required for concurrent therapy with opioid dependence agents, documentation of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - clinical rationale why concurrent therapy with buprenorphine is clinically appropriate.

High-Dose

The following opioids and analgesics require PA for high-dose if used at doses exceeding the following limits.

The accumulated high dose threshold is 120 mg of morphine or morphine equivalent (MME) per day for an individual agent, and 180 MME per day for the entire regimen. All buprenorphine formulations are excluded from the opioid accumulator.

Long-acting		Short-acting	
Belbuca (buprenorphine buccal film)	> 1,800 mcg/day	acetaminophen products	> 4 grams/day
Butrans (buprenorphine transdermal system)	> 20 mcg/hr	acetaminophen with codeine products	> 4 grams acetaminophen/day > 360 mg codeine/day
Conzip (tramadol extended-release capsule)	> 300 mg/day	Apadaz (benzhydrocodone/acetaminophen)	> 65.28 mg benzhydrocodone/day > 4 grams acetaminophen/day
Dolophine, Methadose (methadone)	> 25 mg/day	codeine products	> 360 mg/day
fentanyl transdermal system	> 50 mcg/hr	Dilaudid (hydromorphone)	> 24 mg/day
hydrocodone extended-release capsule	> 80 mg/day	hydrocodone/acetaminophen	> 80 mg hydrocodone/day > 4 grams acetaminophen/day
hydromorphone extended-release	> 24 mg/day	hydrocodone/ibuprofen	> 80 mg hydrocodone/day > 3.2 grams ibuprofen/day
Hysingla ER (hydrocodone extended-release tablet)	> 80 mg/day	morphine immediate-release	> 120 mg/day
levorphanol tablet	> 4 mg/day	oxycodone/acetaminophen	> 80 mg oxycodone/day > 4 grams acetaminophen/day
morphine extended-release capsule	> 120 mg/day	oxycodone/aspirin	> 80 mg oxycodone/day > 4 grams aspirin/day
MS Contin (morphine controlled-release)	> 120 mg/day	oxymorphone immediate-release	> 40 mg/day
Oxycontin (oxycodone extended-release tablet)	> 80 mg/day	Seglentis (celecoxib/tramadol)	> 400 mg tramadol/day
oxymorphone extended-release	> 40 mg/day	tramadol solution	> 400 mg/day
tramadol extended-release tablet	> 300 mg/day	Ultracet (tramadol/acetaminophen)	> 400 mg tramadol/day > 4 grams acetaminophen/day
Xtampza (oxycodone extended-release capsule)	> 72 mg/day	Ultram (tramadol)	> 400 mg/day

- If exceeding four grams/day of an acetaminophen- or aspirin-containing product, or 3.2 grams/day of an ibuprofen-containing product, documentation of the following is required:
  - appropriate diagnosis; **and**
  - individual drug PA criteria must be met first, where applicable; **and**
  - clinical rationale for utilizing greater than four grams of acetaminophen or aspirin, or greater than 3.2 grams of ibuprofen per day.

- If exceeding the above high-dose limits for other agents, documentation of the following is required:
  - appropriate diagnosis; **and**
  - individual drug PA criteria must be met first, where applicable; **and**
  - one of the following:
    - diagnosis of sickle cell disease; **or**
    - diagnosis of active cancer pain; **or**
    - member's pain control is currently managed by palliative care; **or**
    - member is currently in hospice or is transitioning to hospice; **or**
    - one of the following:
      - all of the following:
        - medical records documenting treatment plan, including clinical rationale for high-dose and titration of medication up to current dose; **and**
        - pain consult from a pain specialist supporting the high-dose of opioid requested (Please note, up to three one-month provisional approvals may be allowed to accommodate pain consult scheduling and completion. If requesting a provisional approval to obtain a pain consult, include the specialist contact information and anticipated date of consult); **and**
        - signed and dated patient-prescriber agreement for opioid use; **or**
      - both of the following:
        - medical records documenting treatment plan to initiate a taper of the requested medication within the next 90 days; **and**
        - signed and dated patient-prescriber agreement for opioid use.

High-Dose, Short-Acting Monotherapy

The following opioids and analgesics require PA for monotherapy if used at doses exceeding the limits listed below.

Short-acting	
acetaminophen with codeine products	> 4 grams acetaminophen/day > 360 mg codeine/day
Apadaz (benzhydrocodone/acetaminophen)	> 65.28 mg benzhydrocodone/day > 4 grams acetaminophen/day
codeine products	> 360 mg/day
Dilaudid (hydromorphone)	> 24 mg/day
hydrocodone/acetaminophen	> 80 mg hydrocodone/day > 4 grams acetaminophen/day
hydrocodone/ibuprofen	> 80 mg hydrocodone/day > 3.2 grams ibuprofen/day
morphine immediate-release	> 120 mg/day
oxycodone immediate-release	> 80 mg/day
oxycodone/acetaminophen	> 80 mg oxycodone/day > 4 grams acetaminophen/day
oxycodone/aspirin	> 80 mg oxycodone/day > 4 grams aspirin/day
oxymorphone immediate-release	> 40 mg/day
Seglentis (celecoxib/tramadol)	> 400 mg tramadol/day
tramadol solution	> 400 mg/day

Ultracet (tramadol/acetaminophen)	> 400 mg tramadol/day > 4 grams acetaminophen/day
Ultram (tramadol)	> 400 mg/day

- If exceeding the above high-dose limits and using as monotherapy, documentation of the following is required:
  - individual drug PA criteria must be met first, where applicable; **and**
  - medical records documenting treatment plan, including clinical rationale for high-dose and titration of medication up to current dose; **and**
  - pain consult from a pain specialist supporting the high-dose of opioid requested (Please note, up to three one-month provisional approvals may be allowed to accommodate pain consult scheduling and completion. If requesting a provisional approval to obtain a pain consult, include the specialist contact information and anticipated date of consult); **and**
  - clinical rationale for not utilizing a long-acting agent in a member requiring high-dose, short-acting opioid therapy for the treatment of chronic pain; **and**
  - signed and dated patient-prescriber agreement for opioid use.

Quantity Limits

The following opioids require PA if used at the quantities listed below.

Long-acting	
Butrans (buprenorphine transdermal system)	> 4 patches/28 days
Conzip (tramadol extended-release capsule)	> 1 unit/day
fentanyl transdermal system	> 10 patches/30 days
fentanyl 37.5, 62.5, 87.5 mcg/hr transdermal system	> 10 patches/30 days
hydrocodone extended-release capsule	> 2 units/day
hydromorphone extended-release	> 1 unit/day
Hysingla ER (hydrocodone extended-release tablet)	> 1 unit/day
levorphanol tablet	> 2 units/day
morphine extended-release capsule	> 1 unit/day
Oxycontin (oxycodone extended-release tablet)	> 3 units/day
oxymorphone extended-release	> 2 units/day
tramadol extended-release tablet	> 1 unit/day
Xtampza (oxycodone extended-release capsule)	> 2 units/day

- If exceeding the above quantity limits, documentation of the following is required:
  - appropriate diagnosis; **and**
  - individual drug PA criteria must be met first, where applicable; **and**
  - requested dose cannot be obtained within the established quantity limits.

MassHealth Evaluation Criteria
Table 9 - Growth Hormones and Increlex

Drug Category: Endocrine and Metabolic Agents

Medication Class/Individual Agents: Pituitary Agents

I. Prior-Authorization Requirements

Growth Hormones			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
lonapegsomatropin-tcgd	Skytrofa PD	PA	
somapacitan-beco	Sogroya	PA	
somatrogon-ghla	Ngenla	PA	
somatropin-Genotropin	Genotropin PD	PA	
somatropin-Humatrope	Humatrope	PA	
somatropin-Norditropin	Norditropin	PA	
somatropin-Nutropin AQ	Nutropin AQ	PA	
somatropin-Omnitrope	Omnitrope	PA	
somatropin-Saizen	Saizen	PA	
somatropin-Serostim	Serostim	PA	
somatropin-Zomacton	Zomacton	PA	

Recombinant Human Insulin-Like Growth Factor I			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
mecasermin	Increlex	PA	

Growth Hormone Secretagogue Receptor Agonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
macimorelin	Macrilen		MB

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Contraindications:

- active malignancy
- growth promotion in children with fused epiphyses
- acute critical illness due to complications following open–heart surgery or abdominal surgery

Warnings:

- Dosage and schedule should be individualized.
- Injection sites should be rotated to avoid lipoatrophy.

insulin-like growth factor-1 (IGF-1) or insulin-like growth factor binding protein-3 (IGFBP-3):

Values more than 2 standard deviations (SD) below the mean for IGF-1, also known as somatomedin C, or IGFBP-3 may suggest an abnormality in the growth hormone axis, but results of these tests can depend on transient issues such as poor nutrition or psychosocial deprivation. These tests, therefore, cannot be used as the sole determinant of a growth hormone deficiency diagnosis.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Growth hormone deficiency in children – Genotropin, Humatrope, Ngenla, Norditropin, Nutropin AQ, Omnitrope, Saizen, Skytrofa, Sogroya, Zomacton
- Growth hormone gene deletion with the development of neutralizing antibodies to growth hormone – Increlex
- Growth failure in children associated with chronic renal insufficiency before renal transplant – Nutropin AQ
- Growth failure in children associated with Noonan Syndrome – Norditropin
- Growth failure in children associated with Prader-Willi Syndrome – Genotropin, Omnitrope
- Growth failure in children associated with Turner Syndrome – Genotropin, Humatrope, Norditropin, Nutropin AQ
- Growth failure in children born small for gestational age – Genotropin, Humatrope, Norditropin, Omnitrope
- Growth hormone deficiency in adults – Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Sogroya
- HIV/AIDS-associated wasting or cachexia – Serostim
- Primary insulin-like growth factor (IGF)-1 deficiency – Increlex

non-FDA approved, for example:

- Growth failure in children associated with chronic renal failure post-transplant (growth hormone agents)
- Short stature secondary to sickle cell disease (growth hormone agents)
- Silver-Russel Syndrome (growth hormone agents)

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate

and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Pediatric - Growth hormone (GH) deficiency or panhypopituitarism (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six years to puberty: < 4.5 cm/year (females) or < 4 cm/year (males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**
  - prescriber is an endocrinologist or consult notes from an endocrinology office are provided; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Sogroya or Ngenla, clinical rationale for use of the requested agent instead of Skytrofa; **and**
  - one of the following:
    - results of two abnormal GH stimulation tests; **or**
    - results of one abnormal stimulation test and one abnormal IGF-1 or IGFBP-3 level; **or**
    - results of one abnormal test (IGF-1, IGFBP-3, or GH stimulation test); **and**
      - one of the following:
        - abnormal pituitary imaging; **or**
        - deficiency of at least three other pituitary hormones (TSH, ACTH, LH, FSH, or AVP/ADH); **or**
        - appropriate current medication claims suggesting deficiency of at least three other pituitary hormones (levothyroxine, hydrocortisone or other glucocorticoid, testosterone or estrogen/progesterone, or desmopressin).
- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Pediatric - Hypoglycemia due to GH deficiency (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - test results indicating GH deficiency (at least one abnormal GH stimulation test is required); **and**
  - hypoglycemia-symptoms and low glucose level; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Sogroya or Ngenla, clinical rationale for use of the requested agent instead of Skytrofa.

Pediatric - Noonan, Prader-Willi, or Turner Syndrome (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six years to puberty: < 4.5 cm/year (females) or < 4 cm/year (males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**

- one of the following:
  - rationale for why genetic testing cannot be provided as noted by one of the following:
    - member is new to prescriber and current prescriber has no means of obtaining labs used for diagnosis; **or**
    - diagnosis made many years ago; **or**
  - genetic testing confirming diagnosis; **and**
- for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
- for Sogroya or Ngenla, clinical rationale for use of the requested agent instead of Skytrofa.

- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Pediatric - Chronic renal failure up to time of renal transplantation (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six years to puberty: < 4.5 cm/year (females) or < 4 cm/year (males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**
  - one of the following:
    - other CRF-associated etiologies have been excluded; **or**
    - member is under care of a renal specialist; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Sogroya or Ngenla, clinical rationale for use of the requested agent instead of Skytrofa.
- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Pediatric - Chronic renal failure post-transplant (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six to puberty: < 4.5 cm/year (females) or < 4 cm/year (males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**
  - one of the following:
    - other CRF-associated etiologies have been excluded; **or**
    - member is under the care of a renal specialist; **and**
  - growth has been monitored for at least one-year post-transplant, without catch-up growth documented as height continually less than -2 standard deviations below mean or below third percentile from time of transplant to current request; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Sogroya or Ngenla, clinical rationale for use of the requested agent instead of Skytrofa.

- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Pediatric - Small for gestational age (SGA)/Intrauterine growth restriction (IUGR) with failed catch-up growth between age two - four (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six years to puberty: < 4.5 cm/year (females) or < 4 cm/year (males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**
  - diagnosis of SGA/IUGR (birth weight or length less than -2 standard deviations below mean or below third percentile for gestational age); **and**
  - catch-up growth not achieved between the ages of two to four, as indicated by both of the following:
    - at least one height measurement less than -2 standard deviations below mean or below third percentile between age two to four years; **and**
    - member does not have evidence of consistent catch-up growth [defined as: from age two to current age (or age four, whichever is less), no consecutive years with height measurements greater than -2 standard deviations below mean or greater than third percentile]; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - for Sogroya or Ngenla, clinical rationale for use of the requested agent instead of Skytrofa.
- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Primary IGFD and Growth hormone gene deletion with the development of neutralizing antibodies to growth hormone (Increlex)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - appropriate dosing; **and**
  - prescriber is a pediatric endocrinologist or other growth disorder specialist or consult notes are provided; **and**
  - height standard deviation score ≤ -3; **and**
  - basal IGF-1 standard deviation score ≤ -3; **and**
  - normal or elevated growth hormone level; **and**
  - member has an open epiphysis; **and**
  - other forms of secondary IGF-1 deficiency have been ruled out (i.e. growth hormone deficiency, malnutrition, hypothyroidism, use of chronic pharmacologic doses of anti-inflammatory steroids).
- For recertification, documentation of the following is required:
  - response to therapy; **and**
  - open epiphyses.

Pediatric - Short stature secondary to sickle cell disease (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:

- pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
- height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**

- growth velocity below the tenth percentile for age and gender as defined by one of the following:
  - age two to less than four years: < 5.5 cm/year; **or**
  - age four to less than six years: < 5 cm/year; **or**
  - age six years to puberty: < 4.5 cm/year (females) or < 4 cm/year (males); **and**
- one abnormal test (GH stimulation, IGF-1, or IGFBP-3 test); **and**
- prescriber is an endocrinologist or consult notes from an endocrinology office are provided; **and**
- for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
- for Sogroya or Ngenla, clinical rationale for use of the requested agent instead of Skytrofa.

- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Pediatric - Silver-Russel Syndrome (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - short stature or growth failure, documented by one of the following:
    - pre-treatment height less than -2 standard deviations below mean or below third percentile on standard pediatric growth chart; **or**
    - growth velocity below the tenth percentile for age and gender as defined by one of the following:
      - age two to less than four years: < 5.5 cm/year; **or**
      - age four to less than six years: < 5 cm/year; **or**
      - age six years to puberty: < 4.5 cm/year (females) or < 4 cm/year (males); **or**
    - height dropping below initial percentile curve on standard pediatric growth chart when monitored over one year; **and**
- For recertification, documentation of measured growth velocity of at least 2.5 cm per year is required.

Adult - GH deficiency or panhypopituitarism (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an endocrinologist or consult notes from an endocrinology office are provided; **and**
  - at least one symptom consistent with GH deficiency; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin; **and**
  - one of the following:
    - results of two abnormal GH stimulation tests; **or**
    - results of one abnormal stimulation test and one abnormal IGF-1 or IGFBP-3 level; **or**
    - results of one abnormal test (IGF-1, IGFBP-3, or GH stimulation test); **and**
      - one of the following:
        - abnormal pituitary imaging; **or**
        - deficiency of at least three other pituitary hormones (TSH, ACTH, LH, FSH, or AVP/ADH); **or**
        - appropriate current medication claims suggesting deficiency of at least three other pituitary hormones (levothyroxine, hydrocortisone or other glucocorticoid, testosterone or estrogen/progesterone, or desmopressin).
- For recertification, documentation of the following is required:
  - IGF-1 or IGFBP-3 level within lab-specific reference range; **and**
  - for isolated or idiopathic adult GHD, positive response regarding documented GH complication.

Adult - HIV/AIDS-associated wasting or cachexia (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is receiving concurrent antiretroviral therapy; **and**
  - evidence of wasting, as indicated by one of the following (with or without chronic fever, weakness, or diarrhea):
    - an involuntary loss of at least 10% of body weight within one year; **or**
    - an involuntary loss of at least 7.5% of body weight within six months; **or**
    - a reduction in lean body mass (measured via bioelectrical impedance assay or BIA); **or**
    - BMI < 20 kg/m^2; **and**
  - member has had a trial of an FDA-approved appetite stimulant (i.e., dronabinol or megestrol acetate) prior to initiation of GH therapy if the etiology of wasting or cachexia is decreased caloric intake; **and**
  - one of the following:
    - other causes of weight loss have been ruled out (i.e., gastrointestinal tract opportunistic infections, decrease in food intake due to oral, pharyngeal, esophageal lesions or candidiasis, gonadal dysfunction, adverse effects due to medications, or psychosocial factors); **or**
    - member is under the care of an infectious disease specialist; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin.

Adult - Short-bowel syndrome (growth hormone agents)

- Documentation of the following is required:
  - appropriate diagnosis (in members receiving specialized nutritional support); **and**
  - intended duration of therapy; **and**
  - for all agents other than Genotropin, the prescriber provides clinical rationale for use of the requested agent instead of Genotropin.

MassHealth Evaluation Criteria
Table 10 - Dermatologic Agents - Acne and Rosacea

Drug Category: Dermatological Agents

Medication Class/Individual Agents: Anti-acne and Rosacea Agents

I. Prior-Authorization Requirements

Dermatologic Agents: Acne and Rosacea – Retinoids (Oral)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
acitretin			A90	*Contraindicated in Pregnancy:* • Isotretinoin and acitretin • Isotretinoin – prescribers must comply with the manufacturer's iPLEDGE program (see manufacturer's product information for full details) *Retinoids and Photosensitivity Reactions*: • Minimize exposure to ultraviolet light or sunlight. Quinolones, sulfonamides, thiazide diuretics, and phenothiazines are some other drugs which may also increase sensitivity to the sun.
isotretinoin		PA - ≥ 21 years	A90	
isotretinoin micronized	Absorica LD	PA	A90	
isotretinoin-Absorica	Absorica	PA	BP, A90	

Dermatologic Agents: Acne and Rosacea – Combination Products

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
adapalene 0.1% / benzoyl peroxide 2.5%		PA	A90	*Prior Authorizations:* • Select generic, select brand name, combination topical acne products, and convenience delivery systems (e.g., foams, kits, pads, pledgets) require prior authorization.
adapalene 0.3% / benzoyl peroxide 2.5%		PA	A90	
benzoyl peroxide / erythromycin	Benzamycin	PA	A90	
clindamycin / adapalene / benzoyl peroxide	Cabtreo	PA		
clindamycin / benzoyl peroxide gel	Onexton	PA	A90	
clindamycin / benzoyl peroxide-Acanya	Acanya	PA	A90	
clindamycin / tretinoin-Veltin	Veltin	PA	A90	
clindamycin / tretinoin-Ziana	Ziana	PA	A90	
clindamycin 1% / benzoyl peroxide 5%		PA	A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
clindamycin 1.2% / benzoyl peroxide 5%		PA	A90

Dermatologic Agents: Acne and Rosacea – Agents Not Otherwise Classified

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
azelaic acid foam	Finacea	PA	BP	*Prior Authorizations:* • Select generic, select brand name, combination topical acne products, and convenience delivery systems (e.g., foams, kits, pads, pledgets) require prior authorization. *Azelaic Acid Products:* • Exhibits antimicrobial activity and has comedolytic properties
azelaic acid gel	Finacea	PA	A90	
brimonidine 0.33% topical gel		PA	A90	
clascoterone	Winlevi	PA		
dapsone gel	Aczone	PA	A90	
ivermectin cream		PA	A90	
oxymetazoline cream	Rhofade	PA		

Dermatologic Agents: Acne and Rosacea – Retinoids (Topical)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
adapalene		PA	A90	*Prior Authorizations:* • Select generic, select brand name, combination topical acne products, and convenience delivery systems (e.g., foams, kits, pads, pledgets) require prior authorization. • Prior authorization is also required for generic topical retinoid products for members ≥ 21 years of age. *Contraindicated in Pregnancy:* • Tazarotene *Retinoids and Photosensitivity Reactions*: • Minimize exposure to ultraviolet light or sunlight. Quinolones, sulfonamides, thiazide diuretics, and phenothiazines are some other drugs which may also increase sensitivity to the sun.
tazarotene 0.1% cream, gel		PA	A90	
tazarotene foam	Fabior	PA	BP	
tazarotene lotion	Arazlo	PA		
tretinoin 0.05% gel	Atralin	PA	BP, A90	
tretinoin 0.05% lotion	Altreno	PA - ≥ 21 years		
tretinoin microspheres	Retin-A Micro	PA	BP, A90	
tretinoin-Avita	Avita	PA - ≥ 21 years	# , A90	
tretinoin-Retin-A	Retin-A	PA - ≥ 21 years	BP, A90	

Dermatologic Agents: Acne and Rosacea – Antibiotics (Topical)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
clindamycin foam	Evoclin	PA	A90	*Prior Authorizations:* • Select generic, select brand name, combination topical acne products, and convenience delivery systems (e.g., foams, kits, pads, pledgets) require prior authorization. • Prior authorization is also required for generic
clindamycin gel, solution			A90	
clindamycin gel-Clindagel	Clindagel		BP	
clindamycin lotion	Cleocin T		BP, A90	
clindamycin			A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
pledgets				sulfacetamide 10% lotion agents for members ≥ 21 years of age. *Topical Antibiotics:* • Used in moderate-severe acne (Types 2 and 3) as part of a combination therapy. • Also possesses anti-inflammatory activity. • Long-term use is discouraged due to increased emergence of *P. acnes* resistance. • Combination therapy with another topical medication decreases resistance emergence. • Sulfacetamide products are used for mild inflammatory acne. These products are contraindicated in sulfonamide allergic patients.
erythromycin / ethanol pads, pledgets		PA	A90	
erythromycin gel	Erygel		# , A90	
erythromycin solution			A90	
metronidazole 0.75% cream			A90	
metronidazole 0.75% gel			A90	
metronidazole 1% cream	Noritate			
metronidazole 1% gel		PA	A90	
metronidazole lotion		PA	A90	
sulfacetamide 10% lotion	Klaron	PA - ≥ 21 years	# , A90	

Dermatologic Agents: Acne and Rosacea – Benzoyl Peroxide Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
benzoyl peroxide			*, A90	*Prior Authorizations:* • Select generic, select brand name, combination topical acne products, and convenience delivery systems (e.g., foams, kits, pads, pledgets) require prior authorization. *Benzoyl Peroxide Products:* • Often used alone for noninflammatory, mainly comedonal acne (Type 1). • Used as an adjunctive therapy for mild-moderate inflammatory acne (Type 2) with a retinoid. • Used as an adjunctive therapy for moderate-severe acne (Type 3 to 4) with a retinoid, topical and/or oral antibiotic. • Demonstrates antibacterial activity and some comedolytic activity. • A trial of two to three months is usually required to establish efficacy or treatment failure of any topical product. • High incidence of local irritation is evident with most topical treatments.
benzoyl peroxide 9.8% foam		PA	A90	

Dermatologic Agents: Acne and Rosacea – Salicylic Acid Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
salicylic acid			o, A90	*Salicylic acid products:*

	Clinical Notes
	• Topical salicylic acid products may be used for the treatment of acne vulgaris, psoriasis, removal of warts, or other hyperkeratotic skin disorders.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
o	PA status depends on the drug's formulation.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acne vulgaris – adapalene, Altreno, Arazlo, Avita, benzoyl peroxide, clindamycin, dapsone, erythromycin, sulfacetamide, salicylic acid, tazarotene cream and foam, tretinoin, tretinoin 0.05% gel, tretinoin microspheres, Winlevi
- Keratosis pilaris – azelaic acid, dapsone
- Nodulocystic acne (severe), recalcitrant – Absorica LD, isotretinoin, isotretinoin (generic Absorica)
- Psoriasis – acitretin, tazarotene cream, salicylic acid
- Rosacea – azelaic acid gel, Finacea foam, ivermectin cream, metronidazole, brimonidine topical gel, Rhofade, tazarotene cream

Non-FDA-approved, for example:

- cutaneous warts – adapalene, Altreno, Arazlo, tazarotene cream and foam, tretinoin, tretinoin 0.05% gel, tretinoin microspheres
- folliculitis/pseudofolliculitis – adapalene, Altreno, Arazlo, benzoyl peroxide, clindamycin, tazarotene cream and foam, tretinoin, tretinoin 0.05% gel, tretinoin microspheres
- keratosis pilaris – adapalene 0.1% cream, tretinoin 0.05% cream
- perioral/periorificial dermatitis – erythromycin, metronidazole

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or

clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.

- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

adapalene, tretinoin 0.05% gel, and tretinoin microspheres

- Documentation of all of the following is required for a diagnosis of acne, cutaneous warts, folliculitis/pseudofolliculitis:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis); **and**
  - medical records documenting an adverse reaction or inadequate response to a topical tretinoin agent.
- Documentation of all of the following is required for a diagnosis of rosacea:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following:
    - benzoyl peroxide with a concurrent topical antibiotic; **and**
    - topical metronidazole.
- Documentation of the following is required for adapalene 0.1% cream for a diagnosis of keratosis pilaris:
  - appropriate diagnosis.

Altreno for members ≥ 21 years of age

- Documentation of the following is required for a diagnosis of acne, cutaneous warts, folliculitis/pseudofolliculitis:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis).
- Documentation of all of the following is required for a diagnosis of rosacea:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following:
    - benzoyl peroxide with a concurrent topical antibiotic; **and**
    - topical metronidazole.

Arazlo

- Documentation of all of the following is required for a diagnosis of acne, cutaneous warts, folliculitis/pseudofolliculitis:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis); **and**
  - medical records documenting inadequate response or adverse reaction to a topical tretinoin agent; **and**
  - medical records documenting inadequate response or an adverse reaction to a topical tazarotene agent.

azelaic acid gel

- Documentation of all of the following is required for a diagnosis of acne, cutaneous warts, folliculitis/pseudofolliculitis:
  - appropriate diagnosis (e.g., acne grade II or greater); **and**
  - inadequate response, adverse reaction, or contraindication to benzoyl peroxide with a concurrent topical antibiotic.
- Documentation of all of the following is required for a diagnosis of rosacea:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to topical metronidazole.
- Documentation of all of the following is required for a diagnosis of keratosis pilaris:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: benzoyl peroxide, salicylic acid, urea, topical retinoid.

Brand-name benzoyl peroxide and clindamycin products

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater, folliculitis/pseudofolliculitis, hidradenitis suppurativa, rosacea); **and**
  - medical records documenting an inadequate response or adverse reaction to at least two clinically appropriate generic products with the same active ingredient.

brimonidine topical gel, 0.33%

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., rosacea); **and**
  - inadequate response, adverse reaction, or contraindication to one topical metronidazole agent and azelaic acid agent.

Combination products

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater, folliculitis/pseudofolliculitis, hidradenitis suppurativa, rosacea); **and**
  - medical necessity for the combination product instead of the commercially available separate agents.

dapsone gel

- Documentation of all of the following is required for a diagnosis of acne:
  - appropriate diagnosis (e.g., acne grade II or greater); **and**
  - medical records documenting inadequate response, adverse reaction, or contraindication to a benzoyl peroxide agent used in combination with a topical antibiotic agent; **and**
  - medical records documenting inadequate response or adverse reaction to one or contraindication to all other FDA-approved alternatives: oral tetracycline (i.e., tetracycline, doxycycline, minocycline), sulfacetamide 10% lotion, topical adapalene, topical azelaic acid, topical tretinoin.
- Documentation of all of the following is required for a diagnosis of keratosis pilaris:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: benzoyl peroxide, salicylic acid, urea, topical retinoid.

Fabior

- Documentation of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis, rosacea).

Finacea 15% foam

- Documentation of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater, rosacea).

Generic single-entity sulfacetamide agents for members ≥ 21 years of age

- Documentation of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater, rosacea).

Generic topical retinoids (excludes adapalene, tretinoin 0.05% gel, and tretinoin microspheres) for members ≥ 21 years of age

- Documentation of the following is required for a diagnosis of acne:
  - appropriate diagnosis (e.g., acne grade II or greater).
- Documentation of the following is required for a diagnosis of cutaneous warts, or folliculitis/pseudofolliculitis:
  - appropriate diagnosis.
- Documentation of all of the following is required for a diagnosis of rosacea:
  - appropriate diagnosis; **and**

- inadequate response, adverse reaction, or contraindication to all of the following:
  - benzoyl peroxide with a concurrent topical antibiotic; **and**
  - topical metronidazole.
- Documentation of the following is required for tretinoin 0.05% cream for a diagnosis of keratosis pilaris:
  - appropriate diagnosis.

isotretinoin for members ≥ 21 years of age (excludes generic Absorica and Absorica LD)
- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., treatment -resistant acne grade II or greater, unresponsive to conventional therapy); **and**
  - inadequate response or adverse reaction to a topical retinoid used in combination with a topical/oral antibiotic with or without benzoyl peroxide.

isotretinoin (generic Absorica) and Absorica LD for all ages
- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., treatment-resistant acne grade II or greater, unresponsive to conventional therapy); **and**
  - inadequate response or adverse reaction to a topical retinoid used in combination with a topical/oral antibiotic with or without benzoyl peroxide; **and**
  - medical records documenting an inadequate response or adverse reaction to an oral isotretinoin agent available without PA for members < 21 years of age; **and**
  - for Absorica LD, medical records documenting an inadequate response or adverse reaction to isotretinoin (generic Absorica).

ivermectin cream
- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., rosacea); **and**
  - inadequate response, adverse reaction, or contraindication to a topical metronidazole agent.

metronidazole 0.75% lotion and metronidazole 1% gel
- Documentation of the following is required for a diagnosis of perioral/periorificial dermatitis, rosacea:
  - appropriate diagnosis; **and**
  - medical records documenting inadequate response to one of the following: metronidazole 0.75% gel or metronidazole 0.75% cream.

Rhofade
- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., rosacea); **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: topical metronidazole, azelaic acid, topical brimonidine.

tazarotene cream, gel
- Documentation of all of the following is required for a diagnosis of acne, cutaneous warts, folliculitis/pseudofolliculitis:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis); **and**
  - medical records documenting an inadequate response or adverse reaction to a topical tretinoin agent.
- Documentation of all of the following is required for a diagnosis of psoriasis:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to a topical corticosteroid agent.
- Documentation of all of the following is required for a diagnosis of rosacea:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following:

- benzoyl peroxide with a concurrent topical antibiotic; **and**
- topical metronidazole.

Unique formulations (i.e., foams, kits, pads, pledgets, excludes Fabior and Finacea Foam)

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater, cutaneous warts, folliculitis/pseudofolliculitis, hidradenitis suppurativa, keratosis pilaris, perioral/periorificial dermatitis, rosacea, etc.); **and**
  - medical records documenting an inadequate response or adverse reaction to at least **two** clinically appropriate products with the same active ingredient; **and**
  - medical necessity for the requested formulation.

Winlevi

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., acne grade II or greater); **and**
  - medical records documenting inadequate response, adverse reaction, or contraindication to a benzoyl peroxide agent used in combination with a topical antibiotic agent; **and**
  - medical records documenting inadequate response or adverse reaction to one or contraindication to all other FDA-approved alternatives: oral tetracycline (i.e., tetracycline, doxycycline, minocycline), sulfacetamide 10% lotion, topical adapalene, topical azelaic acid, topical tretinoin.

MassHealth Evaluation Criteria
Table 11 - Nonsteroidal Anti-Inflammatory Drugs

Drug Category: Pain and inflammation

Medication Class/Individual Agents: Nonsteroidal Anti-Inflammatory Drugs (NSAIDS)

I. Prior-Authorization Requirements

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Phenylacetic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
diclofenac / misoprostol	Arthrotec	PA - < 60 years	# , A90
diclofenac 1% gel			A90
diclofenac 18 mg, 35 mg capsule		PA	A90
diclofenac 25 mg capsule		PA	A90
diclofenac extended-release			A90
diclofenac potassium 25 mg tablet		PA	A90
diclofenac potassium 50 mg tablet			A90
diclofenac powder for solution		PA	A90
diclofenac sodium tablet			A90
diclofenac topical patch-Flector	Flector	PA	A90
diclofenac topical patch-Licart	Licart	PA	
diclofenac topical solution	Pennsaid		# , A90

Nonsteroidal Anti-Inflammatory Drugs – COX-2 (Highly Selective) NSAIDs			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
celecoxib	Celebrex		# , A90
celecoxib oral solution	Elyxyb	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Risk factors for NSAID-related GI toxicity:

- Member is ≥ 60 years of age, history of gastric or duodenal ulcer, history of gastrointestinal (GI) bleed, perforation or obstruction, concurrent use of anticoagulants, aspirin (including low doses for cardiovascular prophylaxis), corticosteroids, high daily NSAID doses.

To avoid or minimize GI toxicity:

- Lowest effective dose should be prescribed for the shortest possible duration.
- GI toxicity may be lower with ibuprofen, naproxen, ketoprofen, diclofenac, and higher with indomethacin, flurbiprofen, and piroxicam.

If risk factors are present for NSAID-related GI toxicity as above, consider:

- Etodolac, nabumetone and meloxicam, all of which are preferential COX-2 inhibitors; however, with higher doses of etodolac and nabumetone, preferential inhibition of COX-2 is diminished.
- Highly selective COX-2 inhibitor (see table below).
- An antisecretory agent (PPI or misoprostol) with a non-selective NSAID.

Risk factors for NSAID-related renal toxicity:

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Propionic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fenoprofen capsule	Nalfon	PA	A90
fenoprofen tablet		PA	A90
flurbiprofen			A90
ibuprofen			*, A90
ibuprofen / famotidine	Duexis	PA - < 60 years	# , A90
ketoprofen			A90
ketoprofen extended-release		PA	A90
ketorolac nasal spray		PA	
ketorolac tablets and injection		PA - > 20 units/30 days	
naproxen / esomeprazole	Vimovo	PA - <60 years	# , A90
naproxen capsule, tablet			*, A90
naproxen controlled-release	Naprelan CR	PA	A90
naproxen enteric coated			A90
naproxen suspension		PA - ≥ 13 years	A90
oxaprozin	Daypro		# , A90

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Enolic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
meloxicam capsule		PA	A90
meloxicam tablet			A90
piroxicam	Feldene		# , A90

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Acetic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
etodolac			A90
etodolac extended-release		PA	A90
indomethacin 25 mg, 50 mg			A90
indomethacin			A90

Clinical Notes

- Preexisting renal disease, severe CHF, liver disease, or diuretic use

Ankylosing Spondylitis (AS)/Osteoarthritis(OA)/Rheumatoid Arthritis (RA) Dosing for celecoxib:

- Celecoxib: AS: 200 mg once daily or 100 mg twice daily, up to 400 mg/day; OA: 200 mg once daily or 100 mg twice daily; RA: 100-200 mg twice daily

Sulfonamide Allergy:

- Celecoxib is a sulfonamide derivative. The labeling for celecoxib states that use is contraindicated in sulfonamide-allergic patients.

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Acetic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
extended-release			
indomethacin suppository		PA	
indomethacin suspension		PA	
nabumetone 1000 mg	Relafen DS	PA	
nabumetone 500 mg, 750 mg			A90
sulindac			A90
tolmetin		PA	A90

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Anthranilic Acid Derivatives			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
meclofenamate		PA	A90
mefenamic acid			A90

Non-Selective Nonsteroidal Anti-Inflammatory Drugs – Salicylic Acid Derivative			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
diflunisal			A90
salsalate		PA	A90

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

* The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved:

- Acute pain
- Ankylosing spondylitis
- Familial adenomatous polyposis (FAP)
- Juvenile rheumatoid arthritis
- Mild-to-moderate pain

- Moderate to moderately severe pain
- Osteoarthritis
- Primary dysmenorrhea
- Rheumatoid arthritis

Non-FDA-approved:

- Cutaneous mastocytosis
- Mast cell activiation
- Migraine

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

diclofenac/misoprostol for members < 60 years of age

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction with concurrent therapy of diclofenac (minimum of 50 mg twice daily) and misoprostol (minimum of 200 mcg twice daily).

diclofenac potassium 25 capsule, diclofenac potassium 25 mg tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to an oral diclofenac product available without PA; **and**
  - inadequate response or adverse reaction to two other different NSAIDs.

diclofenac powder for solution

- Documentation of the following is required:
  - diagnosis of migraine; **and**

- one of the following:
  - medical records documenting an inadequate response or adverse reaction to three different NSAIDs, one of which must be diclofenac sodium; **or**
  - for members with a swallowing disorder or condition affecting the ability to swallow tablets, an inadequate response or adverse reaction to both of the following: ibuprofen suspension, naproxen suspension.

diclofenac topical patch (generic Flector)
- Documentation of the following is required:
  - diagnosis of acute pain (caused by minor strains, sprains, and contusions) or osteoarthritis; **and**
  - inadequate response or adverse reaction to diclofenac 1% gel.

Elyxyb
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to celecoxib capsules; **or**
    - medical necessity for the use of the solution formulation as noted by one of the following:
      - requested dose is not available in the capsule formulation; **or**
      - member utilizes tube feeding (G-tube/J-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - member is < 13 years of age.

etodolac ER, ketoprofen ER, naproxen CR
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for an extended-release formulation instead of the immediate-release equivalent.

fenoprofen, meclofenamate, salsalate, tolmetin
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to three different oral NSAIDs.

ibuprofen/famotidine for members < 60 years of age
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction with concurrent therapy of ibuprofen (minimum of 800 mg three times daily) and famotidine (minimum of 20 mg three times daily).

indomethacin suppository
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to ibuprofen suppositories; **and**
  - medical necessity for the requested formulation as noted by nausea/vomiting with oral formulations.

indomethacin suspension for all ages, and naproxen suspension for members ≥ 13 years of age
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to ibuprofen suspension; **and**

- medical necessity for the use of the solution formulation as noted by one of the following:
  - requested dose is not available in the capsule formulation; **or**
  - member utilizes tube feeding (G-tube/J-tube); **or**
  - member has a swallowing disorder or condition affecting ability to swallow; **or**
  - for indomethacin suspension, member is <13 years of age.

ketorolac (tablets and injection) > 20 units/30 days

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to three different NSAIDs; **and**
  - clinical rationale for exceeding FDA-approved dosing/duration.

ketorolac nasal spray

- Documentation of the following is required for a diagnosis of moderate to moderately severe pain:
  - appropriate diagnosis; **and**
  - one of the following:
    - both of the following:
      - inadequate response or adverse reaction to two different NSAIDs; **and**
      - medical records documenting an inadequate response or adverse reaction to one of the following: ketorolac tablets, ketorolac injection; **or**
    - medical necessity for a non-oral NSAID formulation; **and**
  - requested quantity is ≤ five bottles/30 days.
- Documentation of the following is required for treatment of migraine:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to sumatriptan tablets; **or**
    - member has nausea and vomiting with migraines, is unable to take oral medications, and prescriber provides medical records documenting an inadequate response or adverse reaction to sumatriptan nasal spray; **or**
    - medical records documenting an inadequate response or adverse reaction to ketorolac injection or ketorolac tablet; **and**
  - requested quantity is ≤ five bottles/30 days.

Licart

- Documentation of the following is required:
  - diagnosis of acute pain (caused by minor strains, sprains, and contusions) or osteoarthritis; **and**
  - inadequate response or adverse reaction to both of the following: diclofenac 1% gel, diclofenac topical patch (generic Flector).

meloxicam capsule

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to meloxicam tablet; **and**
  - inadequate response or adverse reaction to two other different NSAIDs; **and**
  - requested quantity is ≤ one unit/day.

naproxen/esomeprazole for members < 60 years of age

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction with concurrent therapy of naproxen (minimum of 375 mg twice daily) and omeprazole (minimum of 20 mg twice daily).

Relafen DS

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to an equivalent dose of nabumetone 500 mg or 750 mg; **and**
  - inadequate response or adverse reaction to two other different NSAIDs.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 12 - Antihistamines

Drug Category: Cough/Cold/Allergy

Medication Class/Individual Agents: Antihistamines

I. Prior-Authorization Requirements

First Generation (Nonselective) Antihistamines – Ethanolamines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
carbinoxamine 4 mg/5 mL solution, 4 mg tablet			A90
carbinoxamine 6 mg tablet		PA	A90
carbinoxamine extended-release	Karbinal ER	PA	A90
clemastine tablet			A90
dimenhydrinate injection			
diphenhydramine	Benadryl		# , *, A90

Second Generation (Peripherally Selective) Antihistamines – Piperidines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
desloratadine / pseudoephedrine	Clarinex-D	PA	
desloratadine orally disintegrating tablet		PA	M90
desloratadine tablet	Clarinex	PA	M90
fexofenadine / pseudoephedrine			*, A90
fexofenadine tablet			*, M90
loratadine / pseudoephedrine			*, A90
loratadine tablet, solution			*, M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

OTC

- Some of the former prescription antihistamines are now available over-the-counter (OTC).

Combinations of antihistamines and decongestants (for example, chlorpheniramine/pseudoephedrine) may be payable under MassHealth, but may not be listed in the antihistamine table. Please refer to the OTC drug list.

Second Generation (Peripherally Selective) Antihistamines – Nasal Preparations			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
azelastine 0.15% nasal spray		PA	A90
azelastine 137 mcg nasal spray			A90
olopatadine nasal spray	Patanase	PA	A90

First Generation (Nonselective) Antihistamines – Piperazines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
hydroxyzine hydrochloride			A90
hydroxyzine pamoate	Vistaril		# , A90

First Generation (Nonselective) Antihistamines – Alkylamines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
chlorpheniramine			*, A90
dexchlorpheniramine solution		PA	A90

First Generation (Nonselective) Antihistamines – Phenothiazine			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
promethazine			A90

First Generation (Nonselective) Antihistamines – Piperidines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cyproheptadine			A90

Second Generation (Peripherally Selective) Antihistamines – Piperazines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cetirizine / pseudoephedrine			*, A90
cetirizine syrup,			*, M90

Second Generation (Peripherally Selective) Antihistamines – Piperazines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tablet			
levocetirizine solution		PA	M90
levocetirizine tablet			# , M90

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- perennial or seasonal allergic rhinitis: oral/intranasal antihistamines
- chronic idiopathic urticaria: oral antihistamines only
- vasomotor (i.e., non-allergic) rhinitis: oral/intranasal agents

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.

- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

azelastine 0.15% (generic Astepro) and olopatadine (generic Patanase) nasal sprays

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), or adverse reaction to one, or contraindication to all intranasal corticosteroid agents; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to azelastine 137 mcg nasal spray.
- For quantities greater than one bottle/30 days, in addition to the above criteria, documentation must be provided regarding an inadequate clinical response at the manufacturer's recommended doses.

SmartPA: Claims for one bottle/30 days of azelastine 0.15% nasal spray and olopatadine nasal spray will usually process at the pharmacy without a PA request if the member has MassHealth medical claims for allergic rhinitis or non-allergic rhinitis and a history of paid pharmacy claims for ≥ 14 days out of the last 180 days of one intranasal corticosteroid and azelastine 137 mcg nasal spray.

carbinoxamine 6 mg tablet and carbinoxamine extended-release

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), or adverse reaction to one, or contraindication to all intranasal corticosteroid agents; **and**
  - inadequate response (defined as ≥ 14 days of therapy), or adverse reaction to two, or contraindication to all nonselective antihistamines available without prior authorization; **and**
  - for carbinoxamine extended-release, inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to carbinoxamine immediate-release solution; **and**
  - for carbinoxamine 6 mg tablet, inadequate response or adverse reaction to carbinoxamine 4 mg tablet.

Clarinex-D

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), or adverse reaction to one, or contraindication to all intranasal corticosteroid agents (if the diagnosis is chronic idiopathic urticaria, a trial with an intranasal corticosteroid is not required); **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to both of the following: loratadine/pseudoephedrine and cetirizine/pseudoephedrine.

SmartPA: Claims for Clarinex-D will usually process at the pharmacy without a PA request if the member has MassHealth medical claims for allergic rhinitis or chronic idiopathic urticaria and a history of paid pharmacy claims for ≥ 14 days out of the last 180 days of loratadine/pseudoephedrine, cetirizine/pseudoephedrine, **and** an intranasal corticosteroid.

desloratadine tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one or contraindication to all of the following: cetirizine, fexofenadine, levocetirizine, and loratadine.

SmartPA: Claims for desloratadine tablets will usually process at the pharmacy without a PA request if the member has MassHealth medical claims for allergic rhinitis or chronic idiopathic urticaria and a history of paid pharmacy claims for ≥ 14 days out of the last 180 days for one of the following: loratadine tablets or liquid, cetirizine tablets or liquid, fexofenadine tablet, or levocetirizine tablet.

desloratadine ODT and levocetirizine solution

- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- medical necessity for use of requested agent as noted by one of the following:
  - member utilizes tube feeding (G-tube, J tube); **or**
  - member has a swallowing disorder or condition affecting ability to swallow; **or**
  - member is < 13 years of age; **and**
- inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to two or contraindication to all of the following: cetirizine, levocetirizine, and loratadine.

dexchlorpheniramine solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two antihistamine solutions available without prior authorization.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 13 - Lipid-Lowering Agents

Drug Category: Cardiovascular

Medication Class/Individual Agents: Lipid-Lowering Agent

I. Prior-Authorization Requirements

Lipid-Lowering Agents – Statins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amlodipine / atorvastatin	Caduet	PA	M90
atorvastatin 10 mg, 20 mg, 40 mg tablet	Lipitor	PA - > 1.5 units/day	# , M90
atorvastatin 80 mg tablet	Lipitor	PA - > 1 unit/day	# , M90
atorvastatin suspension	Atorvaliq	PA	
fluvastatin		PA	M90
fluvastatin extended-release	Lescol XL	PA	M90
lovastatin 10 mg, 20 mg		PA - > 1.5 units/day	M90
lovastatin 40 mg		PA - > 2 units/day	M90
lovastatin extended-release	Altoprev	PA	
pitavastatin calcium	Livalo	PA	M90
pitavastatin magnesium	Zypitamag	PA	
pravastatin 10 mg, 20 mg, 40 mg		PA - > 1.5 units/day	M90
pravastatin 80 mg		PA - > 1 unit/day	M90
rosuvastatin 40 mg	Crestor	PA - > 1 unit/day	# , M90
rosuvastatin 5 mg, 10 mg, 20 mg	Crestor	PA - > 1.5 units/day	# , M90
rosuvastatin sprinkle capsule	Ezallor	PA	
simvastatin 5 mg, 10 mg, 20 mg, 40 mg	Zocor	PA - > 1.5 units/day	# , M90
simvastatin 80 mg	Zocor	PA - > 1 unit/day	# , M90

Lipid-Lowering Agents – Bile Acid Sequestrants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cholestyramine / aspartame			M90
cholestyramine /			M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Available treatment guidelines for the management of hyperlipidemia include:

- The National Cholesterol Education Program (NCEP) Adult Treatment Program (ATP) III guideline (2004)[1]
- The American College of Cardiology and American Heart Association Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults (2013)[2]
- The American College of Cardiology and American Heart Association Guideline on the Management of Blood Cholesterol Adults (2019)[3]

1. Grundy SM, Cleeman JI, Merz NB, Brewer Jr B, Clark LT, Hunninghake DB, et al. Implications of recent clinical trials for the National Cholesterol Education Program Adult

Lipid-Lowering Agents – Bile Acid Sequestrants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
sucrose			
colesevelam	Welchol		# , M90
colestipol	Colestid		# , M90

Lipid-Lowering Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bempedoic acid	Nexletol	PA	
bempedoic acid / ezetimibe	Nexlizet	PA	
evinacumab-dgnb	Evkeeza	PA	MB
icosapent ethyl	Vascepa	PA	BP, M90
inclisiran	Leqvio	PA	
lomitapide	Juxtapid	PA	
omega-3 acid ethyl esters	Lovaza		# , M90

Lipid-Lowering Agents – Fibric Acids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fenofibrate 30 mg, 90 mg capsule			M90
fenofibrate 40 mg, 120 mg tablet	Fenoglide	PA	M90
fenofibrate 43 mg, 67 mg, 130 mg, 134 mg, 200 mg capsule			M90
fenofibrate 48 mg, 145 mg tablet	Tricor		# , M90
fenofibrate 50 mg, 150 mg capsule	Lipofen		M90
fenofibrate 54 mg, 160 mg tablet			M90
fenofibric acid	Trilipix		# , M90
fenofibric acid tablet			M90
gemfibrozil	Lopid		# , M90

Lipid-Lowering Agents – PCSK9 Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alirocumab	Praluent	PA	
evolocumab	Repatha	PA	

Clinical Notes

Treatment Panel III Guidelines. Circulation. 2004;110:227-39.

2.Stone NJ, Robinson J, Lichtenstein AH, Bairey Merz CN, Blum CB, Eckel RH, Goldberg AC, Gordon D, Levy D, Lloyd-Jones DM, McBride P, Schwartz JS, Shero ST, Smith SC Jr, Watson K, Wilson PWF. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;00:000–000. DOI: 10.1161/01.cir.0000437738.63853.7a

3. Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS et al. AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: Executive Summary. Circulation. 2018 Nov 10:CIR0000000000000624.

Lipid-Lowering Agents – Nicotinic Acids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
niacin	vitamin B-3		*, M90
niacin extended-release tablet			M90
niacinamide			*, M90

Lipid-Lowering Agents – Cholesterol Absorption Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ezetimibe	Zetia		# , M90
ezetimibe / simvastatin	Vytorin	PA - > 1 unit/day	# , M90

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

Evkeeza

FDA-approved, for example:

- homozygous familial hypercholesterolemia (HoFH)

Fenoglide

FDA-approved, for example:

- hypercholesterolemia
- hypertriglyceridemia
- mixed dyslipidemias

icosapent ethyl

FDA-approved, for example:

- cardiovascular risk reduction (with established cardiovascular disease or diabetes mellitus and risk factors for cardiovascular disease)
- hypertriglyceridemia (not inclusive of those with established cardiovascular disease or diabetes mellitus and cardiovascular risk factors)

Juxtapid

FDA-approved, for example:

- HoFH

Leqvio

FDA-approved, for example:

- hypercholesterolemia in a member with clinical atherosclerotic cardiovascular disease in combination with a statin
- HeFH in combination with a statin

Nexletol, Nexlizet

FDA-approved, for example:

- atherosclerotic cardiovascular disease
- heterozygous familial hypercholesterolemia (HeFH)

Praluent, Repatha

FDA-approved, for example:

- HeFH in combination with a statin
- HoFH in combination with a statin
- hypercholesterolemia in a member with clinical atherosclerotic cardiovascular disease in combination with a statin
- primary hyperlipidemia

Statins

FDA-approved, for example:

- hypercholesterolemia

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Table 1. Statin Quantity Limits

1 unit/day	1.5 units/day	2 units/day

Altoprev 60 mg	Altoprev 20 mg, 40 mg	fluvastatin 40 mg
amlodipine/atorvastatin	atorvastatin 10 mg, 20 mg, 40 mg	lovastatin 40 mg
atorvastatin 80 mg	fluvastatin 20 mg	
Ezallor	pitavastatin calcium 1 mg, 2 mg	
ezetimibe/simvastatin	lovastatin 10 mg, 20 mg	
fluvastatin extended-release 80 mg	pravastatin 10 mg, 20 mg, 40 mg	
pitavastatin calcium 4 mg	rosuvastatin 5 mg, 10 mg, 20 mg	
pravastatin 80 mg	simvastatin 5 mg, 10 mg, 20 mg, 40 mg	
rosuvastatin 40 mg	Zypitamag 1 mg, 2 mg	
simvastatin 80 mg		
Zypitamag 4 mg		

amlodipine/atorvastatin

- Documentation of the following is required:
  - diagnosis of one of the following:
    - heterozygous familial hypercholesterolemia; **or**
    - homozygous familial hypercholesterolemia; **or**
    - hypercholesterolemia in a member with a previous history of any cardiovascular event; **or**
    - hypertriglyceridemia; **or**
    - primary dysbetaliproteinemia; **or**
    - primary hyperlipidemia; **or**
    - primary prevention of cardiovascular events; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents; **and**
  - one of the following:
    - requested quantity is ≤ one tablet/day; **or**
    - medical necessity for exceeding the quantity limits; **or**
    - for requests above the maximum FDA-approved dose, inadequate response (defined as ≥ the last 3 months) to atorvastatin 80 mg daily.

SmartPA: Claims for amlodipine/atorvastatin at a quantity of ≤ one unit/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for 90 days out of the last 120 days or has a history of paid MassHealth pharmacy claims for rosuvastatin at a dose of at least 20 mg or atorvastatin at a dose of at least 40 mg for at least 90 days in all claims history.†

Altoprev, fluvastatin, fluvastatin extended-release, pitavastatin calcium, and Zypitamag

- Documentation of the following is required:
  - diagnosis of one of the following:
    - heterozygous familial hypercholesterolemia; **or**
    - homozygous familial hypercholesterolemia; **or**
    - hypercholesterolemia in a member with a previous history of any cardiovascular event; **or**
    - hypertriglyceridemia; **or**
    - primary dysbetaliproteinemia; **or**
    - primary hyperlipidemia; **or**
    - primary prevention of cardiovascular events; **and**
  - one of the following:
    - inadequate response (defined as ≥ the last 3 months) or adverse reaction to one or contraindication to all high-intensity statins;

or

- clinical rationale for not using a high-intensity statin; **and**

- one of the following:
  - request is within quantity limits; **or**
  - medical necessity for exceeding the quantity limits; **or**
  - for requests above the maximum FDA-approved dose, inadequate response (defined as ≥ the last 3 months) to atorvastatin 80 mg daily.

SmartPA: Claims for Altoprev (60 mg), fluvastatin extended-release (80 mg), pitavastatin calcium (4 mg), or Zypitamag (4 mg) at a quantity of ≤ one unit/day, Altoprev (20 mg, 40 mg), fluvastatin (20 mg), pitavastatin calcium (1 mg, 2 mg), or Zypitamag (1 mg, 2 mg) at a quantity of ≤ 1.5 units/day, and fluvastatin (40 mg) at a quantity of ≤ 2 units/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for 90 days out of the last 120 days or has a history of paid MassHealth pharmacy claims for rosuvastatin at a dose of at least 20 mg or atorvastatin at a dose of at least 40 mg for at least 90 days in all claims history.†

Atorvaliq

- Documentation of the following is required:
  - diagnosis of one of the following:
    - heterozygous familial hypercholesterolemia; **or**
    - homozygous familial hypercholesterolemia; **or**
    - hypercholesterolemia in a member with a previous history of any cardiovascular event; **or**
    - hypertriglyceridemia; **or**
    - primary dysbetaliproteinemia; **or**
    - primary hyperlipidemia; **or**
    - primary prevention of cardiovascular events; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions,suspensions, films, or dispersible tablets); **and**
  - appropriate dosing; **and**
  - clinical rationale for the use of the requested agent instead of Ezallor.

*Recertification of the requested agent will be contingent upon continued medical necessity for the requested formulation instead of tablets.

atorvastatin, ezetimibe/simvastatin, lovastatin, pravastatin, rosuvastatin, and simvastatin over quantity limits

- Documentation of the following is required:
  - diagnosis of one of the following:
    - heterozygous familial hypercholesterolemia; **or**
    - homozygous familial hypercholesterolemia; **or**
    - hypercholesterolemia in a member with a previous history of any cardiovascular event; **or**
    - hypertriglyceridemia; **or**
    - primary dysbetaliproteinemia; **or**
    - primary hyperlipidemia; **or**
    - primary prevention of cardiovascular events; **and**
  - medical necessity for exceeding the quantity limits.

Evkeeza

- Documentation of the following is required:

- diagnosis of homozygous familial hypercholesterolemia confirmed by one of the following:
  - both of the following:
    - baseline LDL-C ≥ 400 mg/dL; **and**
    - current LDL-C ≥ 100 mg/dL; **or**
  - one of the following:
    - member had evidence of xanthoma before 10 years of age; **or**
    - evidence of HeFH in both parents; **or**
  - laboratory test confirming genetic mutation associated with HoFH including low density lipoprotein receptor (LDLR) mutations, PCSK9 mutations and familial defective apoB mutations; **and**
- member is ≥ five years of age; **and**
- prescriber is a specialist (e.g. cardiologist, vascular neurologist, lipid-lowering specialist, endocrinologist) or consultation notes from a specialist regarding the use of the agent are provided; **and**
- one of the following:
  - agent to be used as add-on therapy with a high-intensity statin, ezetimibe, and PCSK9 inhibitor; **or**
  - contraindication or other compelling clinical rationale for omitting one or more of the following standard lipid-lowering therapies: statin, ezetimibe, PCSK9 inhibitor; **and**
- member's current weight; **and**
- appropriate dosing.

*Recertification of the requested agent will be contingent upon MassHealth pharmacy claims history or additional documentation addressing adherence to the entire lipid-lowering regimen, as well as updated information regarding the member's current weight, and positive response to therapy, including decrease in LDL-C laboratory values from baseline.

Ezallor

- Documentation of the following is required:
  - diagnosis of one of the following:
    - heterozygous familial hypercholesterolemia; **or**
    - homozygous familial hypercholesterolemia; **or**
    - hypercholesterolemia in a member with a previous history of any cardiovascular event; **or**
    - hypertriglyceridemia; **or**
    - primary dysbetaliproteinemia; **or**
    - primary hyperlipidemia; **or**
    - primary prevention of cardiovascular events; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions,suspensions, films, or dispersible tablets); **and**
  - appropriate dosing; **and**
  - requested quantity is ≤ one sprinkle capsule/day.

*Recertification of the requested agent will be contingent upon continued medical necessity for the requested formulation instead of tablets.

fenofibrate 40 mg, 120 mg tablet

- Documentation of the following is required:
  - diagnosis of one of the following:
    - hypertriglyceridemia; **or**
    - hypercholesterolemia; **or**
    - mixed dyslipidemia; **and**

- medical records documenting an inadequate response or adverse reaction to a therapeutically equivalent fenofibrate formulation available without PA; **and**
- one of the following:
  - requested quantity is ≤ one unit/day; **or**
  - medical necessity for exceeding the quantity limits.

icosapent ethyl for cardiovascular risk reduction (with established cardiovascular disease or diabetes mellitus and risk factors for cardiovascular disease)

- Documentation of the following is required:
  - diagnosis of cardiovascular risk reduction with one of the following;
    - member has established cardiovascular disease (e.g., prior MI, hospitalization for high-risk NSTE-ACS cerebrovascular or carotid disease: prior ischemic stroke, carotid artery disease, PAD); **or**
    - member has diabetes mellitus with at least one risk factor for CVD (e.g., age [women ≥ 65 years, men ≥ 55 years], smoker, HTN, low HDL-C [≤ 40 mg/dL for men and ≤ 50 mg/dL for women], renal dysfunction [CrCl >30 and < 60 mL/min], retinopathy, micro- or macroalbuminuria), high-sensitivity C-reactive protein (hs-CRP) > 3.0 mg/dL, or ankle-brachial index < 0.9 without symptoms of intermittent claudication; **and**
  - triglyceride level ≥ 135 mg/dL; **and**
  - one of the following:
    - agent to be used in combination with a statin; **or**
    - clinical rationale why member cannot take a statin; **and**
  - one of the following:
    - for icosapent ethyl one gram capsule, requested quantity is ≤ four capsules/day; **or**
    - for icosapent ethyl 0.5 gram capsule, requested quantity is ≤ eight capsules/day; **or**
    - medical necessity for exceeding the quantity limits.

SmartPA: Claims for icosapent ethyl one gram capsule at a quantity of ≤ four units/day will usually process at the pharmacy without a PA request if the member has history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

SmartPA: Claims for icosapent ethyl 0.5 gram capsule at a quantity of ≤ eight units/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for for at least 90 days out of the last 120 days.†

icosapent ethyl for hypertriglyceridemia (not inclusive of those with established cardiovascular disease or diabetes mellitus and cardiovascular risk factors)

- Documentation of the following is required:
  - diagnosis of hypertriglyceridemia (not inclusive of those with established cardiovascular disease or diabetes mellitus and cardiovascular risk factors); **and**
  - triglyceride level ≥ 500 mg/dL; **and**
  - inadequate response, adverse reaction, or contraindication to omega-3 acid ethyl esters; **and**
  - inadequate response, adverse reaction, or contraindication to a fibric acid derivative (i.e., fenofibrate or gemfibrozil); **and**
  - one of the following:
    - for icosapent ethyl one gram capsule, requested quantity is ≤ four capsules/day; **or**
    - for icosapent ethyl 0.5 gram capsule, requested quantity is ≤ eight capsules/day; **or**
    - medical necessity for exceeding the quantity limits.

SmartPA: Claims for icosapent ethyl one gram capsule at a quantity of ≤ four units/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

SmartPA: Claims for icosapent ethyl 0.5 gram capsule at a quantity of ≤ eight units/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last

120 days.†

Juxtapid

- Documentation of the following is required:
  - diagnosis of homozygous familial hypercholesterolemia confirmed by one of the following:
    - both of the following:
      - baseline LDL-C ≥ 400 mg/dL; **and**
      - current LDL-C ≥ 100 mg/dL; **or**
    - one of the following:
      - member had evidence of xanthoma before 10 years of age; **or**
      - evidence of HeFH in both parents; **or**
    - laboratory test confirming genetic mutation associated with HoFH including low density lipoprotein receptor (LDLR) mutations, PCSK9 mutations and familial defective apoB mutations; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g. cardiologist, vascular neurologist, lipid-lowering specialist, endocrinologist) or consultation notes from a specialist regarding the use of the agent are provided; **and**
  - one of the following:
    - inadequate response (defined as ≥ the last 3 months) or adverse reaction to one or contraindication to all high intensity statins; **or**
    - clinical rationale for not using a high intensity statin; **and**
  - one of the following:
    - agent to be used as add-on therapy with a high intensity statin; **or**
    - contraindication to statin therapy; **and**
  - inadequate response or adverse reaction to one additional non-statin lipid-lowering agent or contraindication to all other non-statin lipid-lowering agents.

Leqvio

- Documentation of the following is required*:
  - diagnosis of hypercholesterolemia with one of the following:
    - for members with a diagnosis of heterozygous familial hypercholesterolemia, current LDL-C is ≥ 70 mg/dL; **or**
    - for members with a previous history of a cardiovascular event, current LDL-C is ≥ 55 mg/dL; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - prescriber is a specialist (e.g., cardiologist, endocrinologist, lipid-lowering specialist, vascular neurologist) or consultation notes from a specialist regarding the use of the agent are provided; **and**
  - inadequate response (defined as ≥ the last 3 months)** or adverse reaction to one or contraindication to both of the following: Praluent, Repatha; **and**
  - one of the following:
    - inadequate response (defined as ≥ the last 3 months) to a high intensity statin in combination with ezetimibe; **or**
    - adverse reaction or contraindication to ezetimibe and inadequate response (defined as ≥ the last 3 months) to high intensity statin monotherapy; **or**
    - adverse reaction to one high intensity statin or contraindication to all high intensity statins.

*Recertification of the requested agent will be contingent upon MassHealth pharmacy claims history or additional documentation addressing adherence to the entire lipid-lowering regimen, as well as positive response to therapy, including decrease in LDL-C laboratory values from baseline.

**Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to these agents.

Nexletol and Nexlizet

- Documentation of the following is required:
  - diagnosis of hypercholesterolemia with one of the following:
    - for members with a diagnosis of heterozygous familial hypercholesterolemia, current LDL-C is ≥ 70 mg/dL; **or**
    - for members with a previous history of a cardiovascular event, current LDL-C is ≥ 55 mg/dL; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., cardiologist, endocrinologist, lipid-lowering specialist, vascular neurologist) or consultation notes from a specialist regarding the use of the requested agent are provided; **and**
  - one of the following:
    - inadequate response (defined as ≥ the last 3 months) to a high intensity statin in combination with ezetimibe; **or**
    - adverse reaction or contraindication to ezetimibe and inadequate response (defined as ≥ the last 3 months) to high intensity statin monotherapy; **or**
    - adverse reaction to one high intensity statin or contraindication to all high intensity statins; **and**
  - requested quantity is ≤ one tablet/day.

Praluent

- Documentation of the following is required:
  - diagnosis of hypercholesterolemia with one of the following:
    - for members with a diagnosis of heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia, current LDL-C is ≥ 70 mg/dL; **or**
    - for members with a previous history of a cardiovascular event, current LDL-C is ≥ 55 mg/dL; **or**
    - for members with primary hyperlipidemia without a history of a cardiovascular event and/or heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia, baseline LDL-C is ≥ 190 mg/dL, and current LDL-C is ≥ 70 mg/dL; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - requested quantity is two pens or syringes/28 days; **and**
  - one of the following:
    - inadequate response (defined as ≥ the last 3 months) to a high intensity statin in combination with ezetimibe; **or**
    - adverse reaction or contraindication to ezetimibe and inadequate response (defined as ≥ the last 3 months) to high intensity statin monotherapy; **or**
    - adverse reaction to one high intensity statin or contraindication to all high intensity statins.

Repatha

- Documentation of the following is required:
  - one of the following:
    - diagnosis of heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia and member is ≥ 10 years of age; **or**
    - member is ≥ 18 years of age; **and**
  - diagnosis of hypercholesterolemia with one of the following:
    - for members with a diagnosis of heterozygous or homozygous familial hypercholesterolemia, current LDL-C is ≥ 70 mg/dL; **or**
    - for members with a previous history of a cardiovascular event, current LDL-C is ≥ 55 mg/dL; **or**
    - for members with primary hyperlipidemia without a history of a cardiovascular event and/or heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia, baseline LDL-C is ≥ 190 mg/dL, and current LDL-C is ≥ 70 mg/dL; **and**
  - one of the following:
    - inadequate response (defined as ≥ the last 3 months) to a high intensity statin in combination with ezetimibe; **or**

- adverse reaction or contraindication to ezetimibe and inadequate response (defined as ≥ the last 3 months) to high intensity statin monotherapy; **or**
- adverse reaction to one high intensity statin or contraindication to all high intensity statins; **and**

- appropriate dosing; **and**
- requested quantity is two autoinjectors or syringes/28 days or one to two on-body infusor systems/28 days.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 14 - Headache Therapy

Drug Category: Pain and Inflammation

Medication Class/Individual Agents: Butalbitals, CGRP Inhibitors, Ergot Alkaloids, and Serotonin Receptor Agents

I. Prior-Authorization Requirements

Headache Therapy – Calcitonin Gene-Related Peptide (CGRP) Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
atogepant	Qulipta PD	PA	
eptinezumab-jjmr	Vyepti	PA	MB
erenumab-aooe	Aimovig	PA	
fremanezumab-vfrm for migraine prophylaxis	Ajovy PD	PA	
galcanezumab-gnlm	Emgality PD	PA	
rimegepant	Nurtec PD	PA	
ubrogepant	Ubrelvy PD	PA	
zavegepant	Zavzpret	PA	

Headache Therapy – Serotonin Receptor Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
almotriptan		PA	A90
eletriptan	Relpax	PA	A90
frovatriptan	Frova	PA	BP, A90
lasmiditan	Reyvow	PA	
naratriptan		PA - > 18 units/30 days	A90
rizatriptan orally disintegrating tablet	Maxalt MLT	PA - > 18 units/30 days	# , A90
rizatriptan tablet	Maxalt	PA - > 18 units/30 days	# , A90
sumatriptan / naproxen		PA	A90
sumatriptan 10 mg nasal spray	Tosymra	PA	
sumatriptan 5 mg, 20 mg nasal spray	Imitrex	PA - > 18 units/30 days	# , A90
sumatriptan injection-Imitrex	Imitrex	PA	
sumatriptan injection-	Zembrace	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Contraindications to Triptans:

- history, presence, symptoms, or signs of ischemic heart disease (e.g., angina, MI, stroke, TIA), coronary artery vasospasm, or other significant underlying cardiovascular disease
- uncontrolled hypertension
- concurrent use or use within 24 hours of ergotamine-containing products or ergot-type medications (e.g., dihydroergotamine, methysergide)
- concurrent use with MAO inhibitor therapy or within two weeks of MAO inhibitor discontinuation
- use within 24 hours of treatment with another triptan
- management of hemiplegic or basilar migraine
- hypersensitivity to the product or any of its ingredients

Do not exceed the maximum recommended dose per 24-hour period.

Orally Disintegrating Tablets:

- Place tablet on tongue, where it will be dissolved and swallowed with saliva.
- Inform phenylketonurics that tablets contain phenylalanine.

Migraine prophylaxis (e.g., amitriptyline, propranolol,

Headache Therapy – Serotonin Receptor Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
Zembrace			
sumatriptan tablet	Imitrex	PA - > 18 units/30 days	# , A90
zolmitriptan nasal spray	Zomig	PA	A90
zolmitriptan orally disintegrating tablet		PA	A90
zolmitriptan tablet	Zomig	PA - > 18 units/30 days	# , A90

Headache Therapy – Ergot Alkaloids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dihydroergotamine injection		PA	
dihydroergotamine nasal spray	Migranal	PA	A90
ergotamine / caffeine suppository		PA	A90

Headache Therapy – Butalbital-Containing Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
butalbital / aspirin / caffeine / codeine		PA	
butalbital / aspirin / caffeine capsule		PA - < 18 years and PA > 20 units/30 days	
butalbital 50 mg / acetaminophen 300 mg		PA	
butalbital 50 mg / acetaminophen 300 mg / caffeine 40 mg		PA	
butalbital 50 mg / acetaminophen 300 mg / caffeine 40 mg / codeine 30 mg		PA	
butalbital 50 mg / acetaminophen 325 mg		PA	
butalbital 50 mg / acetaminophen 325 mg / caffeine 40 mg / codeine 30 mg		PA - < 18 years and PA > 20 units/30 days	
butalbital 50 mg /		PA	

Clinical Notes

timolol) may be considered for the following conditions:

- migraine occurs ≥ twice monthly and produces disability lasting ≥ three days per month
- contraindication to, or failure of, acute treatments
- abortive medications are used > twice per week
- other severe migraine conditions

Headache Therapy – Butalbital-Containing Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acetaminophen 325 mg / caffeine 40 mg capsule			
butalbital 50 mg / acetaminophen 325 mg / caffeine 40 mg tablet		PA - < 18 years and PA > 20 units/30 days	

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- acute treatment of migraine (all triptans, dihydroergotamine injection, dihydroergotamine nasal spray, ergotamine/caffeine suppository, Nurtec, Reyvow, Ubrelvy, Zavzpret)
- cluster headache (dihydroergotamine injection, sumatriptan injection)
- chronic tension-type headache (butalbital agents)
- episodic cluster headache (Emgality)
- migraine prophylaxis (Aimovig, Ajovy, Emgality, Nurtec, Qulipta, Vyepti)
- vascular headache (ergotamine/caffeine suppository)

Triptans are NOT intended for prophylactic therapy of migraines.

Non-FDA-approved, for example:

- cluster headache (all triptans except sumatriptan injection, dihydroergotamine nasal spray, ergotamine/caffeine suppository, Reyvow)
- cyclic vomiting syndrome (sumatriptan 5 mg, 20 mg nasal spray, sumatriptan injection)
- migraine headache (butalbital agents)
- vascular headache (all triptans, dihydroergotamine injection, dihydroergotamine nasal spray, Reyvow)

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Aimovig, Ajovy, Emgality

- Documentation of all of the following is required for migraine prophylaxis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - migraine frequency ≥ four days per month; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: atenolol, metoprolol, nadolol, propranolol, timolol; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: topiramate, tricyclic antidepressant, valproic acid, venlafaxine; **and**
  - for Aimovig, inadequate response or adverse reaction to one or contraindication to all of the following: Ajovy, Emgality.
- Documentation of the following is required for Emgality for cluster headache:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing.
- Documentation of the following is required for recertification of Emgality for cluster headache:
  - the member is still actively having a cluster headache; **and**
  - the member has been initiated on prophylactic therapy for the cluster headache; **or**
  - clinical rationale why prophylactic therapy is not appropriate.

almotriptan (≤ 18 units/30 days), eletriptan (≤ 18 units/30 days), and frovatriptan (≤ 18 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - for almotriptan, member is ≥ 12 years of age; **or**
    - for eletriptan or frovatriptan, member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: rizatriptan tablets or orally

disintegrating tablets (ODTs), sumatriptan tablets, zolmitriptan tablets.

SmartPA: Claims for ≤ 18 units/30 days of almotriptan tablets will usually process at the pharmacy without a PA request if there is a history of paid MassHealth pharmacy claims for at least two different oral triptan agents available without PA within quantity limits (sumatriptan tablets, rizatriptan ODTs or tablets, zolmitriptan tablets) and the member is ≥ 12 years of age.†

SmartPA: Claims for ≤ 18 units/30 days of eletriptan or frovatriptan, will usually process at the pharmacy without a PA request if there is a history of paid MassHealth pharmacy claims for at least two different oral triptan agents available without PA within quantity limits (naratriptan, sumatriptan tablets, rizatriptan ODTs or tablets, zolmitriptan tablets) and the member is ≥ 18 years of age.†

almotriptan (> 18 units/30 days), eletriptan (> 18 units/30 days), and frovatriptan (> 18 units/30 days)

- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

Brand name Imitrex 5 mg, 20 mg nasal spray, Imitrex tablet, Maxalt MLT and tablet, and Zomig tablet (≤ 18 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to the generic equivalent of the requested agent; **and**
  - inadequate response or adverse reaction to all other triptans available without PA.

Brand name Imitrex 5 mg, 20 mg nasal spray, Imitrex tablet, Maxalt MLT and tablet, and Zomig tablet (> 18 units/30 days)

- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member’s headache frequency, documentation of neurologist consultation, and prophylactic regimen.

butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg capsule (≤ 20 units/30 days)

Please refer to additional criteria if request is for members < 18 years of age and/or for quantities exceeding 20 units/30 days.

- Documentation of the following is required for a diagnosis of chronic tension-type headache:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg tablets.
- Documentation of the following is required for a diagnosis of migraine headache:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg tablets; **and**
  - inadequate response or adverse reaction to two or contraindication to all triptans; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: NSAIDs, acetaminophen, aspirin, acetaminophen/caffeine, acetaminophen/aspirin/caffeine, and ergot alkaloid; **and**
  - inadequate response or adverse reaction to one or contraindication to all oral CGRP inhibitors.

butalbital-containing agents (formulations that require PA for all quantities, excluding butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg capsule) (≤ 20 units/30 days)

Please refer to additional criteria if request is for members < 18 years of age and/or for quantities exceeding 20 units/30 days.

- Documentation of the following is required for a diagnosis of chronic tension-type headache:
  - appropriate diagnosis; **and**
  - clinical rationale for the requested formulation instead of formulations available without PA within quantity limits.
- Documentation of the following is required for a diagnosis of migraine headache:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all triptans; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: NSAIDs, acetaminophen, aspirin,

acetaminophen/caffeine, acetaminophen/aspirin/caffeine, and ergot alkaloid; **and**
- inadequate response or adverse reaction to one or contraindication to all oral CGRP inhibitors.

butalbital-containing agents exceeding quantity limits (> 20 units/30 days)

For all requests, individual drug PA criteria must be met first where applicable.

- Documentation of the following is required for a diagnosis of tension headache:
  - appropriate diagnosis; **and**
  - headache frequency; **and**
  - current prophylactic regimen; **and**
  - prescriber is a neurologist or neurology consult notes are provided; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: NSAIDs, acetaminophen, aspirin, acetaminophen/caffeine, and acetaminophen/aspirin/caffeine.
- Documentation of the following is required for a diagnosis of migraine headache:
  - appropriate diagnosis; **and**
  - headache frequency; **and**
  - current prophylactic regimen; **and**
  - prescriber is a neurologist or neurology consult notes are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all triptans; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: NSAIDs, acetaminophen, aspirin, acetaminophen/caffeine, acetaminophen/aspirin/caffeine, and ergot alkaloid; **and**
  - inadequate response or adverse reaction to one or contraindication to all oral CGRP inhibitors.

butalbital-containing agents for members < 18 years of age

For all requests, individual drug PA criteria must be met first where applicable.

- Documentation of the following is required for a diagnosis of tension headache:
  - appropriate diagnosis; **and**
  - headache frequency; **and**
  - current prophylactic regimen if member experiences more than four headaches per month or headaches that last longer than 12 hours; **and**
  - prescriber is a neurologist or neurology consult notes are provided that support the use of a butalbital-containing agent; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: NSAIDs, acetaminophen, aspirin, acetaminophen/caffeine, acetaminophen/aspirin/caffeine.
- Documentation of the following is required for a diagnosis of migraine headache:
  - appropriate diagnosis; **and**
  - headache frequency; **and**
  - current prophylactic regimen if member experiences more than four headaches per month or headaches that last longer than 12 hours; **and**
  - prescriber is a neurologist or consult notes from a neurologist are provided that support the use of a butalbital-containing agent; **and**
  - inadequate response or adverse reaction to two or contraindication to all triptans; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: NSAIDs, acetaminophen, aspirin, acetaminophen/caffeine, acetaminophen/aspirin/caffeine.

codeine-containing products for members < 12 years of age

For all requests, individual drug PA criteria and/or butalbital-containing agents age restriction criteria must be met first where applicable.

- Documentation of one of the following is required:
  - CYP2D6 genotyping confirms member is not an ultra-rapid CYP2D6 metabolizer; **or**

- member has previously utilized a codeine-containing product without adverse effect that prevents repeat use.

dihydroergotamine injection

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - cluster headache; **or**
    - nausea or vomiting with migraine; **and**
  - inadequate response, adverse reaction, or contraindication to sumatriptan injection.

dihydroergotamine nasal spray (generic Migranal)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: sumatriptan nasal spray, zolmitriptan nasal spray.

dihydroergotamine nasal spray (generic Migranal)

- Documentation of the following is required:
  - for all requests, individual drug PA criteria must be met first where applicable; **and**
  - headache frequency; **and**
  - neurology consultation should be provided if headache frequency is > 15 headaches/30 days; **and**
  - member is currently on a prophylactic regimen.

ergotamine/caffeine suppository

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by nausea or vomiting with migraine; **and**
  - inadequate response, adverse reaction, or contraindication to sumatriptan nasal spray; **and**
  - requested quantity is ≤ 18 suppositories/30 days.

naratriptan, rizatriptan ODT and tablet, sumatriptan 5 mg, 20 mg nasal spray, sumatriptan tablet, and zolmitriptan tablet (> 18 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for sumatriptan 5 mg, 20 mg nasal spray, member is ≥ 6 years of age; **and**
  - requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

Nurtec

- Documentation of the following is required for a diagnosis of acute treatment of migraine:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse drug reaction to two or contraindication to all oral triptans; **and**
  - requested quantity is ≤ 16 units/30 days.
- Documentation of all of the following is required for a diagnosis of migraine prophylaxis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - migraine frequency ≥ four days per month; **and**

- inadequate response or adverse reaction to one or contraindication to all of the following: Aimovig, Ajovy, Emgality; **and**
- requested quantity is ≤ 16 units/30 days.

Ubrelvy (≤ 16 units/30 days)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse drug reaction to two or contraindication to all oral triptans.

Nurtec and Ubrelvy (> 16 units/30 days)
- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency and prophylactic regimen.

Qulipta
- Documentation of all of the following is required for a diagnosis of migraine prophylaxis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - migraine frequency ≥ four days per month; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: atenolol, metoprolol, nadolol, propranolol, timolol; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Botox, topiramate, tricyclic antidepressant, valproic acid, venlafaxine; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Aimovig, Ajovy, Emgality; **and**
  - requested quantity is ≤ one unit/day.

Reyvow (≤ eight units/30 days)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two different triptan agents or contraindication to all oral triptans; **and**
  - prescriber is a neurologist or consult from a neurologist is provided.

Reyvow (> eight units/30 days)
- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

sumatriptan injection (≤ 18 injections/30 days)
- Documentation of the following is required for a diagnosis of acute treatment of migraine, cluster headache, vascular headache:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - cluster headache; **or**
    - nausea or vomiting with migraine.

- Documentation of the following is required for a diagnosis of acute treatment of cyclic vomiting syndrome:
  - appropriate diagnosis.

sumatriptan injection (> 18 injections/30 days) and zolmitriptan nasal spray (> 18 units/30 days)

- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

sumatriptan/naproxen (≤ 18 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two of the following: sumatriptan tablets, rizatriptan ODT or tablets, and zolmitriptan tablets; **and**
  - medical necessity for the combination product instead of the commercially available separate agents.

sumatriptan/naproxen (> 18 units/30 days)

- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

Tosymra (≤ 18 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by nausea or vomiting with migraine; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following:
    - sumatriptan 5 mg or 20 mg nasal spray; **or**
    - zolmitriptan nasal spray.

Tosymra (> 18 units/30 days)

- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

Vyepti

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - migraine frequency ≥ four days per month; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: atenolol, metoprolol, nadolol, propranolol, timolol; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Botox, topiramate, tricyclic antidepressant, valproic acid, venlafaxine; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Aimovig, Ajovy, Emgality.

Zavzpret (≤ 12 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all triptan nasal sprays; **and**

- medical necessity for the requested formulation as noted by nausea or vomiting with migraine.

Zavzpret (> 12 units/30 days)

- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

Zembrace (≤ 36 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by nausea or vomiting with migraine; **and**
  - inadequate response or adverse reaction to sumatriptan injection (generic Imitrex).

Zembrace (> 36 units/30 days)

- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

zolmitriptan ODT (≤ 18 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two of the following: rizatriptan ODT or tablets, sumatriptan tablets, and zolmitriptan tablets; **or**
  - both of the following:
    - medical necessity for the requested formulation as noted by nausea or vomiting with migraine; **and**
    - inadequate response or adverse reaction to rizatriptan ODT.

zolmitriptan ODT (> 18 units/30 days)

- For all requests, individual drug PA criteria must be met first where applicable.
- Requests will be evaluated on a case-by-case basis, taking into account the member's headache frequency, documentation of neurologist consultation, and prophylactic regimen.

zolmitriptan nasal spray (< 18 units/30 days)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation as noted by nausea or vomiting with migraine.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 15 - Hypnotics

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Hypnotics

I. Prior-Authorization Requirements

Hypnotics				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
daridorexant	Quviviq	PA		**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** **Please note: Concurrent therapy with two or more hypnotics (including hypnotic benzodiazepines) will also require PA. For additional information regarding hypnotic benzodiazepines (estazolam, flurazepam, temazepam, triazolam), please see: Table 69 - Barbiturates, Benzodiazepines and Miscellaneous Antianxiety Agents.** • Nonpharmacologic treatments, such as practicing good sleep hygiene, relaxation training, and cognitive therapy may be more effective than medications in some individuals. See “10 Tips for a Good Night's Sleep.” • There is limited medical evidence on the safety and efficacy of prolonged use of hypnotics. • To avoid tolerance and dependence, use the lowest dose, intermittently, and for the shortest possible duration. • Recommended hypnotic dosages are generally lower in the elderly.
doxepin tablet		PA	A90	
eszopiclone	Lunesta	PA - < 6 years and PA > 1 unit/day	#	
lemborexant	Dayvigo	PA		
ramelteon	Rozerem	PA - > 1 unit/day	BP, A90	
suvorexant	Belsomra	PA		
zaleplon		PA - < 6 years and PA > 1 unit/day		
zolpidem 1.75 mg, 3.5 mg sublingual tablet		PA		
zolpidem 10 mg tablet	Ambien	PA - < 6 years and PA > 1 unit/day	#	
zolpidem 5 mg tablet	Ambien	PA - < 6 years and PA > 1.5 units/day	#	
zolpidem 5 mg, 10 mg sublingual tablet	Edluar	PA		
zolpidem 7.5 mg capsule		PA		
zolpidem extended -release tablet	Ambien CR	PA - < 6 years and PA > 1 unit/day	#	

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acute insomnia
- Chronic insomnia
- Insomnia characterized by middle-of-the-night awakenings with difficulty falling back asleep

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Documentation of the following is required:
  - All PA requests must include clinical diagnosis, drug name, dose, and frequency; **and**
  - Member's current medications.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Belsomra, Dayvigo, and Quviviq

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or a contraindication to all of the following: eszopiclone, ramelteon, zaleplon, zolpidem immediate-release or extended-release; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - medical necessity for > one unit/day; **and**
  - for Dayvigo, an inadequate response, adverse reaction or contraindication to Belsomra; **and**
  - for Quviviq, an inadequate response, adverse reaction, or contraindication to both of the following: Belsomra and Dayvigo.

doxepin tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: Belsomra, Dayvigo or Quviviq, doxepin capsule or liquid, eszopiclone, ramelteon, zaleplon, zolpidem immediate-release or extended-release; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - medical necessity for > one unit/day.

Edluar

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for a sublingual formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - medical necessity for > one unit/day.

eszopiclone, ramelteon, zaleplon, zolpidem 10 mg tablet, and zolpidem extended-release tablet (quantities > one unit/day)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested dose is consolidated; **and**
  - one of the following:
    - requested dose is once daily at bedtime; **or**
    - clinical rationale for requiring more than once daily bedtime dosing; **and**
  - all of the following:
    - inadequate response to established quantity limit; **and**
    - trial of a higher dose was effective in alleviating symptoms; **and**
    - inadequate response or adverse reaction to two of the following other alternatives for sleep (one must be a non-benzodiazepine hypnotic): doxepin, eszopiclone, an orexin receptor antagonist (Belsomra, Dayvigo, Quviviq), ramelteon or melatonin, zaleplon, zolpidem or zolpidem ER.

zolpidem 1.75 mg, 3.5 mg sublingual tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - medical necessity for a sublingual formulation as noted by one of the following:
      - member utilizes tube feeding (G-tube/J-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - inadequate response or adverse reaction to three of the following: eszopiclone, zaleplon, zolpidem immediate-release, zolpidem extended-release; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - medical necessity for > one unit/day.

zolpidem 5 mg tablet (quantities > 1.5 units/day)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested dose is consolidated; **and**
  - one of the following:
    - requested dose is once daily at bedtime; **or**
    - clinical rationale for requiring more than once daily bedtime dosing; **and**
  - all of the following:
    - inadequate response to established quantity limit; **and**
    - trial of a higher dose was effective in alleviating symptoms; **and**
    - inadequate response or adverse reaction to two of the following other alternatives for sleep (one must be a non-benzodiazepine hypnotic): doxepin, eszopiclone, an orexin receptor antagonist (Belsomra, Dayvigo, Quviviq), ramelteon or melatonin, zaleplon, zolpidem or zolpidem ER.

zolpidem 7.5 mg capsule
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to both of the following: zolpidem 5 mg tablet, zolpidem 10 mg tablet; **and**
  - medical necessity for 7.5 mg capsule instead of formulations available without PA; **and**
  - requested quantity is ≤ one unit/day.

Brand-name Ambien CR
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to eszopiclone; **and**
  - medical records documenting an inadequate response or adverse reaction to generic zolpidem extended-release tablet; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - medical necessity for > one unit/day.

Hypnotic Polypharmacy (overlapping pharmacy claims for two or more hypnotics [including benzodiazepine hypnotics (estazolam, flurazepam, quazepam, temazepam, and triazolam) and non-benzodiazepine hypnotics] for at least 60 days within a 90-day period)
- For all requests, individual drug PA criteria must be met first where applicable within established quantity limits for the individual drug.
- Documentation of all of the following is required:
  - diagnosis of insomnia (acute or chronic); **and**
  - clear treatment plan; **and**
  - severity of sleep diagnosis; **and**
  - prescriber is a neurologist, sleep medicine specialist, or psychiatrist, or consultation notes from a specialist are provided; **and**
  - one of the following:
    - inadequate response or adverse reaction to all of the following alternative hypnotics indicated for diagnosis: an orexin receptor antagonist (Belsomra, Dayvigo, Quviviq), doxepin capsules or doxepin tablets, eszopiclone, ramelteon, zaleplon, zolpidem or zolpidem ER; **or**
    - contraindication to all alternative hypnotics indicated for the diagnosis; **and**
  - one of the following:
    - the hypnotic regimen includes two agents with different mechanisms of action; **or**
    - for concomitant zolpidem IR and ER, total dose requested does not exceed FDA-approved dosing of individual agents (not to exceed 12.5 mg/day).

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy (*pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, and viloxazine] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period) for members < 18 years of age*

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.
- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**
      - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
      - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**

- member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and**
- one of the following:
  - cross-titration/taper of mood stabilizer therapy; **or**
  - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Hypnotic agents in members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for members with a diagnosis of insomnia with other behavioral health comorbidities, excluding ADHD/ASD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis of insomnia without behavioral health comorbidities or insomnia with comorbid ASD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis of insomnia with comorbid ADHD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to clonidine; **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**

- family/caregiver does not support the regimen change at this time due to risk of exacerbation; or
- other significant barrier for therapy discontinuation.

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 16 - Corticosteroids - Topical

Drug Category: Dermatological

Medication Class/Individual Agents: Corticosteroids

I. Prior-Authorization Requirements

Topical Corticosteroids – Class II. Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betamethasone dipropionate cream			A90
betamethasone dipropionate spray	Sernivo	PA	
betamethasone dipropionate, augmented cream, lotion			A90
desoximetasone 0.25% cream			A90
desoximetasone 0.25% ointment, 0.05% gel		PA	A90
desoximetasone spray	Topicort	PA	A90
diflorasone cream / emollient	Apexicon-E	PA	
fluocinonide cream, gel, ointment, solution			A90
halcinonide cream, solution	Halog	PA	A90
halcinonide ointment	Halog		
mometasone ointment			A90
triamcinolone 0.5% ointment			A90

Topical Corticosteroids – Class I. Superpotent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betamethasone augmented gel			A90
betamethasone dipropionate lotion, ointment			A90
betamethasone dipropionate,	Diprolene		# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Product Potency:

- Relative potency of a product depends on the characteristics and concentration of the drug and the vehicle.
- Generally, ointments and gels are more potent than creams or lotions; however, some products have been formulated to yield comparable potency.

Product Selection:

- Selection of a specific corticosteroid, strength, and vehicle depends on the nature, location, and extent of the skin condition, member's age, and anticipated duration of treatment.
- Use the least-potent corticosteroid that would be effective.
- Low-potency agents are preferred for the face, intertriginous areas (e.g., groin, axilla), and large areas to reduce the potential for side effects.
- Low-potency agents are preferred in children.
- Reserve higher-potency agents for areas and conditions resistant to treatment with milder agents.

Adverse Reactions:

- Systemic absorption of topical corticosteroids has

Topical Corticosteroids – Class I. Superpotent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
augmented ointment			
clobetasol propionate 0.05% cream			A90
clobetasol propionate cream / emollient			A90
clobetasol propionate foam	Olux		# , A90
clobetasol propionate foam / emollient	Olux-E		BP, A90
clobetasol propionate gel, solution			A90
clobetasol propionate lotion, shampoo, spray			A90
clobetasol propionate ointment	Temovate		# , A90
diflorasone ointment		PA	A90
fluocinonide 0.1% cream	Vanos		# , A90
halobetasol cream, ointment			A90
halobetasol foam	Lexette	PA	A90
halobetasol lotion	Bryhali	PA	
halobetasol lotion	Ultravate	PA	

Topical Corticosteroids – Class VI. Mild Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alclometasone cream, ointment			A90
betamethasone valerate lotion			A90
fluocinolone body oil, scalp oil	Derma-Smoothe-FS		# , A90
fluocinolone solution	Synalar		# , A90
triamcinolone 0.025% cream, lotion			A90

Topical Corticosteroids – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betamethasone /	Enstilar		

Clinical Notes

produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, hyperglycemia, and glycosuria.

- Conditions that augment systemic absorption include application of more-potent steroids, use over large surface areas, prolonged use, addition of occlusive dressings, and member's age.
- Perform appropriate clinical and laboratory tests if a topical corticosteroid is used for long periods or over large areas of the body.

With chronic conditions, gradual discontinuation of therapy may reduce the chance of rebound.

Topical Corticosteroids – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
calcipotriene foam			
betamethasone / calcipotriene ointment		PA	A90
betamethasone / calcipotriene topical suspension	Taclonex	PA	BP, A90
clindamycin/benzoyl peroxide gel pump	Onexton	PA	BP, A90
halobetasol / tazarotene lotion	Duobrii	PA	
hydrocortisone / pramoxine foam			A90
neomycin / fluocinolone cream		PA	A90

Topical Corticosteroids – Class IV. Mid-Strength Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
clocortolone cream		PA	A90
fluocinolone ointment	Synalar		# , A90
flurandrenolide ointment		PA	A90
hydrocortisone valerate			A90
mometasone cream, solution			A90
triamcinolone 0.05% ointment		PA	A90
triamcinolone 0.1% cream			A90
triamcinolone spray	Kenalog	PA	A90

Topical Corticosteroids – Class V. Lower Mid-Strength Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betamethasone valerate cream			A90
desonide			A90
fluocinolone 0.01% cream			A90
fluocinolone 0.025% cream	Synalar		# , A90
flurandrenolide		PA	A90

Topical Corticosteroids – Class V. Lower Mid-Strength Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cream, lotion			
fluticasone cream			A90
fluticasone lotion		PA	A90
hydrocortisone butyrate / emollient	Locoid Lipocream	PA	A90
hydrocortisone butyrate cream, ointment, solution			A90
hydrocortisone butyrate lotion	Locoid	PA	A90
hydrocortisone probutate cream	Pandel		
prednicarbate cream, ointment			A90
triamcinolone 0.1% lotion, 0.025% ointment			A90

Topical Corticosteroids – Class III. Upper Mid-Strength Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amcinonide cream		PA	A90
betamethasone valerate foam	Luxiq		# , A90
betamethasone valerate ointment			A90
desoximetasone 0.05% cream		PA	A90
desoximetasone 0.05% ointment	Topicort	PA	A90
diflorasone cream		PA	A90
fluocinonide / emollient			A90
fluticasone ointment			A90
triamcinolone 0.1% ointment, 0.5% cream			A90

Topical Corticosteroids – Class VII. Least Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
hydrocortisone cream, lotion, ointment			*, A90
hydrocortisone		PA	A90

Topical Corticosteroids – Class VII. Least Potent			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
solution			

Topical Corticosteroids – Dental Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
triamcinolone paste			A90

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Corticosteroid-responsive dermatoses with secondary infection
- Plaque psoriasis
- Psoriasis vulgaris
- Scalp-related conditions (i.e., dermatoses, psoriasis, seborrheic dermatitis)
- Topical inflammatory and pruritic dermatoses

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to,

documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

amcinonide cream, clocortolone cream, desoximetasone 0.05% cream, gel, and ointment, desoximetasone 0.25% ointment and spray, diflorasone cream and ointment, flurandrenolide cream, lotion, and ointment, fluticasone lotion, halcinonide cream, halobetasol foam, hydrocortisone butyrate lotion, hydrocortisone solution, Locoid Lipocream, triamcinolone 0.05% ointment and spray, and brand-name topical corticosteroids (Apexicon-E, Bryhali, Halog solution, Ultravate lotion).
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for Bryhali and desoximetasone spray, member is ≥ 18 years of age; **and**
  - for halobetasol foam and Ultravate lotion, member is ≥ 12 years of age; **and**
  - one of the following:
    - inadequate response or adverse reaction to all topical corticosteroids of the same potency range and formulation available without PA; **or**
    - medical necessity for the requested formulation.

betamethasone/calcipotriene ointment and topical suspension, and neomycin/fluocinolone cream
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for betamethasone/calcipotriene topical suspension, member is ≥ 18 years of age; **and**
  - for betamethasone/calcipotriene ointment, member is ≥ 12 years of age; **and**
  - medical necessity for the combination product instead of the commercially available separate agents.

Duobrii (halobetasol/tazarotene lotion)
- Documentation of all of the following is required:
  - diagnosis of plaque psoriasis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one superpotent or potent topical corticosteroid available without PA; **and**
  - medical necessity for the combination product instead of the commercially available separate agents.

MassHealth Evaluation Criteria
Table 17 - Antidepressants

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Antidepressant

I. Prior-Authorization Requirements

Antidepressants – Tricyclic Antidepressants (TCA)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline tablet		PA - < 6 years	A90
amoxapine		PA	A90
clomipramine	Anafranil	PA	A90
desipramine	Norpramin	PA	A90
doxepin capsule, oral concentrate		PA - < 6 years	A90
imipramine hydrochloride		PA - < 6 years	A90
imipramine pamoate		PA	A90
nortriptyline	Pamelor	PA - < 6 years	# , A90
protriptyline		PA	A90
trimipramine		PA	A90

Antidepressants – Norepinephrine/Dopamine Reuptake Inhibitors (NDRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bupropion hydrobromide extended-release	Aplenzin	PA	
bupropion hydrochloride extended-release 150 mg, 300 mg tablet	Wellbutrin XL	PA - < 6 years and PA > 1 unit/day	# , A90
bupropion hydrochloride extended-release 450 mg tablet	Forfivo XL	PA	A90
bupropion hydrochloride immediate-release		PA - < 6 years	A90
bupropion hydrochloride sustained-release-Wellbutrin SR	Wellbutrin SR	PA - < 6 years	# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- In general, the elderly are more sensitive to side effects of medications, especially to sedation, orthostatic hypotension, and anticholinergic symptoms. Because of changes in drug metabolism, older members need lower doses of antidepressants to reach therapeutic effect. Thus the maxim, “Start low and go slow.”
- MassHealth does not encourage the use of combination products and recommends that the active medications be prescribed individually.
- There is no evidence to support the use of two selective serotonin reuptake inhibitors (SSRIs) or a SSRI in combination with a serotonin/norepinephrine reuptake inhibitor (SNRI) or a serotonin modulator concurrently. These combinations may duplicate drug action, with increased side effects and minimal clinical benefit. PA is required when a member has an overlap of 60 days or more in prescriptions of two SSRIs or a SSRI in combination with a SNRI or serotonin modulator.
- Due to bupropion’s dose-dependent risk of seizure (0.33-0.4% within recommended dosing limits), please dose accordingly. Bupropion immediate-release (IR) should be dosed no greater than 150 mg per dose and 450 mg per day. Bupropion sustained release (SR) should be dosed no greater than 200 mg per dose and 400 mg per day.

Antidepressants – NMDA Receptor Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dextromethorphan / bupropion	Auvelity	PA	
esketamine	Spravato	PA	
ketamine injection	Ketalar	PA	MB

Antidepressants – Selective Serotonin Reuptake Inhibitors (SSRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
citalopram capsule		PA	A90
citalopram solution, tablet	Celexa	PA - < 6 years	# , A90
escitalopram	Lexapro	PA - < 6 years	# , A90
fluoxetine 10 mg, 20 mg tablet for premenstrual dysphoric disorder		PA - < 6 years	A90
fluoxetine 10 mg, 20 mg, 40 mg capsule, solution	Prozac	PA - < 6 years	# , A90
fluoxetine 60 mg tablet		PA	A90
fluoxetine 90 mg delayed-release capsule		PA	A90
fluvoxamine extended-release		PA	A90
fluvoxamine immediate-release		PA - < 6 years	A90
paroxetine controlled-release	Paxil CR	PA	A90
paroxetine hydrochloride	Paxil	PA - < 6 years	# , A90
sertraline capsule		PA	A90
sertraline oral concentrate, tablet	Zoloft	PA - < 6 years	# , A90

Antidepressants – Serotonin/Norepinephrine Reuptake Inhibitors (SNRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
desvenlafaxine extended-release		PA	A90
desvenlafaxine succinate	Pristiq	PA - < 6 years and PA > 1 unit/day	# , A90

Clinical Notes

Bupropion extended-release (XL) requires PA for quantities > one unit per day. It should be dosed no greater than 450 mg a day (300 mg tablet plus 150 mg tablet) as a single dose. Members with seizure disorders, brain injuries, and eating disorders are at highest risk of seizures.

- Brand-name Serzone is no longer available due to reports of life-threatening hepatic failure resulting in death or transplant. Nefazodone is still available from various manufacturers.
- Blood pressure should be monitored during venlafaxine therapy because it may cause a dose-related increase in diastolic blood pressure (reported in 3-13% of members). Sustained increases in diastolic blood pressure are reported with desvenlafaxine succinate as well (1.3-2.3% of members).
- Antidepressant discontinuation syndrome has been commonly reported with SSRIs and SNRIs. Among the SSRIs, this is most commonly reported with paroxetine (whose half-life is short and there is no active metabolite) and reported least with fluoxetine (with a long half-life and an active, long-acting metabolite). Symptoms include dizziness, nausea, fatigue, lethargy, flu-like symptoms, anxiety, irritability, and insomnia. This often occurs one-three days after abruptly stopping the medication. The agents in question should be slowly tapered to avoid this syndrome.

Monoamine Oxidase Inhibitors (MAOIs):

- Hypertensive crisis may occur when MAOIs are coadministered with some prescription and over-the-counter products and foods, especially those high in tyramine.
- Serotonin syndrome can occur when MAOIs are coadministered with other pro-serotonergic medications.
- Members should be counseled about dietary and medication restrictions and be given a list of food and drugs to be avoided.

Antidepressants – Serotonin/Norepinephrine Reuptake Inhibitors (SNRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
extended-release			
duloxetine 20 mg, 30 mg, 60 mg capsule	Cymbalta	PA - < 6 years	# , A90
duloxetine 40 mg capsule		PA	A90
duloxetine sprinkle capsule	Drizalma	PA	
levomilnacipran	Fetzima	PA	
venlafaxine besylate extended -release tablet		PA	A90
venlafaxine extended-release capsule	Effexor XR	PA - < 6 years	# , A90
venlafaxine hydrochloride extended-release tablet		PA	A90
venlafaxine immediate-release		PA - < 6 years	A90

Antidepressants – Monoamine Oxidase Inhibitors (MAOI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
isocarboxazid	Marplan	PA	
phenelzine	Nardil	PA - < 6 years	# , A90
selegiline transdermal patch	Emsam	PA	
tranylcypromine		PA - < 6 years	A90

Antidepressants – Noradrenergic and Specific Serotonergic Antidepressants (NaSSA)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
mirtazapine	Remeron	PA - < 6 years	# , A90
mirtazapine orally disintegrating tablet	Remeron Sol Tab	PA	A90

Antidepressants – Second-Generation (Atypical) Antipsychotic and Selective Serotonin Reuptake Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
olanzapine / fluoxetine	Symbyax	PA	A90

Antidepressants – Serotonin Modulators			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nefazodone		PA - < 6 years	A90
trazodone 300 mg tablet		PA	A90
trazodone 50 mg, 100 mg, 150 mg		PA - < 6 years	A90
vilazodone	Viibryd	PA	A90
vortioxetine	Trintellix	PA	

Antidepressants – Gamma-Aminobutyric (GABA)-A Receptor Positive Modulator			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
brexanolone	Zulresso	PA	MB
zuranolone	Zurzuvae PD	PA	

Antidepressants – Tricyclic Antidepressant (TCA) and Benzodiazepine			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline / chlordiazepoxide		PA	

Antidepressants – Tricyclic Antidepressant (TCA) and First-Generation (Typical) Antipsychotic			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline / perphenazine		PA	A90

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Anxiety disorders
- Bipolar disorder
- Chronic musculoskeletal pain
- Depressive disorders
- Diabetic peripheral neuropathy
- Obsessive-compulsive disorder
- Panic disorders
- Postpartum depression

non-FDA approved, for example:

- Diabetic neuropathy
- Fibromyalgia
- Neuropathic pain
- Other psychiatric or neurologic condition requiring treatment with an antidepressant (i.e., psychotic disorder, neuropathic pain)
- Parkinson's Disease
- Postherpetic neuralgia
- Post-traumatic stress disorder

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status

of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

amitriptyline/chlordiazepoxide, amitriptyline/perphenazine, and fluoxetine/olanzapine
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents.

SmartPA: Claims for amitriptyline/chlordiazepoxide and amitriptyline/perphenazine will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

amoxapine and clomipramine
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to two or contraindication to all SSRIs.

SmartPA: Claims for amoxapine or clomipramine will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested medication for at least 90 days out of the last 120 days, or if the member has a history of MassHealth medical claims for an appropriate diagnosis and a history of paid MassHealth pharmacy claims for at least four weeks of therapy with two SSRIs.†

Aplenzin and bupropion hydrochloride extended-release 450 mg tablet
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to bupropion XL at an equivalent dose to the requested product; **and**
  - requested quantity is ≤ one unit/day.

Aplenzin, bupropion hydrochloride extended-release 150 mg, 300 mg tablet, and desvenlafaxine succinate ER > one unit/day
- Documentation of all of the following required:
  - appropriate diagnosis; **and**
  - clinical rationale why the dose cannot be consolidated; **or**
  - clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA.

Note: Bupropion hydrochloride extended-release quantities of one unit per day of both the 300 mg and the 150 mg tablets are available without PA and can be used in combination for 450 mg total daily dose.

SmartPA: Claims for Aplenzin with a quantity limit of one unit/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

Auvelity
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one SSRI and one other non-SSRI antidepressant or contraindication to all SSRI and non-SSRI antidepressants; **and**
  - requested quantity is ≤ two units/day.

SmartPA: Claims for Auvelity within polypharmacy requirements at a quantity ≤ two units per day will usually process at the

pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days, or if the member is ≥ 18 years of age, has a history of MassHealth medical claims for an appropriate diagnosis, and has a history of paid MassHealth pharmacy claims of at least four weeks of therapy with one SSRI and one non-SSRI.†

citalopram capsule

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to citalopram tablets at an equivalent dose (three 10 mg tablets or one 10mg and one 20 mg tablet).

desipramine

- Documentation of all of the following is required for anxiety disorder, bipolar disorder, depressive disorder, obsessive-compulsive disorder, panic disorder, post-traumatic stress disorder, or other psychiatric or neurologic condition requiring treatment with an antidepressant (i.e., psychotic disorder):
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one or contraindication to both of the following: SSRI, SNRI; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one tricyclic antidepressant available without PA.
- Documentation of all of the following is required for diabetic neuropathy, fibromyalgia, or postherpetic neuralgia:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one other tricyclic antidepressant or contraindication to all other tricyclic antidepressants; **and**
  - appropriate dosing.

SmartPA: Claims for desipramine will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

desvenlafaxine ER

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to desvenlafaxine succinate ER.

Drizalma

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation instead of a solid oral formulation (e.g., swallowing disorder, dysphagia).

duloxetine 40 mg capsule

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to duloxetine at an equivalent dose (two 20 mg capsules).

Emsam

- Documentation of all of the following is required for major depressive disorder:

- appropriate diagnosis; **and**
- member is ≥ 18 years of age; **and**
- one of the following:
  - medical necessity for the use of a transdermal formulation; **or**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to both of the following: SSRI, one other antidepressant that is not a SSRI; **or**
  - contraindication to all SSRI and non-SSRI antidepressants; **and**
- one of the following:
  - both of the following:
    - requested quantity is ≤ one patch/day; **and**
    - requested dose is ≤ 12 mg/day; **or**
  - clinical rationale for dosing higher than the FDA approved limits.

- Documentation of all of the following is required for Parkinson's disease:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical necessity for use of a transdermal formulation; **and**
  - requested quantity is ≤ 9 mg/day.

SmartPA: Claims for Emsam will usually process at the pharmacy without a PA request for members ≥ 18 years of age if the member has a history of MassHealth medical claims for a psychiatric diagnosis, a history of paid MassHealth pharmacy claims of the requested medication for at least 90 days out of the last 120 days, and the request is for ≤ one patch per day or ≤ 12 mg/day.†

Fetzima, Trintellix, and vilazodone

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one SSRI and one other non-SSRI antidepressant or contraindication to all SSRI and non-SSRI antidepressants; **and**
  - requested quantity is ≤ one unit/day.

SmartPA: Claims for Fetzima, Trintellix, and vilazodone within polypharmacy requirements at a quantity ≤ one unit per day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days, or if the member is ≥ 18 years of age, has a history of MassHealth medical claims for an appropriate diagnosis, and has a history of paid MassHealth pharmacy claims of at least four weeks of therapy with one SSRI and one non-SSRI.†

fluoxetine 60 mg tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to fluoxetine at an equivalent dose (three 20 mg capsules or tablets).

fluoxetine 90 mg delayed-release capsule

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to fluoxetine daily at an equivalent dose.

fluvoxamine extended-release

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to fluvoxamine immediate-release at an equivalent dose.

imipramine pamoate

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to imipramine hydrochloride at an equivalent dose.

Ketalar

- Documentation of all of the following is required for a diagnosis of treatment-resistant depression:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., psychiatrist) or consult notes from a specialist are provided; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one SSRI and one other non-SSRI antidepressant; **and**
  - requested agent will be used in combination with an oral antidepressant; **and**
  - medical records documenting an inadequate response (defined as concomitant use of an augmenting agent plus antidepressant therapy combined ≥ four weeks of therapy) or adverse reaction to one or contraindication to all of the following augmentation strategies: second-generation antipsychotic, lithium, a second antidepressant from a different class, or thyroid hormone; **and**
  - appropriate dosing.

Marplan, protriptyline, and trimipramine

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one or contraindication to both of the following: SSRI, SNRI; **and**
  - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one tricyclic antidepressant available without PA.

SmartPA: Claims for Marplan, protriptyline, and trimipramine will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

mirtazapine orally disintegrating tablets

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - medical necessity for the orally disintegrating tablet formulation; **or**
    - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to mirtazapine tablets.

paroxetine controlled-release

- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- member is ≥ 18 years of age; **and**
- medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to paroxetine immediate-release.

sertraline capsule

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to sertraline tablets at an equivalent dose (one 50 mg and one 100 mg tablet [150 mg capsule] or two 100 mg tablets [200 mg capsule]).

Spravato

- Documentation of all of the following is required for a diagnosis of treatment-resistant depression:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., psychiatrist) or consult notes from a specialist are provided; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one SSRI and one other non-SSRI antidepressant; **and**
  - requested agent will be used in combination with an oral antidepressant; **and**
  - medical records documenting an inadequate response (defined as concomitant use of an augmenting agent plus antidepressant therapy combined ≥ four weeks of therapy) or adverse reaction to one or contraindication to all of the following augmentation strategies: second-generation antipsychotic, lithium, a second antidepressant from a different class, or thyroid hormone; **and**
  - appropriate dosing.
- Documentation of all of the following is required for treatment of depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., psychiatrist) or consult notes from a specialist are provided; **and**
  - one of the following:
    - medical records documenting current acute suicidal ideation or behavior related to depressive symptoms of major depressive disorder; **or**
    - member was stabilized on esketamine during a psychiatric hospitalization; **and**
  - requested agent will be used in combination with an oral antidepressant; **and**
  - appropriate dosing.
- For recertification, documentation that the member meets criteria above for treatment-resistant depression is required.

trazodone 300 mg tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to trazodone immediate-release at an equivalent dose (two 150 mg tablets).

venlafaxine besylate extended-release tablet and venlafaxine hydrochloride extended-release tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**

- medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to venlafaxine extended-release capsules at an equivalent dose.

Zulresso
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., obstetrician-gynecologist or psychiatrist) or consult notes from a specialist are provided; **and**
  - member is ≤ six months postpartum at screening with onset of a major depressive episode no earlier than the third trimester and no later than four weeks after delivery; **and**
  - member is not currently pregnant; **and**
  - appropriate dosing.

Zurzuvae
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., obstetrician-gynecologist/family medicine or psychiatrist) or consult notes from a specialist are provided; **and**
  - member is ≤ 12 months postpartum; **and**
  - member is not currently pregnant; **and**
  - one of the following:
    - requirement for rapid symptom reduction; **or**
    - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to one or contraindication to allof the following: bupropion, citalopram, duloxetine, escitalopram, fluoxetine, mirtazapine, sertraline, venlafaxine; **and**
  - one of the following:
    - for 30 mg capsule, requested quantity is ≤ one unit/day for 14 days total (start date required); **or**
    - for 20 mg and 25 mg capsule, requested quantity is ≤ two units/day for 14 days total (start date required); **and**
  - for 30 mg capsule, one of the following:
    - severe hepatic impairment (Child-Pugh Class C); **or**
    - moderate to severe renal impairment.

SSRI, SNRI, or Serotonin Modulator Polypharmacy ***(overlapping pharmacy claims for two or more agents for at least 60 days within a 90-day period)*** **for members ≥ 18 years of age**
- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of all of the following is required:
  - psychiatric diagnosis included severe or treatment-resistant conditions; **and**
  - clear treatment plan including names and doses of current antidepressants and corresponding diagnoses; **and**
  - prescriber is a psychiatrist or consult notes from a psychiatrist are provided; **and**
  - one of the following:
    - cross-titration/taper of antidepressant therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials as clinically appropriate; **or**
    - member had a recent psychiatric hospitalization and was discharged on the current regimen.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional

polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy (*pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, and viloxazine] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)* for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**
      - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
      - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**

- member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and** one of the following:
  - cross-titration/taper of mood stabilizer therapy; **or**
  - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Antidepressant Polypharmacy (*overlapping pharmacy claims for two or more antidepressants for at least 60 days within a 90-day period, except esketamine*) for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate psychiatric diagnosis; **and**
    - treatment plan including names of current antidepressants and corresponding diagnoses; **and**
    - prescriber is a is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation**; and**
    - one of the following:
      - cross-titration/taper of antidepressant therapy; **or**
      - inadequate response (defined as four weeks of therapy) or adverse reaction to two monotherapy trials as clinically appropriate; **or**
      - antidepressant polypharmacy regimen of ≤ two antidepressants includes one of the following: bupropion, mirtazapine, trazodone, zuranolone; **or**
      - one antidepressant in the regimen is indicated for a comorbid condition in which antidepressants may be clinically appropriate.

SmartPA: Claims will usually process at the pharmacy without a PA request if the member is < 18 years of age and has a history of paid MassHealth pharmacy claims for two antidepressants (except esketamine) for at least 60 days of therapy out of the last 90 days and one or both agents are bupropion, trazodone, mirtazapine, or zuranolone.†

Antidepressant for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted

discontinuation), at least one of the following:

- previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
- family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
- other significant barrier for therapy discontinuation.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 18 - Cardiovascular Agents

Drug Category: Cardiovascular Agents

Medication Class/Individual Agents: Cardiovascular Agents

I. Prior-Authorization Requirements

Cardiovascular Agents – Renin Angiotensin System Antagonists - Angiotensin-Converting Enzyme (ACE) Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

benazepril	Lotensin		# , M90	captopril
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response or adverse reaction to two ACE inhibitors available without PA.
				SmartPA: Claims for captopril will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days, or if the member has MassHealth medical claims for hypertension, heart failure, left ventricular dysfunction, myocardial infarction, or diabetic nephropathy and a history of paid MassHealth pharmacy claims for two ACE inhibitors that are available without PA.†
				
				Epaned and Qbrelis
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • medical necessity for the use of a solution formulation as noted by one of the following:
				  • member utilizes tube feeding (G-tube/J-tube); **or**
				  • member has a swallowing disorder or condition affecting ability to swallow; **or**
				  • member is < 13 years of age
				
				Concurrent therapy – ACE inhibitor, ARB, and/or direct renin inhibitor
				Requests for concurrent therapy with two or more renin angiotensin system agents are evaluated on a case-by-case basis.

captopril		PA	M90	
enalapril	Vasotec		# , M90	
enalapril solution	Epaned	PA	M90	
fosinopril			M90	
lisinopril	Zestril		# , M90	
lisinopril			M90	
lisinopril solution	Qbrelis	PA		
moexipril			M90	
perindopril			M90	
quinapril	Accupril		# , M90	
ramipril	Altace		# , M90	
trandolapril			M90	

Cardiovascular Agents – Combination Antihypertensives

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

aliskiren / hydrochlorothiazide	Tekturna HCT			**amlodipine/atorvastatin**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • one of the following:
				  • inadequate response to ≥ 40 mg/day rosuvastatin for at least three months, adverse reaction or contraindication to rosuvastatin; **or**
				  • clinical rationale for not using rosuvastatin; **and**
				  • one of the following:
				  • request is within quantity limits; **or**
				  • medical necessity for the requested agent above quantity limits.
				SmartPA: Claims for amlodipine/atorvastatin at a quantity of ≤ one unit/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for 90 days out of the last 120 days of the requested agent, or has a history of paid MassHealth pharmacy claims for rosuvastatin at a dose of at least 40 mg for at least three months in all claims history.†
				
				amlodipine/olmesartan/hydrochlorothiazide, amlodipine/telmisartan, candesartan/hydrochlorothiazide, captopril/hydrochlorothiazide, trandolapril/verapamil
				• Documentation of one of the following is required:
				  • medical necessity for use of the combination product instead of the commercially available separate agents.
				
				Concurrent therapy – ACE inhibitor, ARB, and/or direct renin inhibitor
				• Requests for concurrent therapy with two or more renin angiotensin system agents are evaluated on a case-by-case basis.

amiloride / hydrochlorothiazide			M90	
amlodipine / atorvastatin	Caduet	PA	M90	
amlodipine / benazepril	Lotrel		# , M90	
amlodipine / olmesartan	Azor		# , M90	
amlodipine / olmesartan / hydrochlorothiazide	Tribenzor	PA	M90	
amlodipine / telmisartan	Twynsta	PA	M90	
amlodipine / valsartan	Exforge		# , M90	
amlodipine / valsartan / hydrochlorothiazide	Exforge HCT		# , M90	
atenolol / chlorthalidone	Tenoretic		# , M90	
azilsartan / chlorthalidone	Edarbyclor			
benazepril / hydrochlorothiazide	Lotensin HCT		# , M90	
bisoprolol / hydrochlorothiazide	Ziac		# , M90	
candesartan / hydrochlorothiazide	Atacand HCT	PA	M90	
captopril / hydrochlorothiazide		PA	M90	
enalapril / hydrochlorothiazide	Vaseretic		# , M90	
fosinopril / hydrochlorothiazide			M90	
hydrochlorothiazide / triamterene	Maxzide		# , M90	
hydrochlorothiazide / triamterene			M90	
irbesartan / hydrochlorothiazide	Avalide		# , M90	
isosorbide dinitrate / hydralazine	Bidil		# , M90	
lisinopril / hydrochlorothiazide	Zestoretic		# , M90	
losartan /	Hyzaar		# , M90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
hydrochlorothiazide			
methyldopa / hydrochlorothiazide			M90
olmesartan / hydrochlorothiazide	Benicar HCT		# , M90
propranolol / hydrochlorothiazide			M90
quinapril / hydrochlorothiazide	Accuretic		# , M90
spironolactone / hydrochlorothiazide			M90
telmisartan / hydrochlorothiazide	Micardis HCT		# , M90
trandolapril / verapamil		PA	M90
valsartan / hydrochlorothiazide	Diovan HCT		# , M90

Cardiovascular Agents – Aldosterone Receptor Antagonists

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

eplerenone	Inspra		BP, M90	Kerendia
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • concurrent therapy with an ACE-I or ARB; **and**
				  • inadequate response or adverse reaction to one or contraindication to all of the following: Farxiga, Inpefa, Invokana, Jardiance, Steglatro; **and**
				  • requested quantity ≤ one unit/day.
				spironolactone suspension
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • medical necessity for the use of a suspension formulation as noted by one of the following:
				  • member utilizes tube feeding (G-tube, J tube); **or**
				  • member has a swallowing disorder or condition affecting ability to swallow; **or**
				  • member is < 13 years of age.

finerenone	Kerendia	PA		
spironolactone suspension	Carospir	PA	M90	
spironolactone tablet	Aldactone		# , M90	

Cardiovascular Agents – Anti-Anginal Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

isosorbide dinitrate 40 mg tablet	Isordil	PA	BP, M90	**Aspruzyo**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response or adverse reaction to one or contraindication to all of the following: beta-blockers, calcium channel blockers, nitrates**,** ranolazine tablets; **and**
				  • one of the following:
				  • member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets); **or**
				  • member utilizes tube feeding; **or**
				  • medical necessity for the requested formulation instead of ranolazine tablets; **and**
				  • appropriate dosing; **and**
				  • requested quantity is ≤ two packets/day.
				
				Gonitro, nitroglycerin lingual spray
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to nitroglycerin sublingual tablets.
				
				isosorbide dinitrate 40mg
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • requested dose is > 40 mg/dose; **and**
				  • medical records documenting an inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to two units of isosorbide dinitrate 20 mg tablet.

isosorbide dinitrate 5 mg, 10 mg, 20 mg, 30 mg tablet	Isordil		# , M90	
isosorbide mononitrate			M90	
nitroglycerin 2% ointment	Nitro-Bid		# , A90	
nitroglycerin injection				
nitroglycerin lingual spray	Nitrolingual	PA	BP, A90	
nitroglycerin patch	Nitro-Dur		# , M90	
nitroglycerin sublingual powder	Gonitro	PA		
nitroglycerin sublingual tablet	Nitrostat		# , A90	
ranolazine extended-release granules	Aspruzyo	PA		
ranolazine extended-release tablet			A90	

Cardiovascular Agents – Renin Angiotensin System Antagonists - Angiotensin II Receptor Antagonists (ARBS)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

azilsartan	Edarbi			**candesartan, eprosartan**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to both of the following: losartan, irbesartan or valsartan.
				SmartPA: Claims for candesartan and eprosartan will usually process at the pharmacy without a PA request if the

candesartan	Atacand	PA	M90	
eprosartan		PA	M90	
irbesartan	Avapro		# , M90	
losartan	Cozaar		# , M90	
olmesartan	Benicar		# , M90	
telmisartan	Micardis		# , M90	
valsartan solution		PA	M90	
valsartan tablet	Diovan		# , M90	

	Clinical Notes

	member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days, or if the member has a history of paid MassHealth pharmacy claims for losartan and irbesartan or valsartan.†
	
	valsartan solution
	Documentation of all of the following is required:
	• appropriate diagnosis; **and**
	• medical necessity for the use of the solution formulation as noted by one of the following:
	  • member utilizes tube feeding (G-tube/J-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • member is < 13 years of age.
	
	Concurrent therapy – ACE inhibitor, ARB, and/or direct renin inhibitor
	Requests for concurrent therapy with two or more renin angiotensin system agents are evaluated on a case-by-case basis.

Cardiovascular Agents – Beta-Adrenergic Blocking Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

acebutolol			M90	**carvedilol extended-release**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction or contraindication to carvedilol immediate-release.
				
				Hemangeol
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • medical necessity for the use of a solution formulation as noted by one of the following:
				  • member utilizes tube feeding (G-tube, J-tube); **or**
				  • member has a swallowing disorder or condition affecting ability to swallow; **or**
				  • member is < 13 years of age.
				
				Inderal XL, Innopran XL

atenolol	Tenormin		# , M90	
betaxolol tablet			M90	
bisoprolol			M90	
carvedilol	Coreg		# , M90	
carvedilol extended-release	Coreg CR	PA	M90	
esmolol	Brevibloc		#	
labetalol			M90	
metoprolol	Lopressor		# , M90	
metoprolol extended-release capsule	Kapspargo	PA		
metoprolol extended-release tablet	Toprol XL		# , M90	
nadolol	Corgard		# , M90	
nebivolol	Bystolic		# , M90	
pindolol			M90	
propranolol extended-release	Inderal LA		# , M90	
propranolol			M90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

immediate-release				• Documentation of all of the following is required for a diagnosis of hypertension:
				  • diagnosis of hypertension; **and**
				  • inadequate response or adverse reaction to all of the following: a long-acting formulation of propranolol that is available without prior authorization, a beta-blocker, and one other antihypertensive agent.
				• Documentation of all of the following is required for a diagnosis of migraine, angina, pulmonary hypertension, Raynaud's syndrome:
				  • diagnosis of migraine, angina, pulmonary hypertension, Raynaud's syndrome; **and**
				  • inadequate response or adverse reaction to a long-acting formulation of propranolol that is available without prior authorization.
				
				Kapspargo
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • medical necessity for the use of a capsule formulation as noted by one of the following:
				  • member utilizes tube feeding (G-tube, J-tube); **or**
				  • member has a swallowing disorder or condition affecting ability to swallow; **or**
				  • member is < 13 years of age.
				
				Sotylize
				• Documentation of all of the following is required:
				  • diagnosis of life-threatening ventricular arrhythmias or highly symptomatic atrial fibrillation or atrial flutter; **and**
				  • medical necessity for the use of a solution formulation as noted by one of the following:
				  • member utilizes tube feeding (G-tube, J-tube); **or**
				  • member has a swallowing disorder or condition affecting ability to swallow; **or**
				  • member is < 13 years of age.

propranolol long-acting capsule	Inderal XL	PA		
propranolol long-acting capsule	Innopran XL	PA		
propranolol solution	Hemangeol	PA	M90	
sotalol solution	Sotylize	PA		
sotalol tablet	Betapace		# , M90	
timolol tablet			M90	

Cardiovascular Agents – Calcium Channel Blocking Agents - Non-Dihydropyridine

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
diltiazem extended-release capsule	Cardizem CD		# , M90	
diltiazem extended-release tablet	Cardizem LA		# , M90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
diltiazem-Cardizem	Cardizem		# , M90
diltiazem-Tiazac ER	Tiazac ER		# , M90
verapamil			M90
verapamil extended-release	Verelan PM		# , M90
verapamil sustained-release	Calan SR		# , M90

Cardiovascular Agents – Not Otherwise Classified

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

droxidopa	Northera	PA	A90	Camzyos
				• Documentation of all of the following is required:
				  • diagnosis of NYHA class II-III obstructive hypertrophic cardiomyopathy; **and**
				  • prescriber is a cardiologist or consultation notes from a cardiologist are provided; **and**
				  • inadequate response or adverse reaction to one or contraindication to all beta blockers; **and**
				  • inadequate response or adverse reaction to one or contraindication to both of the following: diltiazem, verapamil; **and**
				  • inadequate response, adverse reaction, or contraindication to disopyramide; **and**
				  • appropriate dosing; **and**
				  • requested quantity is ≤ one tablet/day
				• For recertification, documentation of positive response to therapy is required.
				droxidopa
				• Documentation of all of the following is required:
				  • diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) caused by one of the following:
				  • primary autonomic failure; **or**
				  • dopamine beta-hydroxylase deficiency; **or**
				  • non-diabetic autonomic neuropathy (NDAN); **and**
				  • inadequate response or adverse reaction to one or contraindication to both of the following: atomoxetine, midodrine; **and**
				  • inadequate response, adverse reaction, or contraindication to fludrocortisone.
				• For recertification, medical records documenting positive response to therapy (e.g., increased standing blood pressure following treatment with droxidopa without increasing supine blood pressure, improvement on the

mavacamten	Camzyos	PA		
metyrosine	Demser		BP	

				Clinical Notes
				Orthostatic Hypotension Questionnaire or Orthostatic Hypotension Symptom Assessment score for dizziness/lightheadedness, decreased symptoms of dizziness, lightheadedness, fainting episodes) is required.

Cardiovascular Agents – Alpha Blocking Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
doxazosin immediate-release	Cardura		# , M90	phenoxybenzamine • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all selective α-1 blockers (prazosin, terazosin or doxazosin).
phenoxybenzamine		PA	M90	
prazosin	Minipress	PA - < 6 years	# , M90	
terazosin			M90	

Cardiovascular Agents – HCN Channel Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
ivabradine	Corlanor	PA	A90	ivabradine • Documentation of all of the following is required for a diagnosis of chronic heart failure with LVEF ≤ 35%: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is a cardiologist or consultation notes from a cardiologist are provided; **and** • member has a resting heart rate of ≥ 70 beats per minute (bpm); **and** • one of the following: • member is currently receiving a beta-blocker (carvedilol, metoprolol succinate or bisoprolol) at maximally tolerated doses; **or** • adverse reaction to one beta-blocker or contraindication to all beta-blockers; **and** • one of the following: • member is currently receiving standard of care therapy with an ACE inhibitor, ARB, or angiotensin -receptor neprilysin inhibitor (ARNI); **or** • contraindication to all ACE inhibitors, ARBs and ARNIs; **and** • for tablet formulation, requested quantity is ≤ two tablets/day; **and**

	Clinical Notes

	• for solution formulation, medical necessity for the use of the solution formulation as noted by one of the following:
	  • member utilizes tube feeding (G-tube, J-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow.
	
	• Documentation of all of the following is required for a diagnosis of heart failure due to dilated cardiomyopathy:
	  • appropriate diagnosis; **and**
	  • member is ≥ six months of age and < 18 years of age; **and**
	  • member has normal sinus rhythm with an elevated heart rate; **and**
	  • prescriber is a cardiologist or consultation notes from a cardiologist are provided; **and**
	  • one of the following:
	  • member is currently receiving a beta-blocker (carvedilol, metoprolol succinate or bisoprolol) at maximally tolerated doses; **or**
	  • adverse reaction to one beta-blocker or contraindication to all beta-blockers; **and**
	  • one of the following:
	  • member is currently receiving standard of care therapy with an ACE inhibitor, ARB, or angiotensin -receptor neprilysin inhibitor (ARNI); **or**
	  • adverse reaction to one or contraindication to all ACE inhibitors, ARBs and ARNIs; **and**
	  • for tablet formulation, requested quantity is ≤ two tablets/day; **and**
	  • for solution formulation, medical necessity for use of the solution formulation as noted by one of the following:
	  • member is < 13 years of age; **or**
	  • requested dose is < 2.5 mg; **or**
	  • member utilizes tube feeing (G-tube, J-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow.
	
	• Documentation of all of the following is required for a diagnosis of postural tachycardia syndrome (POTS):
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to two or contraindication to all of the following: a beta blocker,

	Clinical Notes
	droxidopa, fludrocortisone, midodrine, pyridostigmine; **and** • for tablet formulation, requested quantity is ≤ two tablets/day; **and** • for solution formulation, medical necessity for use of the solution formulation as noted by one of the following: • member is < 13 years of age; **or** • member utilizes tube feeing (G-tube, J-tube); **or** • member has a swallowing disorder or condition affecting ability to swallow. • Documentation of all of the following is required for a diagnosis of inappropriate sinus tachycardia: • appropriate diagnosis; and • for tablet formulation, requested quantity is ≤ two tablets/day; **and** • for solution formulation, medical necessity for use of the solution formulation as noted by one of the following: • member is < 13 years of age; **or** • member utilizes tube feeing (G-tube, J-tube); **or** • member has a swallowing disorder or condition affecting ability to swallow.

Cardiovascular Agents – Diuretics

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amiloride			M90	**ethacrynic acid tablet** • Documentation of all of the following is required: • appropriate diagnosis; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: furosemide, bumetanide, torsemide. **SmartPA:** Claims for ethacrynic acid tablet will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for furosemide, bumetanide or torsemide.† **Furoscix** • Documentation of all of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is a specialist (e.g., cardiologist, heart failure specialist) or consultation notes from a
bumetanide			M90	
chlorothiazide	Diuril		# , M90	
chlorthalidone	Thalitone			
chlorthalidone			M90	
ethacrynic acid tablet	Edecrin	PA	M90	
furosemide on-body infusor	Furoscix	PA		
furosemide tablet, solution, injection	Lasix		# , M90	
hydrochlorothiazide			M90	
indapamide			M90	
metolazone			M90	
torsemide			M90	
triamterene		PA	M90	

	Clinical Notes
	specialist are provided; **and** • member is on background loop diuretic therapy with 40 to 160 mg of oral furosemide equivalents; **and** • treatment with oral diuretics will be discontinued until transitioned back to oral diuretic maintenance therapy; **and** • requested quantity is ≤ eight kits. **triamterene** • Documentation of all of the following is required: • appropriate diagnosis; **and** • inadequate response or adverse reaction to one or contraindication to both of the following: amiloride, spironolactone. **SmartPA:** Claims for triamterene will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for amiloride or spironolactone.†

Cardiovascular Agents – Renin Angiotensin System Antagonists – Angiotensin Receptor Neprilysin Inhibitor (ARNI)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
sacubitril / valsartan	Entresto	PA		**Entresto** • Documentation of all the following is required for a diagnosis of chronic heart failure: • appropriate diagnosis; **and** • member is ≥ one year of age; **and** • requested quantity is ≤ two tablets/day. • Documentation of all the following is required for a diagnosis of acute heart failure: • appropriate diagnosis; **and** • prescriber is a heart failure or cardiology specialist, or consult notes from a specialist are provided; **and** • requested quantity is ≤ two tablets/day. **SmartPA:** Claims for Entresto at a quantity of ≤ two tablets/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days or if the member is ≥ one year of age and has a history of MassHealth medical claims for a diagnosis of chronic heart failure.†

Cardiovascular agents – Renin Angiotensin System Antagonists – Endothelin Type A Receptor and Angiotensin II Type 1 Receptor Antagonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

sparsentan	Filspari	PA		**Filspari**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a nephrologist or consult notes from a nephrologist are provided; **and**
				  • medical records documenting one of the following despite treatment with a maximally tolerated dose of an ACE inhibitor or ARB for ≥ 90 days:
				  • urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g; **or**
				  • proteinuria >1.0 g/day; **and**
				  • both of the following:
				  • requested initial dose of 200 mg daily for two weeks followed by 400 mg daily for maintenance treatment; **and**
				  • requested quantity is ≤ one tablet/day; **and**
				  • one of the following:
				  • inadequate response (defined as ≥ 90 days of therapy) to the maximum FDA-approved dose of an ACE inhibitor or ARB; **or**
				  • both of the following:
				  • inadequate response (defined as ≥ 90 days of therapy) to the maximally tolerated dose of an ACE inhibitor or ARB; **and**
				  • medical records documenting intolerance to an ACE inhibitor or ARB at a dose above the maximally tolerated dose.

Cardiovascular Agents – Calcium Channel Blocking Agents - Dihydropyridine

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

amlodipine	Norvasc		# , M90	**Katerzia and Norliqva**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • medical necessity for the use of a suspension formulation as noted by one of the following:
				  • member utilizes tube feeding (G-tube, J-tube); **or**
				  • member has a swallowing disorder or condition affecting ability to swallow; **or**
				  • member is < 13 years of age.
				
				levamlodipine
				• Documentation of all the following is required:

amlodipine solution	Norliqva	PA		
amlodipine suspension	Katerzia	PA		
felodipine extended-release			M90	
isradipine immediate-release		PA	M90	
levamlodipine		PA	M90	
nicardipine capsule		PA	M90	
nicardipine injection				
nifedipine capsule			M90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
nifedipine extended-release	Procardia XL		# , M90	• appropriate diagnosis; **and** • inadequate response, adverse drug reaction or contraindication to amlodipine; **and** • inadequate response or adverse drug reaction to one or contraindication to all other calcium channel blockers available without prior authorization. **nimodipine capsule and Nymalize > 21 days treatment/365 days** • Documentation of all of the following is required: • appropriate diagnosis (subsequent episode of subarachnoid hemorrhage); **and** • appropriate dosing; **and** • for solution formulation, medical necessity for the use of a solution formulation as noted by one of the following: • member utilizes tube feeding (G-tube, J-tube); **or** • member has a swallowing disorder or condition affecting ability to swallow. **isradipine, nicardipine capsules, nisoldipine** • Documentation of all of the following is required: • appropriate diagnosis; **and** • inadequate response or adverse reaction to two or contraindication to all calcium channel blockers available without PA. **SmartPA:** Claims for isradipine, nicardipine capsules, and nisoldipine will usually process at the pharmacy without a PA request if the member has MassHealth medical claims for an appropriate clinical indication (for example: hypertension, migraine, angina, pulmonary hypertension, or Raynaud's phenomenon), and a history of paid MassHealth pharmacy claims for two calcium channel blockers available without PA.†
nifedipine tablet			M90	
nimodipine capsule		PA - > 21 days treatment/365 days		
nimodipine oral solution	Nymalize	PA - > 21 days treatment/365 days		
nisoldipine	Sular	PA	M90	

Cardiovascular Agents – Cardiac glycosides

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
digoxin	Lanoxin		# , M90	

Cardiovascular Agents – Antiarrhythmics

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amiodarone injection			MB	**quinidine gluconate extended-release**

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amiodarone tablet			M90	• Documentation of all of the following is required: • appropriate diagnosis; **and** • inadequate response, adverse reaction, or contraindication to quinidine sulfate. **SmartPA:** Claims for quinidine gluconate extended-release will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for quinidine sulfate.†
disopyramide controlled-release	Norpace CR			
disopyramide immediate-release	Norpace		# , A90	
dofetilide	Tikosyn		# , M90	
dronedarone	Multaq		A90	
flecainide			M90	
mexiletine			M90	
propafenone extended-release	Rythmol SR		# , M90	
propafenone immediate-release			M90	
quinidine gluconate extended-release		PA	A90	
quinidine sulfate			M90	

Cardiovascular Agents – Vasopressin Antagonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
tolvaptan-Samsca	Samsca	PA	BP, A90	**tolvaptan (generic Samsca)** • Documentation of all of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • member is currently stabilized on the requested agent; **and** • one of the following: • for 15 mg tablet, requested quantity is ≤ one unit/day; **or** • for 30 mg tablet, requested quantity is ≤ two units/day; **or** • clinical rationale for high dose.

Cardiovascular Agents – Renin Angiotensin System Antagonists - Direct Renin Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
aliskiren	Tekturna	PA	BP, M90	**aliskiren** • Documentation of the following is required: • appropriate diagnosis; **and** • inadequate response, adverse reaction, or contraindication to both of the following: ARB and ACE inhibitor. **Concurrent therapy – ACE inhibitor, ARB, and/or direct**

	Clinical Notes
	renin inhibitor Requests for concurrent therapy with two or more renin angiotensin system agents are evaluated on a case-by-case basis.

Cardiovascular Agents – Soluble Guanylate Cyclase (sGC) Stimulator

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

vericiguat	Verquvo	PA		**Verquvo**
				• Documentation of all of the following is required:
				  • diagnosis of chronic heart failure NYHA Class II to IV; **and**
				  • left ventricular ejection fraction (LVEF) < 45%; **and**
				  • member is ≥ 18 years of age; **and**
				  • one of the following:
				  • member has had a hospitalization related to heart failure within the last six months; **or**
				  • member has received outpatient IV diuretic therapy for heart failure within the last three months; **and**
				  • prescriber is a cardiologist or consultation notes from a cardiologist are provided; **and**
				  • one of the following:
				  • member has remained symptomatic despite receiving standard of care therapy with an ACEI/ARB/ARNI in combination with a β-blocker (carvedilol, metoprolol succinate or bisoprolol); **or**
				  • adverse reaction to one ACE inhibitor, ARB, ARNI and/or beta blocker, or contraindication to all ACE inhibitors, ARBs, ARNIs and beta blockers; **and**
				  • requested quantity is ≤ one unit/day.

Cardiovascular Agents – Alpha Agonists / Centrally Acting Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

clonidine extended -release 0.17 mg tablet		PA	A90	**clonidine extended-release 0.17 mg tablet**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to clonidine immediate-release tablets; **and**
				  • inadequate response or adverse reaction to two or contraindication to all other antihypertensive agents;

clonidine patch		PA	A90	
clonidine tablet		PA - < 3 years	A90	
guanfacine		PA - < 3 years	A90	
methyldopa			M90	

	Clinical Notes

	and
	• appropriate dosing.
	
	clonidine patch
	• Documentation of all of the following is required for a diagnosis of hypertension:
	  • appropriate diagnosis; **and**
	  • one of the following:
	  • medical records documenting an inadequate response or adverse reaction to oral clonidine; **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **and**
	  • inadequate response or adverse reaction to two or contraindication to all other antihypertensive agents.
	• Documentation of all of the following is required for a diagnosis of ADHD:
	  • appropriate diagnosis; **and**
	  • one of the following:
	  • medical records documenting an inadequate response (defined as > seven days of therapy) or adverse reaction to oral clonidine; **or**
	  • medical necessity for the transdermal formulation; **and**
	  • inadequate response (defined as > seven days of therapy) or adverse reaction to one or contraindication both of the following: an amphetamine product, a methylphenidate product.
	• Documentation of all of the following is required for a diagnosis of ASD:
	  • appropriate diagnosis; **and**
	  • one of the following:
	  • medical records documenting an inadequate response (defined as > seven days of therapy) or adverse reaction to oral clonidine; **or**
	  • medical necessity for the transdermal formulation.
	In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions (see below).

Cardiovascular Agents – Direct Vasodilators

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
hydralazine			M90

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
minoxidil			M90	

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Angina pectoris
- Arrhythmias, paroxysmal supraventricular tachycardia
- Cardiac arrhythmias
- Cardiovascular events risk reduction
- Chronic kidney disease associated with type 2 diabetes (Kerendia)
- Congestive heart failure
- Congestive heart failure post-MI
- Coronary artery disease (stable or variant angina)
- Diabetic nephropathy
- Euvolemic hyponatremia (SIADH)
- Heart failure
- Hypertension
- Hypertrophic subaortic stenosis
- Hypervolemic hyponatremia (CHF)
- Immunoglobulin A nephropathy (IgAN)
- Left ventricular dysfunction
- Left ventricular dysfunction following MI
- Migraine prophylaxis
- Myocardial infarction
- New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) (Camzyos)
- Pheochromocytoma
- Post-myocardial infarction
- Proliferating infantile hemangioma

- Raynaud phenomenon
- Reduction of stroke risk with left ventricular hypertrophy
- Subarachnoid hemorrhage (nimodipine)

non-FDA-approved, for example:

- Angina pectoris
- Arrhythmias, paroxysmal supraventricular tachycardia
- Attention deficit hyperactivity disorder (ADHD)
- Cardiac arrhythmias
- Postural tachycardia syndrome (POTS)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Please see clinical criteria for agents requiring PA in the table above under the Clinical Notes section.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy ***(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, and viloxazine] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**

    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**
      - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
      - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
      - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and** one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Alpha Agonist for members < three years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**

- member has a cardiovascular diagnosis only; **or**
- all of the following:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - treatment plan including names of current alpha agonist(s) and corresponding diagnoses; **and**
  - clinical rationale for use of alpha agonist in member < three years of age.

prazosin for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **and**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 19 - Benign Prostatic Hyperplasia (BPH) Agents

Drug Category: Men's Health

Medication Class/Individual Agents: Alpha-1 Blockers, 5-Alpha-Reductase Inhibitors, & Phosphodiesterase Inhibitors

I. Prior-Authorization Requirements

Benign Prostatic Hyperplasia (BPH) Agents – 5-Alpha-Reductase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
dutasteride	Avodart		# , M90
finasteride	Proscar		# , M90

Benign Prostatic Hyperplasia (BPH) Agents – Alpha-1 Blockers

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
alfuzosin extended -release			M90
doxazosin extended-release	Cardura XL		
doxazosin immediate-release	Cardura		# , M90
prazosin	Minipress	PA - < 6 years	# , M90
silodosin	Rapaflo	PA	M90
tamsulosin	Flomax		# , M90
terazosin			M90

Benign Prostatic Hyperplasia (BPH) Agents – Phosphodiesterase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
tadalafil tablet-Cialis	Cialis	PA	

Benign Prostatic Hyperplasia (BPH) Agents – Combination Products

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
dutasteride / tamsulosin	Jalyn	PA	M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

FDA-approved indications:

- Hypertension: doxazosin, prazosin, terazosin
- BPH: alfuzosin, doxazosin, silodosin, tadalafil, tamsulosin, terazosin

Dose and administration:

- Doxazosin, prazosin, and terazosin: take first dose and subsequent first increased dose at bedtime to minimize lightheadedness and syncope.
- Titrate to therapeutic maintenance doses to minimize dizziness and orthostatic hypotension.
- If therapy is discontinued or interrupted for two or more days, reinstitute therapy cautiously.

Benign Prostatic Hyperplasia (BPH) Agents – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
finasteride / tadalafil	Entadfi	PA	

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

M90 Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- BPH
- status post-transurethral resection of the prostate (TURP) with persistent urinary symptoms

Non-FDA-approved, for example:

- kidney stones

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

dutasteride/tamsulosin

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- inadequate response or adverse reaction to one or contraindication to all of the following: alfuzosin, doxazosin, tamsulosin, or terazosin; **or**
- inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to finasteride; **and**
- medical necessity for use of the combination product instead of the commercially available separate agents.

Entadfi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one unit/day; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents; **and**
  - one of the following:
    - requested duration of therapy is ≤ 26 weeks; **or**
    - medical necessity for use beyond 26 weeks of therapy.

silodosin

- Documentation of the following is required for a diagnosis of BPH or TURP:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: alfuzosin, tamsulosin; **and**
  - requested quantity is ≤ one unit/day.
- Documentation of the following is required for a diagnosis of kidney stones:
  - appropriate diagnosis; **and**
  - prescriber is a urologist; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: a calcium channel blocker, tamsulosin; **and**
  - requested duration of therapy is ≤ 60 days.

SmartPA: Claims for silodosin at a quantity of ≤ one unit/day will usually process at the pharmacy without a PA request if the member is ≥ 18 years of age, has a history of MassHealth medical claims for BPH or status post-TURP, and has a history of paid MassHealth pharmacy claims for alfuzosin and tamsulosin or a history of MassHealth medical claims for swallowing disorder.†

tadalafil

- Documentation of the following is required:
  - diagnosis of BPH; **and**
  - member is ≥ 18 years of age; **and**
  - requested strength is 5 mg daily; **and**
  - requested quantity is ≤ one unit/day.

Please Note: The MassHealth agency does not pay for any drug when used for the treatment of sexual dysfunction as described in 130 CMR 406.413(B) “Limitations on Coverage of Drugs – Drug Exclusions” (see link below).

https://www.mass.gov/regulations/130-CMR-406000-pharmacy-services

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 20 - Anticonvulsants

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Anticonvulsants

I. Prior-Authorization Requirements

Anticonvulsants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
brivaracetam injection	Briviact		MB
brivaracetam solution, tablet	Briviact	PA	
cannabidiol	Epidiolex	PA	
carbamazepine extended-release	Carbatrol	PA - < 6 years	# , A90
carbamazepine extended-release	Equetro	PA - < 6 years	
carbamazepine extended-release	Tegretol XR	PA - < 6 years	BP, A90
carbamazepine-Tegretol	Tegretol	PA - < 6 years	# , A90
cenobamate	Xcopri	PA	
clobazam film	Sympazan	PA	
clobazam suspension, tablet	Onfi		#
diazepam buccal film	Libervant	PA - ≥ 6 years and PA > 10 units/30 days	
diazepam nasal spray	Valtoco	PA - > 10 units/30 days	
diazepam rectal gel	Diastat	PA - > 5 kits (10 syringes)/30 days	#
divalproex extended-release	Depakote ER	PA - < 6 years	# , A90
divalproex immediate-release	Depakote	PA - < 6 years	# , A90
divalproex sprinkle capsule	Depakote	PA - < 6 years	BP, A90
eslicarbazepine	Aptiom	PA	
ethosuximide	Zarontin		# , A90
everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg	Afinitor	PA	BP, A90
everolimus tablets for oral suspension	Afinitor Disperz	PA	BP, A90
felbamate	Felbatol		# , A90
fenfluramine	Fintepla	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Everolimus is indicated as adjunctive therapy in epilepsy associated with tuberous sclerosis complex (TSC).
- Diazepam buccal film, diazepam nasal spray, diazepam rectal gel, and midazolam nasal spray are indicated for use as needed (intermittent) for the treatment of acute seizure clusters that are distinct from a member's usual seizure pattern.

Precautions/warnings:

- About 25% to 35% of members who experience a hypersensitivity reaction to carbamazepine will experience a hypersensitivity reaction to oxcarbazepine.
- Carbamazepine has been associated with rare cases of aplastic anemia and agranulocytosis. Hematologic studies should be performed before therapy is initiated.
- Felbamate is not a first-line antiepileptic agent and is recommended only in members who have shown an inadequate response to alternative treatments and whose epilepsy is so severe that the benefits outweigh the potential risks of aplastic anemia or liver failure.
- Lamotrigine has been associated with serious, life-threatening rashes, which required hospitalization and discontinuation of treatment. Most cases of life-threatening rashes occurred within two-to-eight weeks of treatment initiation.

Anticonvulsants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fosphenytoin	Cerebyx		MB
ganaxolone	Ztalmy	PA	
lacosamide extended-release capsule	Motpoly XR	PA	
lacosamide injection	Vimpat		MB
lacosamide tablet, solution	Vimpat		# , A90
lamotrigine dispersible tablet	Lamictal	PA - < 6 years	# , A90
lamotrigine extended-release tablet	Lamictal XR	PA	A90
lamotrigine extended-release tablet starter kit	Lamictal XR	PA	
lamotrigine orally disintegrating tablet	Lamictal ODT	PA	A90
lamotrigine orally disintegrating tablet starter kit	Lamictal ODT	PA	
lamotrigine tablet	Lamictal	PA - < 6 years	# , A90
lamotrigine tablet starter kit	Lamictal	PA	
levetiracetam extended-release-Elepsia XR	Elepsia XR	PA	
levetiracetam extended-release-Keppra XR	Keppra XR		# , A90
levetiracetam injection	Keppra		MB
levetiracetam solution, tablet	Keppra		# , A90
levetiracetam tablet for oral suspension	Spritam	PA	
methsuximide	Celontin		# , A90
midazolam nasal spray	Nayzilam	PA - > 10 units/30 days	
oxcarbazepine extended-release	Oxtellar XR	PA	BP
oxcarbazepine suspension	Trileptal	PA - < 6 years	BP, A90
oxcarbazepine tablet	Trileptal	PA - < 6 years	# , A90
perampanel	Fycompa	PA	
phenytoin chewable tablet	Dilantin Infatab		# , A90
phenytoin extended 200 mg and 300 mg capsule			A90

Clinical Notes

- Phenytoin may cause gingival hyperplasia; the incidence may be reduced by good oral hygiene.
- Valproic acid and its derivatives have been associated with hepatic failure resulting in fatalities. Liver function tests should be performed before initiating therapy and subsequently at frequent intervals, especially during the first six months of therapy.

Anticonvulsants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
phenytoin extended 30 mg and 100 mg capsule	Dilantin		# , A90
phenytoin injection			MB
phenytoin suspension	Dilantin-125		# , A90
primidone	Mysoline		# , A90
rufinamide	Banzel	PA	BP, A90
stiripentol	Diacomit	PA	
tiagabine	Gabitril	PA	A90
topiramate extended-release capsule-Qudexy XR	Qudexy XR	PA - < 6 years	BP, A90
topiramate extended-release capsule-Trokendi XR	Trokendi XR	PA	BP, A90
topiramate solution	Eprontia	PA	
topiramate sprinkle capsule	Topamax	PA - < 6 years	# , A90
topiramate tablet	Topamax	PA - < 6 years	# , A90
valproate injection			MB
valproate solution			
valproic acid	Depakene	PA - < 6 years	# , A90
vigabatrin	Sabril	PA	BP, A90
zonisamide capsule			A90
zonisamide suspension	Zonisade	PA	

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- bipolar disorder
- fibromyalgia
- migraine prophylaxis
- neuropathic pain associated with diabetic peripheral neuropathy
- postherpetic neuralgia
- seizure disorder(s) including Dravet syndrome, treatment-resistant epilepsy associated with tuberous sclerosis complex (TSC), infantile spasms, Lennox-Gastaut syndrome (LGS), partial seizures, and primary generalized tonic-clonic seizures

Non-FDA-approved, for example:

- non-FDA-approved refractory epilepsy syndrome, refractory epilepsy, or refractory seizures

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Aptiom

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - member is ≥ four years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for Aptiom will usually process at the pharmacy without a PA request if the member is ≥ four years of age, has a history of MassHealth medical claims for epilepsy/seizures, the prescriber is a neurologist, and the member has a history of paid MassHealth pharmacy claims for any two anticonvulsants. Claims for Aptiom will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days of the requested agent and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Briviact

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - prescriber is a neurologist or consult notes from neurology office are provided; **and**
  - inadequate response or adverse reaction to any two anticonvulsants; **and**
  - for the tablet formulation, requested quantity is ≤ two tablets/day.

SmartPA: Claims for Briviact (within the quantity limit of two tablets/day for the tablet formulation) will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for epilepsy/seizures, the prescriber is a neurologist, and if the member has a history of paid MassHealth pharmacy claims for any two anticonvulsants. Claims for Briviact (within the quantity limit of two tablets/day for the tablet formulation) will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days of the requested agent and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Diacomit

- Documentation of the following is required:
  - diagnosis of Dravet syndrome; **and**
  - member is ≥ two years of age; **and**
  - prescriber is a neurologist or consult notes from neurology office are provided; **and**
  - requested medication will be used in combination with clobazam; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

Diacomit, Epidiolex, and Fintepla for non-FDA approved refractory epilepsy syndrome, refractory epilepsy, or refractory seizures

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from neurology office are provided; **and**
  - for Diacomit and Fintepla, member is ≥ two years of age; **and**
  - inadequate response or adverse reaction to three anticonvulsants; **and**
  - member will be using the requested agent as adjunctive therapy.

diazepam rectal gel > 5 kits (10 syringes)/30 days, Nayzilam > 10 units/30 days, and Valtoco > 10 units/30 days

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - for diazepam rectal gel, medical necessity for greater than 5 kits (10 syringes)/30 days; **or**
    - for Nayzilam and Valtoco, medical necessity for greater than 10 units/30 days; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided.

Elepsia XR

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for the requested agent instead of the levetiracetam extended-release formulation available without PA.

Epidiolex

- Documentation of the following is required for the diagnosis of Dravet syndrome or Lennox-Gastaut syndrome:
  - medical records supporting the diagnosis; **and**
  - prescriber is a neurologist or consult notes from neurology office are provided; **and**
  - member will be using the requested agent as adjunctive therapy; **and**

- inadequate response or adverse reaction to any two anticonvulsants.
- Documentation of the following is required for the diagnosis of seizures associated with tuberous scleroris complex (TSC):
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from neurology office are provided; **and**
  - member will be using the requested agent as adjunctive therapy.

Eprontia
- Documentation of the following is required:
  - one of the following:
    - diagnosis of epilepsy or a seizure disorder; **or**
    - diagnosis of migraine prophylaxis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - one of the following:
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed; **or**
    - member utilizes tube feeding (G-tube/J-tube) and is unable to utilize crushed tablets; **or**
    - member is ≤ 16 years of age and requested dose cannot be obtained from topiramate formulations available without PA; **or**
    - medical necessity for the requested formulation instead of other topiramate formulations available without PA.

everolimus tablets for oral suspension and everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg
- Documentation of the following is required:
  - diagnosis of treatment-resistant epilepsy associated with tuberous sclerosis complex (TSC); **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response to combination therapy with at least two anticonvulsants or contraindication to all other anticonvulsants; **and**
  - requested agent will be used as adjunctive therapy with at least one anticonvulsant agent; **and**
  - requested quantity is ≤ one unit/day.

Fintepla
- Documentation of the following is required:
  - diagnosis of Dravet syndrome or Lennox-Gastaut Syndrome; **and**
  - member is ≥ two years of age; **and**
  - prescriber is a neurologist or consult notes from neurology office are provided; **and**
  - member will be using the requested agent as adjunctive therapy; **and**
  - inadequate response or adverse reaction to any two anticonvulsants; **and**
  - one of the following:
    - if not used in combination with stiripentol, requested quantity is ≤ 11.9 mL/day (26 mg/day); **or**
    - if used in combination with stiripentol and clobazam, requested quantity is ≤ 7.8 mL/day (17 mg/day).

Fycompa
- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - member is ≥ four years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for Fycompa will usually process at the pharmacy without a PA request if the member is ≥ four years of age, has a history of MassHealth medical claims for epilepsy/seizures, the prescriber is a neurologist, and the member has a history of paid MassHealth pharmacy claims for any two anticonvulsants. Claims for Fycompa will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Lamictal XR starter kit and lamotrigine extended-release

- Documentation of the following is required for the diagnosis of bipolar disorder:
  - appropriate diagnosis; **and**
  - prescriber is a psychiatrist or consult notes from a psychiatry office are provided; **and**
  - medical necessity for the extended-release formulation instead of the immediate-release formulation.
- Documentation of the following is required for the diagnosis of epilepsy or a seizure disorder:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for the extended-release formulation instead of the immediate-release formulation.

SmartPA: Claims for lamotrigine extended-release will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures or bipolar disorder.†

lamotrigine tablet starter kit

- Documentation of the following is required for the diagnosis of bipolar disorder:
  - appropriate diagnosis; **and**
  - prescriber is a psychiatrist or consult notes from a psychiatry office are provided; **and**
  - medical necessity for use instead of lamotrigine tablets.
- Documentation of the following is required for the diagnosis of epilepsy or a seizure disorder:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for use instead of lamotrigine tablets.

lamotrigine ODT and lamotrigine ODT starter kit

- Documentation of the following is required for the diagnosis of bipolar disorder:
  - appropriate diagnosis; **and**
  - prescriber is a psychiatrist or consult notes from a psychiatry office are provided; **and**
  - medical necessity for the requested formulation instead of formulation available without PA; **and**
  - inadequate response or adverse reaction to lamotrigine dispersible tablets.
- Documentation of the following is required for the diagnosis of epilepsy or a seizure disorder:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for the requested formulation instead of formulation available without PA; **and**
  - inadequate response or adverse reaction to lamotrigine dispersible tablets.

SmartPA: Claims for lamotrigine ODT (excluding starter kit) will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures or bipolar disorder.†

Libervant > 10 units/30 days, ≥ six years of age

- Documentation of all of the following is required for > 10 units/30 days:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - single requested dose does not exceed 15 mg; **and**
  - medical necessity for exceeding the quantity limit.
- Documentation of all of the following is required for members ≥ six years of age:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**

- inadequate response, adverse reaction, or contraindication to Valtoco nasal spray; **and**
- single requested dose does not exceed 15 mg; **and**
- appropriate dose.

Motpoly XR

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member weight is ≥ 50 kg; **and**
  - medical necessity for the extended-release formulation instead of the immediate-release; **and**
  - requested dose is once daily; **and**
  - one of the following:
    - for Motpoly XR 100 mg, requested quantity is ≤ one unit/day; **or**
    - for Motpoly XR 150 mg, 200 mg, requested quantity is ≤ two units/day.

SmartPA: Claims for Motpoly (within the quantity limit of two units/day for the 150 mg and 200 mg or within the quantity limit of one unit/day for the 100 mg) will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days of the requested agent and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Oxtellar XR

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - member is ≥ six years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for this branded extended-release formulation instead of both of the following: oxcarbazepine tablets, oxcarbazepine suspension; **and**
  - one of the following:
    - member has been stabilized on oxcarbazepine (any formulation); **or**
    - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for Oxtellar XR will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

rufinamide

- Documentation of the following is required:
  - diagnosis of Lennox-Gastaut Syndrome, epilepsy, or a seizure disorder; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for rufinamide will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for epilepsy/seizures, the prescriber is a neurologist, and the member has a history of paid MassHealth pharmacy claims for any two anticonvulsants. Claims for rufinamide will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Spritam

- Documentation of the following is required:
  - diagnosis of myoclonic seizures, epilepsy, or a seizure disorder; **and**
  - medical necessity for this oral tablet for suspension formulation instead of levetiracetam solution; **and**

- prescriber is a neurologist or consult notes from a neurology office are provided; **and**
- one of the following:
  - diagnosis of myoclonic seizures **and** member is ≥ 12 years of age; **or**
  - diagnosis of epilepsy or a seizure disorder and all of the following:
    - member is ≥ four years of age; **and**
    - one of the following:
      - member has been stabilized on levetiracetam (any formulation); **or**
      - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for Spritam will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Sympazan

- Documentation of the following is required:
  - diagnosis of Lennox-Gastaut Syndrome, epilepsy, or a seizure disorder; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member will be using the requested agent as adjunctive therapy; **and**
  - member is ≥ two years of age; **and**
  - medical necessity for this branded film formulation instead of both of the following: clobazam tablets and clobazam suspension; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for clobazam suspension and tablet will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

tiagabine

- Documentation of the following is required:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - member is ≥ 12 years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member will be using the requested agent as adjunctive therapy; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

SmartPA: Claims for tiagabine will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

topiramate extended-release capsules (generic Trokendi XR)

- Documentation of the following is required for the diagnosis of Lennox-Gastaut Syndrome, epilepsy, or a seizure disorder:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for use instead of topiramate extended-release capsules (generic Qudexy XR); **and**
  - inadequate response or adverse reaction to any two anticonvulsants.

- Documentation of the following is required for the diagnosis of migraine prophylaxis:
  - appropriate diagnosis; **and**

- member is ≥ 12 years of age; **and**
- prescriber is a neurologist or consult notes from a neurology office are provided; **and**
- medical necessity for use instead of topiramate extended-release capsules (generic Qudexy XR); **and**
- inadequate response or adverse reaction to topiramate tablets; **and**
- inadequate response or adverse reaction to one or contraindication to all of the following prophylactic treatments:
  - beta-blocker; **or**
  - calcium channel blocker; **or**
  - divalproex or valproic acid; **or**
  - tricyclic antidepressant.

SmartPA: Claims for topiramate extended-release capsules (generic Trokendi XR) will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

vigabatrin

- Documentation of the following is required for the diagnosis of epilepsy or a seizure disorder:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member is ≥ two years of age; **and**
  - member will be using the requested agent as adjunctive therapy; **and**
  - inadequate response or adverse reaction to any two anticonvulsants.
- Documentation of the following is required for the diagnosis of infantile spasms:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member is < two years of age.

SmartPA: Claims for vigabatrin will usually process at the pharmacy without a PA request if the member is < two years of age, has a history of MassHealth medical claims for infantile spasms, and the prescriber is a neurologist. Claims for vigabatrin will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures. †

Xcopri

- Documentation of the following is required for members ≥ 18 years of age:
  - diagnosis of epilepsy or a seizure disorder; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a neurologist or consult notes from neurology office are provided; **and**
  - inadequate response or adverse reaction to any two anticonvulsants; **and**
  - one of the following:
    - for the 25 mg tablet, 50 mg tablet, 100 mg tablet, or titration pack formulation, requested quantity is ≤ one unit/day; **or**
    - for the 150 mg tablet, 200 mg tablet, or dose pack formulation, requested quantity is ≤ two units/day.

SmartPA: Claims for Xcopri (within the quantity limit) will usually process at the pharmacy without a PA request if the member is ≥ 18 years of age, has a history of MassHealth medical claims for epilepsy/seizures, the prescriber is a neurologist, and if the member has a history of paid MassHealth pharmacy claims for any two anticonvulsants. Claims for Xcopri (within the quantity limit) will also usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Zonisade

- Documentation of the following is required:

- diagnosis of epilepsy or a seizure disorder; **and**
- prescriber is a neurologist or consult notes from neurology office are provided; **and**
- one of the following:
  - member has severe dysphagia and is currently utilizing only formulations that can be easily swallowed; **or**
  - member utilizes tube feeding; **or**
  - member is < 13 years of age; **or**
  - medical necessity for the requested formulation instead of zonisamide formulations available without prior authorization; **and**
- requested quantity is ≤ 30 mL/day.

SmartPA: Claims for Zonisade (within the quantity limit) will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days and if the member has a history of MassHealth medical claims for epilepsy/seizures.†

Ztalmy
- Documentation of the following is required:
  - diagnosis of CDKL5 deficiency disorder (CDD); **and**
  - member is ≥ 2 years of age; **and**
  - prescriber is a neurologist or consult notes from neurology office are provided; **and**
  - genetic testing to confirm pathogenic or likel-pathogenic CDKL5 mutation; **and**
  - inadequate response or adverse reaction to any two anticonvulsants; **and**
  - requested quantity is ≤ 36 mL/day (1,800 mg/day).

Non-preferred Brand Name
- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - diagnosis of epilepsy or a seizure disorder and member is stable on the requested formulation; **or**
    - medical records documenting one of the following:
      - allergic response or adverse reaction to the generic product or history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain product; **or**
      - inadequate response to the generic product.

Non-preferred generic
- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - medical records documenting one of the following:
    - allergic response or adverse reaction to the Brand Name product or history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain product; **or**
    - inadequate response to the Brand Name product.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy ***(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, and viloxazine] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**
      - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
      - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
      - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with and without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and** one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Mood Stabilizer Polypharmacy (*overlapping pharmacy claims for three or more mood stabilizers [agents considered to be used only*

for seizure diagnoses are not included] for at least 60 days within a 90-day period) for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for members with seizure diagnosis only:
  - appropriate diagnosis (seizure) without comorbid condition.

- Documentation of the following is required for members with psychiatric diagnoses, with or without seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate psychiatric diagnoses; **and**
    - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - one of the following:
      - cross-titration/taper of mood stabilizer therapy; **or**
      - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain); **and**
    - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
    - other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed.

- Documentation of the following is required for members with a psychiatric diagnosis and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - psychiatric diagnosis and diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain); **and**
    - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **and**
    - one of the following:
      - cross-titration/taper of mood stabilizer therapy; **or**

- inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **and**
- if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation.

Mood Stabilizer for members < six years of age ***(agents considered to be used only for seizure diagnoses are not included)***

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a seizure diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding indications; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; and
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

SmartPA: Claims for mood stabilizers or benzodiazepines will usually process at the pharmacy without a PA request if the member is < six years of age, has a history of MassHealth medical claims for seizure, and does not have a history of MassHealth medical claims for psychiatric diagnoses and/or other diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain).†

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 21 - Cystic Fibrosis Agents

Drug Category: Respiratory Agents

Medication Class/Individual Agents: Cystic Fibrosis Transmembrane Conductance Regulator Modulators

I. Prior-Authorization Requirements

Cystic Fibrosis Agents – Mucolytics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dornase alfa	Pulmozyme		
mannitol inhalation powder	Bronchitol	PA	

Cystic Fibrosis Agents – Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Modulators			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
elexacaftor / tezacaftor / ivacaftor	Trikafta PD	PA	
ivacaftor	Kalydeco PD	PA	
lumacaftor / ivacaftor	Orkambi PD	PA	
tezacaftor / ivacaftor	Symdeko PD	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

ivacaftor

- A potentiator of the CFTR protein thought to work by facilitating increased chloride transport by potentiating the channel-open probability of the CFTR protein.
- Approved for individuals ≥ one month of age with cystic fibrosis (CF) and one of the FDA-approved mutations in the CFTR gene that is responsive to ivacaftor.
- Strongly recommended by the CFF for individuals with CF and specific gene mutation noted above to improve lung function and quality of life, and to reduce exacerbations.[1]
- Dosing for individuals one to < two months of age and weight 3 kg or greater: 5.8 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat -containing food.*
- Dosing for individuals two to < four months of age and weight 3 kg or greater: 13.4 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat -containing food.*
- Dosing for individuals four months to < six months of age and weight 5 kg or greater: 25 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat-containing food.*
- Dosing for individuals six months to < six years of age

	Clinical Notes
	and weight < 7 kg: 25 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat-containing food.* • Dosing for individuals six months to < six years of age and weight 7 kg to < 14 kg: 50 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat-containing food.* • Dosing for individuals six months to < six years of age and weight 14 kg or greater: 75 mg packet every 12 hours - mix with 5 mL soft food or liquid and administer with fat-containing food.* • Dosing for individuals ≥ six years of age: 150 mg every 12 hours with fat-containing food.* *Notes: Adjust dose for individuals with concomitant use of moderate and strong CYP3A inhibitors, moderate hepatic impairment, and use with caution in those with severe hepatic impairment. If possible, avoid concomitant use of CYP3A inducers (e.g., carbamazepine, rifampin, phenobarbital, phenytoin, St. John's wort, etc). lumacaftor/ivacaftor • A combination product that contains ivacaftor, a potentiator of the CFTR protein as well as lumacaftor, a CFTR corrector. • Approved for individuals ≥ one year of age with CF and two copies (homozygous) of the F508del mutation in the CFTR gene. • Dosing for individuals one to two years of age and weight seven kg to < nine kg: One packet (75 mg/94 mg) every 12 hours- mix with 5 mL of soft food or liquid and administer with fat-containing food.** • Dosing for individuals one to two years of age and weight nine kg to < 14 kg: One packet (100 mg/125 mg) every 12 hours- mix with 5 mL of soft food or liquid and administer with fat-containing food.** • Dosing for individuals one to two years of age and weight 14 kg or greater: One packet (150 mg/188 mg) every 12 hours- mix with 5 mL of soft food or liquid and administer with fat-containing food.** • Dosing for individuals two to five years of age and weight < 14 kg: One packet (100mg/125 mg) every 12 hours- mix with 5 mL soft food or liquid and administer with fat-containing food.** • Dosing for individuals two to five years of age and

	Clinical Notes
	weight 14 kg or greater: One packet (150mg/188 mg) every 12 hours- mix with 5 mL soft food or liquid and administer with fat-containing food.** • Dosing for individuals six to < 12 years of age: Two tablets (100mg/125 mg) every 12 hours with fat-containing food.** • Dosing for individuals ≥ 12 years of age: Two tablets (200mg/125 mg) every 12 hours with fat-containing food.** **Notes: Adjust dose for individuals with hepatic impairment and concomitant use of strong CYP3A inhibitors (e.g., azole antifungals, clarithromycin, etc). If possible, avoid concomitant use of CYP3A inducers (e.g., carbamazepine, rifampin, phenobarbital, phenytoin, St. John's wort, etc). tezacaftor/ivacaftor • A combination product that contains ivacaftor, a potentiator of the CFTR protein, as well as tezacaftor, a CFTR corrector. • Approved for individuals ≥ six years of age with CF and two copies (homozygous) of the F508del mutation in the CFTR gene or who have at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor. • Dosing for individuals six to < 12 years of age weighing < 30 kg: One tablet (50mg/75 mg) every morning and one ivacaftor 75 mg tablet every evening with fat-containing food.*** • Dosing for individuals six to < 12 years of age weighing ≥ 30 kg: One tablet (100mg/150 mg) every morning and one ivacaftor 150 mg tablet every evening with fat-containing food.*** • Dosing for individuals ≥ 12 years of age: One tablet (100mg/150 mg) every morning and one ivacaftor 150 mg tablet every evening with fat-containing food.*** ***Notes: Adjust dose for individuals with moderate or severe hepatic impairment or when coadministered with moderate or strong CYP3A inhibitors (e.g., azole antifungals, clarithromycin, etc). elexacaftor/tezacaftor/ivacaftor • The newest agent that now contains two CFTR correctors, elexacaftor and tezacaftor as well as the

	Clinical Notes
	potentiator, ivacaftor. • Approved for individuals aged two years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to elexacaftor/tezacaftor/ivacaftor. • Dosing for individuals 2 to < 6 years of age and weighing < 14 kg is one elexacaftor 80 mg/ tezacaftor 40 mg/ ivacaftor 60 mg packet every morning and one ivacaftor 59.5 mg packet every evening.*** • Dosing for individuals 2 to < 6 years of age and weighing ≥ 14 kg is one elexacaftor 100 mg /tezacaftor 50 mg/ ivacaftor 75 mg packet every morning and one ivacaftor 75 mg packet every evening.*** • Dosing for individuals six to < 12 years of age weighing < 30 kg is two elexacaftor 50 mg/ tezacaftor 25 mg/ ivacaftor 37.5 mg tablets in the morning and one ivacaftor 75 mg tablet in the evening.*** • Dosing for individuals six to < 12 years of age weighing ≥ 30 kg is two elexacaftor 100 mg/ tezacaftor 50 mg/ ivacaftor 75 mg tablets in the morning and one ivacaftor 150 mg tablet in the evening.*** • Dosing for individuals ≥ 12 years of age is two elexacaftor 100 mg/ tezacaftor 50 mg/ ivacaftor 75 mg tablets in the morning and one ivacaftor 150 mg tablet in the evening.*** ***Notes: Adjust dose for individuals with moderate hepatic impairment or when coadministered with moderate or strong CYP3A inhibitors (e.g., azole antifungals, clarithromycin, etc). Do not use in individuals with severe hepatic impairment or with concomitant strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, etc). References *1. Mogayzel PJ, Naureckas ET, Robinson KA, Mueller G, Hadjiliadis D, Hoag JB, et al. Cystic fibrosis pulmonary guidelines: chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013 Apr 1;187(7):680-9.*

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

II. Therapeutic Uses

FDA-approved, for example:

- treatment of cystic fibrosis (CF)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Bronchitol

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member has passed the Bronchitol Tolerance Test; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: Pulmozyme, sodium chloride for inhalation; **and**
  - appropriate dosing.

Kalydeco

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ one month of age; **and**
  - requested quantity is ≤ two units/day; **and**
  - baseline body mass index (BMI); **and**
  - for members > six years of age, baseline percent predicted forced expiratory volume in one second (ppFEV1).

- For recertification, documentation of positive response to therapy (e.g., improvement in BMI, ppFEV1, decrease in clinical exacerbations) is required.

Orkambi
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - one of the following:
    - for tablets, requested quantity is ≤ four tablets/day; **or**
    - for granules, requested quantity is ≤ two packets/day; **and**
  - baseline BMI; **and**
  - for members > six years of age, baseline ppFEV1.
- For recertification, documentation of positive response to therapy (e.g., improvement in BMI, ppFEV1, decrease in clinical exacerbations) is required.

Symdeko
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - requested quantity is ≤ two tablets/day; **and**
  - baseline BMI; **and**
  - for members > six years of age, baseline ppFEV1.
- For recertification, documentation of positive response to therapy (e.g., improvement in BMI, ppFEV1, decrease in clinical exacerbations) is required.

Trikafta
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - one of the following:
    - for tablets, requested quantity is ≤ three tablets/day; **or**
    - for granules, requested quantity is ≤ 2 packets/day; **and**
  - baseline BMI; **and**
  - for members > six years of age, baseline ppFEV1.
- For recertification, documentation of positive response to therapy (e.g., improvement in BMI, ppFEV1, decrease in clinical exacerbations) is required.

MassHealth Evaluation Criteria

Table 22 - Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents

Drug Category: Endocrine/metabolic and Gastrointestinal Agents

Medication Class/Individual Agents: Acromegaly Agents, Carcinoid Syndrome Agents, and Cushing's Syndrome Agents

I. Prior-Authorization Requirements

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
osilodrostat	Isturisa	PA	

Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents – Cortisol Receptor Blocker

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
levoketoconazole	Recorlev	PA	
mifepristone 300 mg	Korlym	PA	A90

Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents – Somatostatin Analogs

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
lanreotide	Somatuline		
lanreotide			
octreotide capsule	Mycapssa	PA	
octreotide injectable suspension	Sandostatin LAR		
octreotide injection	Sandostatin		#
pasireotide	Signifor	PA	
pasireotide injectable suspension	Signifor LAR	PA	MB

Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents – Growth Hormone Receptor Antagonists

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
pegvisomant	Somavert	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Guidelines from Association of Clinical Endocrinologists for the treatment of acromegaly recommend surgery as a primary treatment option for acromegaly and reserve medical therapy for use in members with persistent disease following surgery.[1,2]
- Pharmacologic options for the treatment of acromegaly include: somatostatin analogs, growth hormone receptor antagonists and dopamine analogs.[1,2]
- For additional information regarding the management of dopamine analogs, please see: Table 48 - Antiparkinsonian Agents.
- Guidelines from the Endocrine Society for the treatment of Cushing’s syndrome recommend surgical resection of primary lesions as initial treatment of underlying Cushing’s disease.[3]
- For members with adrenocorticotrophic hormone (ACTH)-dependent Cushing’s syndrome who underwent a noncurative surgery or who were not candidates for surgery, there are several second-line treatment options including: repeat transsphenoidal surgery, radiotherapy, medical therapy, and bilateral adrenalectomy.[3]
- Pharmacologic options for the treatment of Cushing’s syndrome include glucocorticoid receptor-directed agents (e.g. mifepristone), pituitary-directed agents (e.g.

Acromegaly, Carcinoid Syndrome, and Cushing's Syndrome Agents – Carcinoid Syndrome Agents				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	cabergoline and pasireotide), and steroidogenesis inhibitors (e.g. ketoconazole and mitotane).[3]
telotristat ethyl	Xermelo	PA		[1] Katznelson L, Laws ER Jr, Melmed S, Molitch ME, Murad MH, Utz A, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014 Nov;99(11):3933-51. [2] Katznelson L, Atkinson JL, Cook DM, Ezzat SZ, Hamrahian AH, Miller KK et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly–2011 update. Endocr Pract. 2011 Jul-Aug;17 Suppl 4:1-44. [3]Nieman LK, Biller BM, Findling JW, Murad MH, Newell-Price J, Savage MO, et al; Endocrine Society. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015 Aug;100(8):2807-31.

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acromegaly (Mycapssa, Signifor LAR, Somavert)
- Carcinoid syndrome diarrhea (Xermelo)
- Cushing's disease (Isturisa, Signifor, Signifor LAR)
- Hyperglycemia secondary to hypercortisolism in adults with endogenous Cushing’s syndrome who have type 2 diabetes mellitus or glucose intolerance (mifepristone 300 mg)

Note: the above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name

Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Isturisa

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - one of the following:
    - member has failed surgical intervention (reoccurrence after surgery or failed tumor removal); **or**
    - surgical interventions are not an option at this time; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: cabergoline, ketoconazole tablet, Lysodren; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Signifor, Signifor LAR.

mifepristone 300 mg

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member has failed surgical intervention (reoccurrence after surgery or failed tumor removal); **or**
    - surgical interventions are not an option at this time; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: cabergoline, ketoconazole tablet, Lysodren; **and**
  - requested quantity is ≤ four tablets/day.

Mycapssa

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is under the care of an endocrinologist; **and**
  - member has responded to and tolerated treatment with octreotide or lanreotide; **and**
  - requested quantity is ≤ four capsules/day.

Recorlev

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**

- one of the following:
  - member has failed surgical intervention (reoccurrence after surgery or failed tumor removal); **or**
  - surgical interventions are not an option at this time; **and**
- inadequate response or adverse reaction to ketoconazole tablet; **and**
- inadequate response or adverse reaction to one or contraindication to both of the following: cabergoline, Lysodren.

Signifor

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member has failed surgical intervention (reoccurrence after surgery or failed tumor removal); **or**
    - surgical interventions are not an option at this time; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: cabergoline, ketoconazole tablet, Lysodren; **and**
  - requested quantity is ≤ two vials/day.

Signifor LAR

- Documentation of all of the following is required for a diagnosis of acromegaly:
  - appropriate diagnosis; **and**
  - member is under the care of an endocrinologist; **and**
  - requested quantity is ≤ one kit or vial/30 days; **and**
  - one of the following:
    - member has persistent or recurring disease following surgery and/or radiation; **or**
    - member is not a candidate for surgery; **and**
  - one of the following:
    - inadequate response or adverse reaction to one somatostatin analog available without PA; **or**
    - contraindication to somatostatin analogs; **and**
  - one of the following:
    - member has moderate-to-severe disease symptoms; **or**
    - member has mild disease and one of the following:
      - inadequate response or adverse reaction to one dopamine analog (e.g., cabergoline, bromocriptine) in combination with a somatostatin analog; **or**
      - adverse reaction to one somatostatin analog available without PA; **or**
      - contraindication to dopamine analogs.

- Documentation of all of the following is required for a diagnosis of Cushing's disease:
  - appropriate diagnosis; **and**
  - one of the following:
    - member has failed surgical intervention (reoccurrence after surgery or failed tumor removal); **or**
    - surgical interventions are not an option at this time; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: cabergoline, ketoconazole tablet, Lysodren; **and**
  - requested quantity is ≤ one kit or vial/30 days.

Somavert

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is under the care of an endocrinologist; **and**

- requested quantity is ≤ one vial/day; **and**
- one of the following:
  - member has persistent or recurring disease following surgery and/or radiation; **or**
  - member is not a candidate for surgery; **and**
- one of the following:
  - inadequate response or adverse reaction to one somatostatin analog available without PA; **or**
  - contraindication to somatostatin analogs; **and**
- one of the following:
  - member has moderate-to-severe disease symptoms; **or**
  - member has mild disease and one of the following:
    - inadequate response or adverse reaction to one dopamine analog (e.g., cabergoline, bromocriptine) in combination with a somatostatin analog; **or**
    - adverse reaction to one somatostatin analog available without PA; **or**
    - contraindication to dopamine analogs.

Xermelo

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to one somatostatin analog therapy; **and**
  - requested agent will be given in combination with somatostatin analog therapy; **and**
  - requested quantity is ≤ three tablets/day.

MassHealth Evaluation Criteria
Table 23 - Respiratory Agents - Inhaled

Drug Category: Respiratory Tract Agents

Medication Class/Individual Agents: Respiratory Inhalants

I. Prior-Authorization Requirements

Inhaled Respiratory Agents – Short-Acting Beta Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
albuterol inhalation powder-Proair Digihaler	Proair Digihaler	PA	
albuterol inhalation powder-Proair Respiclick	Proair Respiclick		
albuterol inhalation solution	Accuneb		# , A90
albuterol inhaler		PA	
albuterol inhaler-Ventolin	Ventolin		BP, A90
levalbuterol inhalation solution		PA	A90
levalbuterol inhaler	Xopenex HFA		# , A90

Inhaled Respiratory Agents – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aclidinium / formoterol	Duaklir	PA	
albuterol / ipratropium inhalation solution			A90
albuterol / ipratropium inhalation spray	Combivent		
albuterol/budesonide	Airsupra	PA	
budesonide / formoterol	Symbicort		BP, A90
budesonide / glycopyrrolate / formoterol	Breztri	PA	
fluticasone / salmeterol inhalation	Airduo Digihaler	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Quick-relief medications:

- Inhaled short-acting beta$_2$-agonists (SABAs) are no longer recommended as reliever medication for adults and adolescents ≥ 12 years of age.
- Inhaled corticosteroid (ICS)-formoterol is the preferred AIR for adults and adolescents ≥ 12 years of age.
- Alternative option for AIR is to give an ICS whenever as needed SABA is used.
- Overuse of SABAs increases the risk of asthma exacerbations.

Maintenance medications:

Asthma:

- The Global Initiative for Asthma (GINA) guidelines recommend the use of ICS-formoterol as the preferred maintenance treatment for adults and adolescents ≥ 12 years of age.
- GINA recommends the use of low dose ICS for children ≤ 11 years of age. The addition of a leukotriene receptor agonist (LTRA) can be considered for some children.
- For children six to 11 years of age inadequately controlled with low dose ICS or low dose ICS plus

Inhaled Respiratory Agents – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
powder-Airduo Digihaler			
fluticasone / salmeterol inhalation powder-Airduo Respiclick	Airduo Respiclick	PA	BP, A90
fluticasone / salmeterol inhalation-Advair	Advair		BP, A90
fluticasone / vilanterol	Breo		BP, A90
fluticasone furoate / umeclidinium / vilanterol	Trelegy	PA	
glycopyrrolate / formoterol	Bevespi	PA	
mometasone / formoterol	Dulera		BP
tiotropium / olodaterol	Stiolto	PA	
umeclidinium / vilanterol	Anoro		

Inhaled Respiratory Agents – Corticosteroids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
beclomethasone inhaler	Qvar Redihaler	PA	
budesonide inhalation powder	Pulmicort		
budesonide inhalation suspension	Pulmicort	PA - ≥ 13 years	# , A90
ciclesonide inhaler	Alvesco	PA	
fluticasone furoate inhalation powder	Arnuity		
fluticasone propionate inhalation aerosol		PA - ≥ 12 years	A90
fluticasone propionate inhalation powder		PA	A90
fluticasone propionate inhalation powder-Armonair Digihaler	Armonair Digihaler	PA	
mometasone 110 mcg inhalation powder	Asmanex Twisthaler	PA - ≥ 12 years	

Clinical Notes

LTRA, consideration can be given to starting low dose ICS-formoterol, increasing ICS to medium dose, or starting very low dose ICS-formoterol.
- GINA also recommends consideration for phenotypic assessment for potential add-on biologics in severe cases of asthma not adequately controlled on maintenance inhalers.

Chronic obstructive pulmonary disease (COPD):
- The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guideline states that inhaled bronchodilators are preferred for the management of COPD.
- Short-acting, as-needed bronchodilators are recommended as a first choice for members with mild or infrequent symptoms.
- For Group B members (i.e., those with moderate-to-severe symptoms and low exacerbation risk), a long-acting muscarinic antagonist (LAMA) plus a long-acting beta agonist (LABA) is recommended as first-line treatment.
- The recommended first choice therapy for Group E members (i.e., those with ≥ two moderate exacerbations or ≥ one leading to hospitalization) is a LABA plus LAMA inhaler. If exacerbations are persistent, or blood eosinophils are ≥ 300, an ICS can be added to the LABA plus LAMA regimen.

The incidence of oral candidiasis with ICS may be reduced by using a spacer/holding chamber and rinsing the mouth with water after inhalation.

Exercise-induced bronchospasm (EIB):
- Inhaled ICS-formoterol, ICS-SABA or SABA can be given prior to or during exercise as needed.

Inhaled Respiratory Agents – Corticosteroids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
mometasone 220 mcg inhalation powder	Asmanex Twisthaler	PA - < 12 years	
mometasone inhalation aerosol	Asmanex HFA		

Inhaled Respiratory Agents – Anticholinergics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aclidinium	Tudorza		
glycopyrrolate inhalation solution	Lonhala	PA	
ipratropium inhalation aerosol	Atrovent HFA		
revefenacin	Yupelri	PA	
tiotropium inhalation powder	Spiriva Handihaler		BP, A90
tiotropium inhalation solution	Spiriva Respimat		
umeclidinium	Incruse		

Inhaled Respiratory Agents – Long-Acting Beta Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
arformoterol	Brovana	PA	A90
formoterol	Perforomist	PA	
olodaterol	Striverdi	PA	
salmeterol	Serevent		

Inhaled Respiratory Agents – Mast Cell Stabilizers			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cromolyn inhalation			A90

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- asthma
- COPD
- EIB

Non-FDA-approved, for example:

- eosinophilic esophagitis (budesonide inhalation suspension, fluticasone priopionate inhalation aerosol)
- chronic sinusitis, pansinusitis, rhinitis, nasal polyposis (budesonide inhalation suspension)
- COPD (budesonide inhalation suspension)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Airduo Digihaler

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: fluticasone/salmeterol inhalation aerosol, powder (generic Advair), fluticasone/salmeterol inhalation powder (generic Airduo Respiclick); **and**
  - requested quantity is ≤ one inhaler/30 days.

Airsupra

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**

- one of the following:
  - inadequate response, adverse reaction, or contraindication to budesonide/formoterol; **or**
  - inadequate response or adverse reaction to the separate agents: albuterol and Pulmicort (budesonide inhalation powder) used concomitantly as needed; **or**
  - clinical rationale why the member cannot utilize the combination of the separate agents albuterol and Pulmicort (budesonide inhalation powder) concomitantly as needed.

albuterol inhaler

- Documentation of the following is required:
  - diagnosis of asthma, COPD, or EIB; **and**
  - medical records documenting an inadequate response or adverse reaction to an albuterol product available without PA.

Alvesco, Armonair Digihaler, fluticasone propionate inhalation aerosol ≥ 12 years of age, fluticasone propionate inhalation powder, Qvar Redihaler

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - inadequate response or adverse reaction to two or contraindication to all inhaled corticosteroids available without PA.

SmartPA: Claims for Alvesco and Qvar Redihaler will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

arformoterol and formoterol

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - member has a recent paid pharmacy claim for a nebulized respiratory product and no recent paid pharmacy claims for inhalers; **or**
    - medical necessity for nebulized formulation; **and**
  - requested quantity is ≤ 120 mL/30 days.

SmartPA: Claims for arformoterol and formoterol will usually process at the pharmacy within the quantity limit of 120 mL/30 days without a PA request if the member (≥ 18 years of age) has a history of MassHealth medical claims for COPD, has a history of paid MassHealth pharmacy claims for a nebulized solution within the last 30 days or has a history of paid MassHealth pharmacy claims for any nebulized solution for ≥ 15 days of therapy within the last 30 days, and there is no history of paid MassHealth pharmacy claims for an inhaler within the last 30 days, and there is no history of paid MassHealth pharmacy claims for an inhaler for ≥ 15 days of therapy within the last 30 days.†

Asmanex Twisthaler 110 mcg in members ≥ 12 years of age

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - clinical rationale for use of 110 mcg strength in members ≥ 12 years of age.

SmartPA: Claims for Asmanex Twisthaler 110 mcg will usually process at the pharmacy without a PA request if the member is < 12 years of age.†

Asmanex Twisthaler 220 mcg in members < 12 years of age

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - clinical rationale for use of 220 mcg strength in members < 12 years of age.

SmartPA: Claims for Asmanex Twisthaler 220 mcg will usually process at the pharmacy without a PA request if the member is ≥ 12

years of age.†

Bevespi and Duaklir

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one inhaler/30 days; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Anoro, Stiolto.

SmartPA: Claims for Bevespi and Duaklir will usually process at the pharmacy within the quantity limit of one inhaler/30 days without a PA request if the member (≥ 18 years of age) has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

Breztri

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to the separate agents Bevespi and Pulmicort inhalation powder twice daily; **or**
    - clinical rationale why member cannot utilize the combination of the separate agents Bevespi and Pulmicort inhalation powder twice daily; **and**
  - requested quantity is ≤ one inhaler/30 days.

SmartPA: Claims for Breztri will usually process at the pharmacy within the quantity limit of one inhaler/30 days without a PA request if the member (≥ 18 years of age) has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

budesonide inhalation suspension ≥ 13 years of age

- Documentation of the following is required for a diagnosis of asthma:
  - appropriate diagnosis; **and**
  - one of the following:
    - member has a recent paid pharmacy claim for a nebulized respiratory product and no recent paid pharmacy claims for inhalers; **or**
    - medical necessity for nebulized formulation.
- Documentation of the following is required for a diagnosis of eosinophilic esophagitis:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., allergy/immunology, gastroenterology, otolaryngology, rhinology, pulmonology, ENT).
- Documentation of the following is required for a diagnosis of chronic sinusitis, pansinusitis, rhinitis, nasal polyposis:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., allergy/immunology, otolaryngology, rhinology, pulmonology, ENT), **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to one commercially available intranasal steroid, **or**
    - clinical rationale for budesonide irrigation/rinse with suspension formulation.
- Documentation of the following is required for a diagnosis of COPD:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., pulmonology), **and**
  - one of the following:
    - member has a recent claim for a nebulized respiratory product and no recent paid pharmacy claims for inhalers; **or**
    - medical necessity for nebulized formulation.

SmartPA: Claims for budesonide inhalation suspension will usually process at the pharmacy without a PA request if the member is ≥ 13 years of age and has a history of paid MassHealth pharmacy claims for a nebulized solution within the last 30 days or has a history of paid MassHealth pharmacy claims for any nebulized solution for ≥ 15 days of therapy within the last 30 days, and there is no history of paid MassHealth pharmacy claims for an inhaler within the last 30 days, and there is no history of paid MassHealth pharmacy claims for an inhaler for ≥ 15 days of therapy within the last 30 days.†

fluticasone propionate inhalation aerosol ≥ 12 years of age

- Documentation of the following is required:
  - diagnosis of eosinophilic esophagitis; **and**
  - prescriber is a specialist (e.g., allergy/immunology, gastroenterology, otolaryngology, rhinology, pulmonology, ENT).

fluticasone/salmeterol inhalation powder (generic Airduo Respiclick)

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - one of the following:
    - inadequate response or adverse reaction to fluticasone/salmeterol inhalation aerosol, powder (generic Advair); **or**
    - clinical rationale for lower dose of fluticasone/salmeterol; **or**
    - member is already receiving another Respiclick formulation; **and**
  - requested quantity is ≤ one inhaler/30 days.

levalbuterol solution

- Documentation of the following is required:
  - diagnosis of asthma, COPD, or EIB; **and**
  - inadequate response, adverse reaction, or contraindication to inhaled albuterol solution; **and**
  - one of the following:
    - member is < 13 years of age; **or**
    - medical necessity for nebulized formulation.

Smart PA: Claims for levalbuterol solution will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

Lonhala and Yupelri

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - member has a recent paid pharmacy claim for a nebulized respiratory product and no recent paid pharmacy claims for inhalers; **or**
    - medical necessity for nebulized formulation; **and**
  - inadequate response, adverse reaction, or contraindication to ipratropium inhalation nebulizer solution; **and**
  - one of the following:
    - for Lonhala, requested quantity is ≤ 60 mL/30 days; **or**
    - for Yupelri, requested quantity is ≤ 90 mL/30 days.

SmartPA: Claims for Lonhala within the quantity limit of 60 mL/30 days and Yupelri within the quantity limit of 90 mL/30 days will usually process at the pharmacy without a PA request if the member (≥ 18 years of age) has a history of MassHealth medical claims for COPD, has a history of paid MassHealth pharmacy claims for a nebulized solution within the last 30 days or has a history of paid MassHealth pharmacy claims for any nebulized solution for ≥ 15 days of therapy within the last 30 days, there is no history of paid MassHealth pharmacy claims for an inhaler within the last 30 days, there is no history of paid MassHealth pharmacy claims for an

inhaler for ≥ 15 days of therapy within the last 30 days, and has a history of paid MassHealth pharmacy claims for ipratropium inhalation nebulizer solution.†

Proair Digihaler

- Documentation of the following is required:
  - diagnosis of asthma, COPD, or EIB; **and**
  - inadequate response, adverse reaction, or contraindication to an albuterol product available without prior authorization (Proair Respiclick or Ventolin).

Stiolto

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one inhaler/30 days.

SmartPA: Claims for Stiolto will usually process at the pharmacy within the quantity limit of one inhaler/30 days without a PA request if the member has a history of MassHealth medical claims for COPD and the member is ≥ 18 years of age.†

Striverdi

- Documentation of the following is required:
  - diagnosis of COPD; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one inhaler/30 days.

SmartPA: Claims for Striverdi will usually process at the pharmacy within the quantity limit of one inhaler/30 days without a PA request if the member has a history of MassHealth medical claims for COPD and the member is ≥ 18 years of age.†

Trelegy

- Documentation of the following is required:
  - diagnosis of asthma or COPD; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response (defined as at least 90 days of therapy) or adverse reaction to the separate agents fluticasone/vilanterol and Incruse once daily; **or**
    - inadequate response (defined as at least 90 days of therapy) or adverse reaction to the separate agents Anoro and Arnuity once daily; **or**
    - clinical rationale why member cannot utilize the combination of the separate agents fluticasone/vilanterol and Incruse once daily or Anoro and Arnuity once daily; **and**
  - requested quantity is ≤ one inhaler/30 days.

SmartPA: Claims for Trelegy will usually process at the pharmacy within the quantity limit of one inhaler/30 days without a PA request if the member (≥ 18 years of age) has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 24 - Antipsychotics

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Antipsychotics

I. Prior-Authorization Requirements

Antipsychotics – Second-Generation (Atypical)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aripiprazole extended-release injection	Abilify Asimtufii	PA	
aripiprazole extended-release injection	Abilify Maintena	PA	
aripiprazole lauroxil 1,064 mg	Aristada PD	PA - < 10 years and PA > 1 injection/56 days	
aripiprazole lauroxil 441 mg, 662 mg, 882 mg	Aristada PD	PA - < 10 years and PA > 1 injection/28 days	
aripiprazole lauroxil 675 mg	Aristada Initio PD	PA - < 10 years and PA > 1 injection/28 days	
aripiprazole orally disintegrating tablet		PA	A90
aripiprazole solution		PA - < 10 years or ≥ 18 years and PA > 25 mL/day	A90
aripiprazole tablet	Abilify	PA - < 10 years and PA > 2 units/day	# , A90
aripiprazole tablet with sensor	Abilify Mycite	PA	
asenapine sublingual tablet	Saphris	PA	A90
asenapine transdermal	Secuado	PA	
brexpiprazole	Rexulti	PA	
cariprazine	Vraylar PD	PA	
clozapine orally disintegrating tablet		PA	A90
clozapine suspension	Versacloz	PA	A90
clozapine tablet	Clozaril	PA - < 10 years	# , A90
iloperidone	Fanapt	PA	
lumateperone	Caplyta	PA	
lurasidone 20 mg, 40 mg, 60 mg, 120 mg	Latuda	PA - < 10 years and PA > 1 unit/day	# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Limited scientific data supports the concomitant use of two or more antipsychotics. It is recommended that monotherapy trials be attempted before polypharmacy is used.
- Dissolvable tablets do not have a faster onset of action compared to their conventional oral dosage formulations. They possess the same side effects and have similar pharmacokinetic profiles as the oral tablet. Since dissolvable tablets offer no therapeutic advantage, and they are generally more costly than other oral formulations, all dissolvable tablets will require PA except for olanzapine orally disintegrating tablet and risperidone 0.25 mg, 0.5 mg, 1 mg, and 2 mg orally disintegrating tablet within established quantity limits. Asenapine has minimal-to-no absorption if swallowed and must be dissolved in the mouth to be absorbed via buccal/sublingual sites.
- All second-generation (atypical) antipsychotics have a black-box warning for increased mortality in elderly patients with dementia-related psychosis.
- Second-generation (atypical) antipsychotics have been associated with substantial weight gain. This risk is statistically greater with some products compared to others.

Antipsychotics – Second-Generation (Atypical)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
lurasidone 80 mg	Latuda	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 15 mg orally disintegrating tablet	Zyprexa Zydis	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 15 mg, 20 mg tablet	Zyprexa	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 2.5 mg, 5 mg, 7.5 mg, 10 mg tablets	Zyprexa	PA - < 10 years and PA > 3 units/day	# , A90
olanzapine 210 mg, 300 mg extended-release injection	Zyprexa Relprevv	PA - < 10 years and PA > 2 injections/28 days	
olanzapine 405 mg extended-release injection	Zyprexa Relprevv	PA - < 10 years and PA > 1 injection/28 days	
olanzapine 5 mg, 10 mg, 20 mg orally disintegrating tablet	Zyprexa Zydis	PA - < 10 years and PA > 1 unit/day	# , A90
olanzapine injection	Zyprexa		#
paliperidone 1.5 mg, 3 mg, 9 mg tablet	Invega	PA - < 10 years and PA > 1 unit/day	# , A90
paliperidone 6 mg tablet	Invega	PA - < 10 years and PA > 2 units/day	# , A90
paliperidone extended-release 1-month injection	Invega Sustenna PD	PA - < 10 years, PA > 2 injections/28 days within the first 28 days of therapy and PA > 1 injection/28 days after 28 days of therapy	
paliperidone extended-release 3-month injection	Invega Trinza PD	PA - < 10 years and PA > 1 injection/84 days	
paliperidone extended-release 6-month injection	Invega Hafyera PD	PA - < 10 years and PA > 1 injection/168 days	
pimavanserin	Nuplazid	PA	
quetiapine	Seroquel	PA - < 10 years and PA > 3 units/day	# , A90
quetiapine extended-release	Seroquel XR	PA - < 10 years and PA > 2 units/day	# , A90
risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg orally		PA - < 10 years and PA > 2 units/day	A90

Clinical Notes

- In November 2003, the FDA mandated that the following information be added to the WARNINGS section of all second-generation (atypical) antipsychotic drug labeling. "Hyperglycemia in extreme progressing to ketoacidosis, hyperosmolar coma and/or death has been reported for this class of drugs. Fasting glucose should be obtained at the beginning of treatment and periodically. Patients with established diagnosis of diabetes mellitus should be monitored for worsening of glycemic control (for complete details see package insert)."
- A consensus statement issued by the APA, ADA, and others suggested a scheduled monitoring of the following members on these drugs: weight/BMI, waist circumference, blood pressure, fasting glucose, and fasting lipid profile.[1]
- Antipsychotic-induced metabolic complications such as weight increases, glucose increases, and triglyceride increases are more pronounced in children and adolescents compared to the adult population.

[1] *American Diabetes Association; American Psychiatric Association; American Association of Clinical Endocrinologists; North American Association for the Study of Obesity. Consensus development conference on antipsychotic drugs and obesity and diabetes. J Clin Psych 2004;65(2):267-72.*

Please see the following link to find out more information regarding Second-Generation (Atypical) Antipsychotics. https://www.mass.gov/lists/second-generation-antipsychotics-also-known-as-atypical-antipsychotics

Antipsychotics – Second-Generation (Atypical)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
disintegrating tablet			
risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg tablets	Risperdal	PA - < 10 years and PA > 3 units/day	# , A90
risperidone 12.5 mg, 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection-Risperdal Consta	Risperdal Consta	PA - < 10 years and PA > 2 injections/28 days	BP
risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection	Uzedy PD	PA - < 10 years and PA > 1 injection/56 days	
risperidone 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection-Rykindo	Rykindo	PA	
risperidone 3 mg, 4 mg orally disintegrating tablet		PA	A90
risperidone 4 mg tablet	Risperdal	PA - < 10 years and PA > 4 units/day	# , A90
risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection	Uzedy PD	PA - < 10 years and PA > 1 injection/28 days	
risperidone 90 mg, 120 mg extended-release subcutaneous injection	Perseris PD	PA - < 10 years and > 1 injection/28 days	
risperidone solution	Risperdal	PA - < 10 years and PA > 16 mL/day	# , A90
ziprasidone capsule	Geodon	PA - < 10 years and PA > 2 units/day	# , A90
ziprasidone injection	Geodon		#

Antipsychotics – First-Generation (Typical)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline / perphenazine		PA	A90

Antipsychotics – First-Generation (Typical)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
chlorpromazine		PA - < 10 years	A90
fluphenazine		PA - < 10 years	A90
haloperidol	Haldol	PA - < 10 years	# , A90
loxapine capsule	Loxitane	PA - < 10 years	# , A90
molindone		PA - < 10 years	A90
perphenazine		PA - < 10 years	A90
pimozide	Orap	PA - < 10 years	# , A90
thioridazine		PA - < 10 years	A90
thiothixene	Navane	PA - < 10 years	# , A90
trifluoperazine		PA - < 10 years	A90

Antipsychotics – Second-Generation (Atypical) Antipsychotic and Opioid Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
olanzapine / samidorphan	Lybalvi	PA	

Antipsychotics – Second-Generation (Atypical) Antipsychotic and Selective Serotonin Reuptake Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
olanzapine / fluoxetine	Symbyax	PA	A90

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Agitation associated with dementia due to Alzheimer’s Disease
- Bipolar disorder
- Hallucinations/delusions associated with Parkinson's Disease Psychosis

- Irritability associated with autistic disorder
- Major depressive disorder
- Schizoaffective disorder
- Schizophrenia
- Tourette syndrome

non-FDA-approved, for example:

- Autism spectrum disorders
- Bipolar disorder
- Schizoaffective disorder
- Schizophrenia
- Tourette syndrome

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Abilify Asimtufii

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to Aristada; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for Abilify Asimtufii will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

Abilify Maintena

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - one of the following:

- inadequate response, adverse reaction, or contraindication to Aristada; **or**
- member refuses gluteal injections and requires a dose of Aristada that must be administered gluteally only (> 441 mg); **and**

- requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for Abilify Maintena will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days out of the last 120 days.†

Abilify Mycite

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Abilify Maintena and Aristada; **and**
  - medical necessity for monitoring member's ingestion of oral aripiprazole as noted by one of the following:
    - requirement of witnessed or recorded medication ingestion; **or**
    - alternative medication adherence methods were insufficient, including all of the following: medication alarms or reminders, pill boxes, pill counts, refill frequency assessment; **and**
  - member has been trained to use the Abilify Mycite (aripiprazole tablet with sensor) system; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- For recertification, documentation of continued medical necessity for use instead of alternatives is required.

aripiprazole ODT and solution

- Documentation of all of the following is required for requests for aripiprazole ODT for members < 18 years of age:
  - appropriate diagnosis; **and**
  - medical necessity for the orally disintegrating formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - need for witnessed administration; **or**
    - intolerance to other aripiprazole formulations; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for members ≥ 18 years of age with a diagnosis of autism spectrum disorder:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to risperidone; **and**
  - medical necessity for the orally disintegrating formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - need for witnessed administration; **or**
    - intolerance to other aripiprazole formulations; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for members ≥ 18 years of age with a diagnosis of major depressive disorder or treatment-resistant depression:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all antidepressants (either alone or in combination); **and**
  - requested agent will be used as adjunctive antidepressant therapy; **and**
  - medical necessity for the orally disintegrating formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - need for witnessed administration; **or**
    - intolerance to other aripiprazole formulations; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for members ≥ 18 years of age with a psychiatric diagnosis not listed above:
  - appropriate diagnosis; **and**

- inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
- medical necessity for the orally disintegrating formulation as noted by one of the following:
  - member has a swallowing disorder or condition affecting ability to swallow; **or**
  - need for witnessed administration; **or**
  - intolerance to other aripiprazole formulations; **and**
- requested quantity does not exceed established quantity limits (please refer to the reference table below).

asenapine sublingual tablet

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for asenapine sublingual tablet will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two second-generation (atypical) antipsychotics or of the requested agent for 90 days out of the last 120 days.†

Caplyta

- Documentation of all of the following is required for all members with a diagnosis of bipolar depression:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to both of the following: olanzapine monotherapy or in combination with fluoxetine, quetiapine immediate-release or extended-release; **or**
    - inadequate response or adverse reaction to two different or contraindication to all second-generation (atypical) antipsychotics; **and**
  - one of the following:
    - request is for Caplyta 42 mg capsule; **or**
    - for Caplyta 10.5 mg capsule, member is being treated with a strong CYP3A4 inhibitor; **or**
    - for Caplyta 21 mg capsule, member is being treated with a moderate CYP3A4 inhibitor or has moderate or severe hepatic impairment (Child-Pugh Class B or C); **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for members < 18 years of age with a psychiatric diagnosis not listed above:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone; **and**
  - inadequate response or adverse reaction to two different or contraindication to all atypical and typical antipsychotics; **and**
  - one of the following:
    - request is for Caplyta 42 mg capsule; **or**
    - for Caplyta 10.5 mg capsule, member is being treated with a strong CYP3A4 inhibitor; **or**
    - for Caplyta 21 mg capsule, member is being treated with a moderate CYP3A4 inhibitor or has moderate or severe hepatic impairment (Child-Pugh Class B or C); **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for members ≥ 18 years of age with a psychiatric diagnosis not listed above:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
  - one of the following:
    - request is for the 42 mg capsule; **or**
    - for the 10.5 mg capsule, member is being treated with a strong CYP3A4 inhibitor; **or**
    - for the 21 mg capsule, member is being treated with a moderate CYP3A4 inhibitor or has moderate or severe hepatic

impairment (Child-Pugh Class B or C); **and**

- requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for Caplyta for members < 18 years of age will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of one of the following second-generation (atypical) antipsychotics available without PA: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, or ziprasidone, and any two other atypical or typical antipsychotics, or of the requested agent for at least 90 days out of the last 120 days. Claims within quantity limits and polypharmacy requirements for Caplyta for members ≥ 18 years of age will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two second-generation (atypical) antipsychotics or of the requested agent for at least 90 days out of the last 120 days.†

clozapine ODT, risperidone ODT 3 mg and ODT 4 mg

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - medical necessity for the orally disintegrating formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - need for witnessed administration; **or**
    - intolerance to other formulations of the requested agent; **and**
  - for risperidone ODT 3 mg or ODT 4 mg, requested quantity does not exceed established quantity limits (please refer to reference table below).

Fanapt

- Documentation of all of the following is required for members < 18 years of age:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone; **and**
  - inadequate response or adverse reaction to two different or contraindication to all atypical and typical antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for members ≥ 18 years of age:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for Fanapt for members < 18 years of age will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of one of the following second-generation (atypical) antipsychotics available without PA: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, or ziprasidone, and any two other atypical or typical antipsychotics, or of the requested agent for at least 90 days out of the last 120 days. Claims within quantity limits and polypharmacy requirements for Fanapt for members ≥ 18 years of age will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two second-generation (atypical) antipsychotics or of the requested agent for at least 90 days out of the last 120 days.†

Lybalvi

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
  - both of the following:
    - member is not being treated with an opioid; **and**
    - member is not being treated for acute opioid withdrawal; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within specified quantity limits and polypharmacy requirements will usually process and pay at the pharmacy without PA if the member has a history of paid claims for the reference agent for at least 90 out of the last 120 days.†

Nuplazid

- Documentation of all the following is required for all members:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist (including neurology nurse practitioners or physician assistants) or consult notes (dated within one year) from a specialist are provided; **and**
  - for Nuplazid 10 mg tablet, requested medication will be used in combination with a strong CYP3A4 inhibitor; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

perphenazine/amitriptyline and olanzapine/fluoxetine

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents.

SmartPA: Claims for perphenazine/amitriptyline will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days of therapy out of the last 120 days.†

Rexulti

- Documentation of all of the following is required for all members with a diagnosis of major depressive disorder (MDD) or treatment -resistant depression:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all antidepressants (either alone or in combination); **and**
  - Rexulti will be used as adjunctive antidepressant therapy; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for all members with a psychiatric diagnosis not listed above:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation (atypical) antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for Rexulti will usually process at the pharmacy without a PA request if the member has a diagnosis of major depressive disorder, a history of paid MassHealth pharmacy claims for any two antidepressants, and a history of paid MassHealth pharmacy claims for an antidepressant in the last 30 days. Claims within quantity limits and polypharmacy requirements for Rexulti will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two second-generation (atypical) antipsychotics or of the requested agent for at least 90 days out of the last 120 days.†

Rykindo

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: risperidone extended-release intramuscular injection (generic Risperdal Consta), Perseris, Uzedy; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within specified quantity limits will usually process and pay at the pharmacy without PA if the member has a history of paid claims for the reference agent for at least 90 days out of the last 120 days.†

Secuado

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- inadequate response or adverse reaction to two second-generation (atypical) antipsychotics; **and**
- one of the following:
  - inadequate response or adverse reaction to asenapine sublingual; **or**
  - medical necessity for the transdermal formulation; **and**
- requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within specified quantity limits and polypharmacy requirements will usually process and pay at the pharmacy without PA if the member has a history of paid claims for the reference agent for at least 90 days out of the last 120 days.†

Versacloz

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - medical necessity for the oral suspension formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - need for witnessed administration; **or**
    - intolerance to other clozapine formulations.

Vraylar

- Documentation of all of the following is required for all members for adjunctive treatment for MDD or treatment-resistant depression:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all antidepressants (either alone or in combination); **and**
  - Vraylar will be used as adjunctive antidepressant therapy; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for all members with a diagnosis of bipolar depression:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: olanzapine monotherapy or in combination with fluoxetine, quetiapine immediate-release or extended-release; **or**
    - inadequate response or adverse reaction to one different or contraindication to all second-generation (atypical) antipsychotics; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).
- Documentation of all of the following is required for all members with a psychiatric diagnosis not listed above:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, ziprasidone; **and**
  - requested quantity does not exceed established quantity limits (please refer to the reference table below).

SmartPA: Claims within quantity limits and polypharmacy requirements for Vraylar will usually process at the pharmacy without a PA request if the member has a diagnosis of major depressive disorder, a history of paid MassHealth pharmacy claims for any one antidepressant, and a history of paid MassHealth pharmacy claims for an antidepressant in the last 30 days. Claims within quantity limits and polypharmacy requirements for Vraylar will usually process and pay at the pharmacy without prior authorization if the member has a history of a paid claim for the reference agent for at least 90 out of 120 days. Claims for Vraylar will usually also process and pay without prior authorization for members who have a history of paid claims for one of the following: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, or ziprasidone in all claims history.†

Exceeding quantity limits

- Documentation of all of the following is required for all members:
  - appropriate diagnosis; **and**
  - one of the following:

- clinical rationale why the dose cannot be consolidated; **or**
- clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA.

Polypharmacy *(overlapping pharmacy claims for two or more antipsychotics [includes first-generation and/or second-generation antipsychotics, except clozapine, Nuplazid, and injectable formulations] for at least 60 days within a 90-day period)* for members ≥ 18 years of age

- Documentation of all of the following is required:
  - psychiatric diagnosis including treatment-resistant conditions; **and**
  - treatment plan including names of current antipsychotics and corresponding diagnoses; **and**
  - prescriber is a specialist (e.g., psychiatrist, neurologist [including psychiatric/neurological nurse practitioners or physician assistants]) or consult notes (dated within one year) from a specialist are provided; **and**
  - one of the following:
    - inadequate response or adverse reaction to two monotherapy trials as clinically appropriate; **or**
    - member had a recent psychiatric hospitalization and was discharged on the current regimen; **or**
    - cross-titration/taper of antipsychotic therapy.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy (*pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, and viloxazine] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period*) for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**

- treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
- prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation; **and**
- one of the following:
  - member has a seizure diagnosis only; **or**
  - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
  - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
  - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and** one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Antipsychotic Polypharmacy (*overlapping pharmacy claims for 2 or more antipsychotics [includes first-generation and/or second-generation antipsychotics, except short-acting injectable formulations] for at least 60 days within a 90-day period*) for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - treatment plan including name, dose, and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses; **and**
    - a comprehensive behavioral health plan (i.e., non-pharmacologic interventions) is in place; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - stage of treatment is acute, maintenance, or discontinuation; **and**
    - one of the following:
      - for acute stage (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects), one of the following:
        - cross-titration/taper of antipsychotic therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials as clinically appropriate; **or**
      - for maintenance stage (response to antipsychotic treatment with goal of remission or recovery), all of the following:
        - regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place; **and**
        - if member has been on the antipsychotic regimen for the last 12 months, clinical rationale for extended therapy including at least one of the following: previous efforts to reduce/simplify the antipsychotic regimen in the last 24 months resulted

in symptom exacerbation; or family/caregiver does not support the antipsychotic regimen change at this time due to risk of exacerbation; or other significant barrier for antipsychotic therapy discontinuation; **or**

- for discontinuation stage (clinically indicated that the antipsychotic regimen can likely be successfully tapered), cross-titration/taper of antipsychotic therapy.

Antipsychotic for members < ten years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - for requests for aripiprazole or risperidone for members ≥ six years of age and < ten years of age, a diagnosis of autism spectrum disorder (ASD); **or**
  - all of the following:
    - complete medication treatment plan including name, dose, and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses; **and**
    - a comprehensive behavioral health treatment plan (i.e., non-pharmacological interventions) is in place; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatry [including psychiatric nurse practitioners], neurologist, pediatric neurology, developmental and behavioral pediatrics) or consult is provided; **and**
    - one of the following:
      - member is in acute stage of treatment (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects); **or**
      - all of the following:
        - member is in maintenance stage of treatment (response to antipsychotic treatment with goal of remission or recovery); **and**
        - regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place; **and**
        - if member has been on the antipsychotic regimen for the last 12 months, clinical rationale for extended therapy including at least one of the following: previous efforts to reduce/simplify the antipsychotic regimen in the last 12 months resulted in symptom exacerbation; or family/caregiver does not support the antipsychotic regimen change at this time due to risk of exacerbation; or other significant barrier for antipsychotic therapy discontinuation; **or**
      - all of the following:
        - member is in discontinuation stage of treatment (clinically indicated that the antipsychotic regimen can likely be successfully tapered); **and**
        - cross-titration/taper of antipsychotic therapy.

Reference Table:

Drug	Quantity Limits
Abilify (aripiprazole tablet)	2 units/day
Abilify Asimtufii (aripiprazole extended-release injection)	1 injection/56 days
Abilify Maintena (aripiprazole extended-release injection)	1 injection/28 days
Abilify Mycite (aripiprazole tablet with sensor)	1 unit/day
aripiprazole orally disintegrating tablet	1 unit/day

aripiprazole solution	25 mL/day (750 mL/30 days)
Aristada (aripiprazole lauroxil 441 mg, 662 mg, 882 mg)	1 injection/28 days
Aristada (aripiprazole lauroxil 1,064 mg)	1 injection/56 days
Aristada Initio (aripiprazole lauroxil 675 mg)	1 injection/28 days
Caplyta (lumateperone)	1 unit/day
Fanapt (iloperidone)	2 units/day
Geodon (ziprasidone)	2 units/day
Invega (paliperidone tablet) 1.5 mg, 3 mg, 9 mg	1 unit/day
Invega (paliperidone tablet) 6 mg	2 units/day
Invega Hafyera (paliperidone IM)	1 injection/168 days
Invega Sustenna (paliperidone IM)	2 injections within first 28 days, 1 injection/28 days thereafter
Invega Trinza (paliperidone IM)	1 injection/84 days
Latuda (lurasidone) 20 mg, 40 mg, 60 mg, 120 mg	1 unit/day
Latuda (lurasidone) 80 mg	2 units/day
Lybalvi (olanzapine/samidorphan)	1 unit/day
Nuplazid (pimavanserin)	1 unit/day
Perseris (risperidone 90 mg, 120 mg extended-release subcutaneous injection)	1 injection/28 days
Rexulti (brexpiprazole)	1 unit/day
Risperdal (risperidone tablet) 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg	3 units/day
Risperdal (risperidone tablet) 4 mg	4 units/day
Risperdal (risperidone solution)	16 mL/day (480 mL/30 days)
Risperdal Consta (risperidone intramuscular injection)	2 injections/28 days
risperidone orally disintegrating tablet 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg	2 units/day
Rykindo (risperidone intramusuclar injection)	2 injections/28 days
Saphris (asenapine sublingual tablet)	2 units/day
Secuado (asenapine transdermal)	1 unit/day
Seroquel (quetiapine)	3 units/day
Seroquel XR (quetiapine extended-release) 50 mg,150 mg, 200 mg, 300 mg, 400 mg	2 units/day
Uzedy (risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection)	1 injection/28 days
Uzedy (risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection)	1 injection/56 days
Vraylar (cariprazine)	1 unit/day
Zyprexa (olanzapine tablet) 2.5 mg, 5 mg, 7.5 mg, 10 mg	3 units/day
Zyprexa (olanzapine tablet) 15 mg, 20 mg	2 units/day
Zyprexa Relprevv (olanzapine pamoate long-acting injection) 210 mg, 300 mg	2 injections/28 days
Zyprexa Relprevv (olanzapine pamoate long-acting injection) 405 mg	1 injection/28 days

Zyprexa Zydis (olanzapine orally disintegrating tablet) 5 mg, 10 mg, 20 mg	1 unit/day
Zyprexa Zydis (olanzapine orally disintegrating tablet) 15 mg	2 units/day

† **Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.**

Please see the following link to find out more information regarding Second-Generation (Atypical) Antipsychotics: https://www.mass.gov/lists/second-generation-antipsychotics-also-known-as-atypical-antipsychotics.

MassHealth Evaluation Criteria
Table 25 - Corticosteroids - Intranasal

Drug Category: Cough, Cold and Allergy

Medication Class/Individual Agents: Intranasal Steroids

I. Prior-Authorization Requirements

Intranasal Corticosteroids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
azelastine / fluticasone propionate	Dymista		BP, M90
beclomethasone nasal aerosol	Qnasl	PA	
beclomethasone nasal spray	Beconase AQ	PA - > 1 inhaler/30 days	
budesonide OTC nasal spray		PA - > 1 inhaler/30 days	M90
ciclesonide 37 mcg nasal aerosol	Zetonna	PA	
ciclesonide 50 mcg nasal spray	Omnaris	PA - > 1 inhaler/30 days	
flunisolide nasal spray		PA	M90
fluticasone propionate 50 mcg nasal spray		PA - > 1 inhaler/30 days	M90
fluticasone propionate 93 mcg nasal spray	Xhance	PA	
mometasone nasal spray		PA	M90
mometasone sinus implant	Sinuva	PA	
olopatadine / mometasone	Ryaltris	PA	
triamcinolone OTC nasal spray		PA - > 1 inhaler/30 days	M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Intranasal corticosteroids are effective in managing symptoms of itching, nasal congestion, rhinorrhea, and sneezing associated with perennial and seasonal rhinitis.
- Symptoms may begin to improve in two to three days but full benefit may not be achieved for two to three weeks.
- Dosage may be reduced after a response has been achieved.
- At the recommended doses, side effects are usually minimal and include stinging, sneezing, headache, and epistaxis.
- Please see the MassHealth Over-the-Counter Drug List for additional information.

FDA-approved ages:

- ≥ 18 years of age: fluticasone propionate 93 mcg
- ≥ 12 years of age: ciclesonide 37 mcg nasal aerosol
- ≥ six years of age: azelastine/fluticasone propionate, beclomethasone nasal spray, budesonide, ciclesonide 50 mcg nasal spray, flunisolide
- ≥ four years of age: beclomethasone nasal aerosol, fluticasone propionate 50 mcg
- ≥ two years of age: fluticasone furoate, mometasone, triamcinolone

BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Allergic rhinitis
- Nasal polyps
- Nasal polyps and a history of ethmoid sinus surgery
- Non-allergic rhinitis

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

flunisolide nasal spray (one inhaler/30 days), mometasone nasal spray (one inhaler/30 days), and Qnasl (one inhaler/30 days) for members six years of age and older

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as at least 14 days of therapy), adverse reaction, or contraindication to budesonide OTC, fluticasone propionate 50 mcg, and triamcinolone OTC nasal sprays.

SmartPA: Claims for flunisolide nasal spray, mometasone nasal spray, and Qnasl for members ≥ six years will usually process at the pharmacy without a PA request if the claim is for ≤ one inhaler/30 days and the member has a history of paid MassHealth pharmacy claims for budesonide OTC, fluticasone propionate 50 mcg, and triamcinolone OTC nasal sprays.†

flunisolide nasal spray (one inhaler/30 days), mometasone nasal spray (one inhaler/30 days), and Qnasl (one inhaler/30 days), for

members four and five years of age

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as at least 14 days of therapy), adverse reaction, or contraindication to fluticasone propionate 50 mcg and triamcinolone OTC nasal sprays.

Smart PA: Claims for flunisolide nasal spray, mometasone nasal spray, and Qnasl for members ages four or five years of age will usually process at the pharmacy without a PA request if the claim is for ≤ one inhaler/30 days and the member has a history of paid MassHealth pharmacy claims for fluticasone propionate 50 mcg and triamcinolone OTC nasal sprays.†

flunisolide nasal spray (one inhaler/30 days), mometasone nasal spray (one inhaler/30 days), and Qnasl (one inhaler/30 days) for members less than four years of age

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as at least 14 days of therapy), adverse reaction or contraindication to triamcinolone OTC nasal spray.

Smart PA: Claims for flunisolide nasal spray, mometasone nasal spray, and Qnasl for members < four years of age will usually process at the pharmacy without a PA request if the claim is for ≤ one inhaler/30 days and the member has a history of paid MassHealth pharmacy claims for triamcinolone OTC nasal spray.†

flunisolide nasal spray (> one inhaler/30 days), mometasone nasal spray (> one inhaler/30 days), Qnasl (> one inhaler/30 days), Ryaltris (> one inhaler/30 days), Xhance (> one inhaler/30 days), and Zetonna (>one inhaler/30 days)

- Documentation of all of the following is required:
  - member must meet age-specific criteria for the individual agent requested (see approval criteria for individual agent); **and**
  - medical records demonstrating an inadequate response to an adequate trial of the manufacturer's recommended doses; **and**
  - inadequate response (defined as at least 14 days of therapy) or adverse reaction to two or contraindication to all of the following: azelastine, cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine, olopatadine.

Beconase AQ (> one inhaler/30 days), fluticasone propionate 50 mcg (> one inhaler/30 days), and Omnaris (> one inhaler/30 days)

- Documentation of all of the following is required:
  - medical records demonstrating an inadequate response to an adequate trial of the manufacturer's recommended doses; **and**
  - inadequate response (defined as at least 14 days of therapy) or adverse reaction to two or contraindication to all of the following: azelastine, cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine, olopatadine.

Ryaltris (one inhaler/30 days)

- Documentation of all of the following is required:
  - member is ≥ 12 years of age; **and**
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as at least 14 days of therapy) or adverse reaction to one intranasal corticosteroid agent used in combination with one intranasal antihistamine agent; **or**
    - inadequate response (defined by at least 14 days of therapy), adverse reaction, or contraindication to azelastine/fluticasone propionate nasal spray.

Sinuva

- Documentation of all of the following is required:
  - member is ≥ 18 years of age; **and**
  - appropriate diagnosis; **and**
  - prescriber is an otolaryngologist; **and**

- appropriate dosing; **and**
- one of the following:
  - inadequate response or adverse reaction to an oral corticosteroid and an inadequate response (defined as at least 14 days of therapy) or adverse reaction to an intranasal corticosteroid; **or**
  - contraindication to oral corticosteroids and an inadequate response (defined as at least 14 days of therapy) or adverse reaction to two intranasal corticosteroids.

Xhance (one inhaler/30 days)

- Documentation of all of the following is required:
  - member is ≥ 18 years of age; **and**
  - appropriate diagnosis; **and**
  - medical necessity for use of Xhance instead of all other intranasal corticosteroids.

Zetonna (one inhaler/30 days)

- Documentation of all of the following is required:
  - member is ≥ 12 years of age; **and**
  - appropriate diagnosis; **and**
  - inadequate response (defined as at least 14 days of therapy), adverse reaction, or contraindication to budesonide OTC, fluticasone propionate 50 mcg, and triamcinolone OTC nasal sprays.

SmartPA: Claims for Zetonna for members ≥ 12 years will usually process at the pharmacy without a PA request if the claim is for ≤ one inhaler/30 days and the member has a history of paid MassHealth pharmacy claims for budesonide OTC, fluticasone propionate 50 mcg, and triamcinolone OTC nasal sprays.†

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 26 - Antidiabetic Agents

Drug Category: Endocrine/Metabolic

Medication Class/Individual Agents: Antidiabetic Agents

I. Prior-Authorization Requirements

Antidiabetic Agents – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alogliptin / metformin	Kazano	PA	M90
alogliptin / pioglitazone	Oseni	PA	M90
canagliflozin / metformin	Invokamet		
canagliflozin / metformin extended-release	Invokamet XR		
dapagliflozin / metformin extended-release	Xigduo XR		BP, M90
dapagliflozin / saxagliptin	Qtern	PA	
empagliflozin / linagliptin	Glyxambi	PA	
empagliflozin / linagliptin / metformin extended-release	Trijardy XR	PA	
empagliflozin / metformin	Synjardy		
empagliflozin / metformin extended-release	Synjardy XR		
ertugliflozin / metformin	Segluromet	PA	
ertugliflozin / sitagliptin	Steglujan	PA	
glimepiride / pioglitazone	Duetact	PA	BP, M90
glipizide / metformin			M90
glyburide / metformin			M90
linagliptin / metformin	Jentadueto		
linagliptin / metformin extended-release	Jentadueto XR		
pioglitazone / metformin	Actoplus Met		# , M90
repaglinide /		PA	M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Alpha-glucosidase inhibitors:

- If hypoglycemia occurs, treat with oral glucose (dextrose) and not cane sugar (sucrose).
- Contraindications include inflammatory bowel disease, colon ulcerations, and intestinal obstruction.

Biguanides:

- Hold metformin therapy for 48 hours after receiving iodinated contrast and reinstitute only after confirming normal renal function.
- May cause lactic acidosis; contraindicated in members predisposed to acidosis (e.g., major surgery, congestive heart failure, hepatic failure).
- Contraindicated in females and males with renal disease or dysfunction (e.g., serum creatinine greater than or equal to 1.4 mg/dL and 1.5 mg/dL, respectively).

Insulin:

- Rapid-acting: aspart, glulisine, lispro
  - onset: 15-30 minutes
  - duration: three-five hours
- Short-acting: regular
  - onset: 30-60 minutes
  - duration: five-eight hours

Antidiabetic Agents – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
metformin			
saxagliptin / metformin extended-release	Kombiglyze XR		BP, M90
sitagliptin / metformin	Janumet		
sitagliptin / metformin extended-release	Janumet XR		

Antidiabetic Agents – Thiazolidinediones			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
pioglitazone	Actos		# , M90

Antidiabetic Agents – Insulin			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
insulin aspart			
insulin aspart 70/30			
insulin aspart 70/30-Novolog	Novolog	PA	
insulin aspart-Fiasp	Fiasp	PA	
insulin aspart-Novolog	Novolog	PA	
insulin degludec	Tresiba		BP
insulin detemir	Levemir		
insulin glargine-aglr	Rezvoglar	PA	
insulin glargine-Basaglar	Basaglar	PA	
insulin glargine-Basaglar	Basaglar Tempo	PA	
insulin glargine-Lantus	Lantus PD		BP
insulin glargine-Toujeo	Toujeo		BP
insulin glargine-yfgn	Semglee	PA	
insulin glulisine	Apidra		
insulin human inhalation powder	Afrezza	PA	
insulin lispro 100 units/mL cartridge	Humalog		
insulin lispro 100 units/mL			

Clinical Notes

- Intermediate-acting: NPH
  - onset: one-three hours
  - duration: 12-16 hours
- Long-acting: degludec, detemir, glargine
  - onset: one-two hours
  - duration: 20-42 hours

Meglitinides:

- Take before meals; hold dose if meal is missed.
- Use with caution in members with moderate-to-severe hepatic impairment.

Sulfonylureas:

- Use with caution in elderly members and in members with renal or hepatic impairment.

Thiazolidinediones:

- Use with caution in members with edema.
- Contraindicated in members with NYHA class III or IV cardiac status.
- Not recommended for members with abnormal liver function tests.
- May cause resumption of ovulation and increase risk of pregnancy in premenopausal anovulatory women with insulin resistance.

Pregnancy/lactation:

- Insulin is the agent of choice during pregnancy and lactation.

Antidiabetic Agents – Insulin			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
prefilled syringe, vial			
insulin lispro 100 units/mL prefilled syringe, vial-Humalog	Humalog	PA	
insulin lispro 100 units/mL prefilled syringe-Humalog Tempo	Humalog Tempo	PA	
insulin lispro 200 units/mL	Humalog		
insulin lispro 50/50	Humalog		
insulin lispro 75/25 prefilled syringe			
insulin lispro 75/25 prefilled syringe-Humalog	Humalog	PA	
insulin lispro 75/25 vial	Humalog		
insulin lispro-aabc	Lyumjev	PA	
insulin lispro-aabc	Lyumjev Tempo	PA	
insulin lispro-Admelog	Admelog	PA	
insulin NPH	Humulin N	PA	
insulin NPH	Novolin N		
insulin NPH / regular insulin 70/30	Humulin		
insulin NPH / regular insulin 70/30	Novolin		
insulin regular	Humulin R		
insulin regular	Novolin R		

Antidiabetic Agents – Sulfonylureas - Second Generation			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
glimepiride	Amaryl		# , M90
glipizide			M90
glipizide extended -release	Glucotrol XL		# , M90
glyburide			M90
glyburide, micronized	Glynase		# , M90

Antidiabetic Agents – Glucagon Like Peptide (GLP)-1 Agonists and GLP-1 Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dulaglutide	Trulicity PD	PA - > 2 mL/28 days	
exenatide 10 mcg injection	Byetta	PA - > 2.4 mL/30 days	BP
exenatide 5 mcg injection	Byetta	PA - > 1.2 mL/30 days	BP
exenatide extended-release auto-injection	Bydureon Bcise	PA	
insulin degludec / liraglutide	Xultophy	PA	
insulin glargine / lixisenatide	Soliqua	PA	
liraglutide-Victoza	Victoza	PA - >9 mL/30 days	BP
semaglutide injection-Ozempic	Ozempic	PA	
semaglutide tablet	Rybelsus	PA	

Antidiabetic Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bromocriptine 0.8 mg tablet	Cycloset		
colesevelam	Welchol		# , M90
pramlintide	Symlinpen		

Antidiabetic Agents – Sodium Glucose Cotransporter (SGLT)-2 Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
canagliflozin	Invokana		
dapagliflozin	Farxiga		BP, M90
empagliflozin	Jardiance		
ertugliflozin	Steglatro	PA	
sotagliflozin	Inpefa	PA	

Antidiabetic Agents – Biguanides			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
metformin extended-release suspension	Riomet ER	PA	

Antidiabetic Agents – Biguanides			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
metformin extended-release, gastric tablet	Glumetza	PA	M90
metformin extended-release, osmotic tablet		PA	M90
metformin extended-release, XR tablet			M90
metformin immediate-release 500 mg, 850 mg, 1,000 mg tablet			M90
metformin immediate-release 625 mg tablet		PA	M90
metformin immediate-release solution	Riomet	PA - ≥ 13 years	# , M90

Antidiabetic Agents – Dipeptidyl Peptidase (DPP)-4 Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alogliptin	Nesina	PA	M90
linagliptin	Tradjenta		
saxagliptin	Onglyza		# , M90
sitagliptin-Januvia	Januvia		
sitagliptin-Zituvio	Zituvio	PA	M90

Antidiabetic Agents – Glucose-Dependent Insulinotropic Polypeptide (GIP) and Glucagon Like Peptide (GLP)-1 Agonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tirzepatide-Mounjaro	Mounjaro	PA	

Antidiabetic Agents – Alpha-Glucosidase Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acarbose	Precose		# , M90
miglitol		PA	M90

Antidiabetic Agents - Anti-CD3 antibodies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
teplizumab-mzwv	Tzield	PA	

Antidiabetic Agents – Meglitinides			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nateglinide			M90
repaglinide			M90

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Diabetes mellitus (Admelog, Afrezza, Basaglar, Basaglar Tempo, Fiasp, Humalog Tempo, Humulin N, Lyumjev, Lyumjev Tempo)
- Heart failure (Inpefa)
- Type 1 diabetes mellitus, Stage 2 (Tzield)
- Type 2 diabetes mellitus (alogliptin, alogliptin/metformin, alogliptin/pioglitazone, Bydureon Bcise, glimepiride/pioglitazone, Glyxambi, metformin extended-release, gastric tablet (generic Glumetza), metformin extended-release, osmotic tablet (generic Fortamet), metformin immediate-release 625 mg tablet, metformin immediate-release solution, miglitol, Mounjaro, Ozempic, Qtern, repaglinide/metformin, Riomet ER, Rybelsus, Segluromet, sitagliptin (generic Zituvio), Soliqua, Steglatro, Steglujan, Trijardy XR, Xultophy)
- Type 2 diabetes mellitus and chronic kidney disease (Inpefa)

non-FDA approved, for example:

- Gestational diabetes (metformin extended-release, gastric tablet (generic Glumetza), metformin extended-release, osmotic tablet (generic Fortamet), metformin immediate-release solution, Riomet ER)
- Obesity (Bydureon Bcise, liraglutide [generic Victoza], Mounjaro, Ozempic, Rybelsus)
- Oligomenorrhea related to polycystic ovarian syndrome (PCOS) (metformin extended-release, gastric tablet [generic Glumetza], metformin extended-release, osmotic tablet [generic Fortamet], metformin immediate-release solution, Riomet ER)
- Overweight (Bydureon Bcise, liraglutide [generic Victoza], Mounjaro, Ozempic, Rybelsus)
- Prediabetes (Bydureon Bcise, metformin extended-release, gastric tablet [generic Glumetza], metformin extended-release, osmotic tablet [generic Fortamet], metformin immediate-release solution, Ozempic, Riomet ER, Rybelsus)
- Prevention of diabetes related to PCOS (metformin extended-release, gastric tablet [generic Glumetza], metformin extended-release, osmotic tablet [generic Fortamet], metformin immediate-release solution, Riomet ER)

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Admelog

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 180-day time period) or adverse reaction to one of the following: Apidra, insulin aspart, insulin lispro.

Afrezza

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical necessity for the use of an inhaled insulin product instead of an injectable or prefilled insulin syringe.

alogliptin

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with Januvia, saxagliptin, or Tradjenta; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to Januvia, saxagliptin, or Tradjenta; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to Januvia, saxagliptin, or Tradjenta; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to Januvia, saxagliptin, and Tradjenta; **and**

- one of the following:
  - requested quantity is ≤ one tablet/day; **or**
  - clinical rationale for exceeding FDA-approved dosing.

SmartPA: Claims for alogliptin within the quantity limit (described above) will usually process at the pharmacy without a PA request if the member has a history of type 2 diabetes mellitus and paid MassHealth pharmacy claims for metformin and Januvia, saxagliptin, or Tradjenta for at least 90 days within the last 120-day time period.†

alogliptin/metformin, alogliptin/pioglitazone, glimepiride/pioglitazone, Glyxambi, Qtern, repaglinide/metformin, Segluromet, Steglujan, and Trijardy XR

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to combination therapy with metformin used in combination with at least one of the non-metformin agents in the requested combination; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to at least one of the non-metformin agents in the requested combination; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to at least one of the non-metformin agents in the requested combination; **and**
  - for Trijardy XR, medical necessity for use of the combination product instead of the commercially available separate agents.

Basaglar and Basaglar Tempo

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 180-day time period) or adverse reaction to insulin glargine prefilled syringe or vial (branded or unbranded Lantus solostar or Lantus vial); **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 180-day time period) or adverse reaction to one of the following: insulin glargine-yfgn prefilled syringe or vial, Rezvoglar prefilled syringe; **and**
  - for Basaglar Tempo, medical necessity for use of Tempo pen formulation instead of Kwikpen formulation.

Bydureon Bcise, Ozempic, Rybelsus

- Documentation of the following is required for the diagnosis of prediabetes or type 2 diabetes:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to Byetta, liraglutide (generic Victoza), or Trulicity; **and**
  - if requested quantity exceeds quantity limits, clinical rationale for exceeding FDA-approved dosing.

- Documentation of the following is required for diagnosis of obesity or overweight:
  - appropriate diagnosis; **and**
  - one of the following:
    - for Ozempic and Rybelsus, member is ≥18 years of age; **or**
    - for Bydureon Bcise, member is ≥ 12 years of age; **and**

- member weight (dated within the last 90 days); **and**
- member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
- if requested quantity exceeds quantity limits, clinical rationale for exceeding FDA-approved dosing; **and**
- the requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
- one of the following:
  - member BMI is ≥30 kg/m2 (dated within the last 90 days); **or**
  - for Bydureon Bcise, both of the following:
    - member is ≥12 years of age and <17 years of age; **and**
    - BMI is in the 95th percentile or greater (dated within the last 90 days); **or**
  - both of the following:
    - member BMI is ≥27 kg/m2 (dated within the last 90 days); **and**
    - one of the following weight-related comorbid conditions:
      - coronary heart disease or other atherosclerotic disease; **or**
      - dyslipidemia; **or**
      - hypertension; **or**
      - non-alcoholic steatohepatitis (NASH); **or**
      - obstructive sleep apnea; **or**
      - systemic osteoarthritis; **or**
      - type 2 diabetes mellitus.
- For recertification for the diagnosis of obesity or overweight, documentation of the following is required:
  - member weight (dated within the last 90 days); **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - clinical rationale for continuation of therapy.
- Please note for the quantity limits listed above:
  - a 28 day-supply should consist of:
    - one carton of four 2 mg autoinjectors (Bydureon Bcise)
    - one prefilled pen (Ozempic)
    - one tablet per day (Rybelsus)

SmartPA: Claims for Bydureon Bcise, Ozempic, and Rybelsus within the quantity limit (as described above) will usually process at the pharmacy without a PA request if the member has a history of type 2 diabetes mellitus and paid MassHealth pharmacy claims for metformin and Byetta, liraglutide (generic Victoza), or Trulicity for at least 90 days within the last 120-day time period.†

Byetta and Trulicity exceeding quantity limits

- Documentation of the following is required:
  - appropriate diagnosis: **and**
  - clinical rationale for exceeding FDA-approved dosing.

Fiasp, Lyumjev, and Lyumjev Tempo

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - for Fiasp, member is ≥ two years of age; **or**
    - for Lyumjev, member is ≥ 18 years of age; **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 180-day time period) or adverse reaction to one of the following: Apidra, insulin aspart, insulin lispro; **and**

- for Lyumjev Tempo, medical necessity for use of Tempo pen formulation instead of Kwikpen formulation.

Humalog 100 units/mL prefilled syringe, Humalog 100 units/mL vial, Humalog 75/25 prefilled syringe, Novolog, and Novolog 70/30
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic formulation.

Humalog Tempo
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for use of Tempo pen formulation instead of Kwikpen formulation.

Humulin N
- Documentation of the following is required:
  - appropriate diagnosis: **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 180-day time period) or adverse reaction to Novolin N prefilled syringe or vial.

Inpefa
- Documentation of the following is required for heart failure:
  - indication of reduction of risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to both dapagliflozin and Jardiance; **and**
  - requested quantity is ≤ one tablet/day.
- Documentation of the following is required for type 2 diabetes and chronic kidney disease:
  - indication of reduction of risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in type 2 diabetes mellitus and chronic kidney disease with other cardiovascular risk factors; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: dapagliflozin, Invokana, Jardiance; **and**
  - requested quantity is ≤ one tablet/day.

liraglutide (generic Victoza) exceeding quantity limits
- Documentation of the following is required for the diagnosis of type 2 diabetes or prediabetes:
  - appropriate diagnosis; **and**
  - clinical rationale for exceeding FDA-approved dosing.
- Documentation of the following is required for the diagnosis of obesity or overweight:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member is ≥ 12 years of age; **and**
  - member weight (dated within the last 90 days); **and**
  - member will be counseled to continue reduced-calorie diet and increased physical activity; **and**
  - requested quantity is ≤ five pens/30 days; **and**
  - the requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
  - one of the following:
    - member BMI is ≥30 kg/m2 (dated within the 90 days prior to treatment initiation); **or**
    - both of the following:
      - member is ≥12 years of age and <18 years of age; **and**
      - member BMI is in the 95th percentile or greater (dated within the 90 days prior to treatment initiation); **or**

    - both of the following:
      - member BMI is ≥27 kg/m2 (dated within the 90 days prior to treatment initiation); **and**
      - one of the following weight-related comorbid conditions:
        - coronary heart disease or other atherosclerotic disease; **or**
        - dyslipidemia; **or**
        - hypertension; **or**
        - non-alcoholic steatohepatitis (NASH); **or**
        - obstructive sleep apnea; **or**
        - systemic osteoarthritis; **or**
        - type 2 diabetes mellitus.
- For recertification for the diagnosis of obesity or overweight, documentation of the following is required:
  - member weight (dated within the last 90 days); **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - clinical rationale for continuation of therapy.

metformin extended-release, gastric tablet (generic Glumetza) and metformin extended-release, osmotic tablet (generic Fortamet)

- Documentation of the following is required for type 2 diabetes, or prevention of diabetes related to PCOS:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) or adverse reaction, at the requested dose, to the metformin extended-release, XR tablet formulation available without PA; **and**
  - for metformin extended-release, gastric tablet, medical necessity for the use of requested product instead of metformin formulations available without PA.
- Documentation of the following is required for gestational diabetes:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) or adverse reaction, at the requested dose, to the metformin extended-release, XR tablet formulation available without PA; **and**
  - for metformin extended-release, gastric tablet, medical necessity for the use of requested product instead of metformin formulations available without PA; **and**
  - inadequate response, adverse reaction, or contraindication to insulin therapy.
- Documentation of the following is required for oligomenorrhea related to PCOS:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) or adverse reaction, at the requested dose, to the metformin extended-release, XR tablet formulation available without PA; **and**
  - for metformin extended-release, gastric tablet, medical necessity for the use of requested product instead of metformin formulations available without PA; **and**
  - inadequate response, adverse reaction, or contraindication to combined oral contraceptives.

metformin immediate-release 625 mg tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the requested formulation instead of metformin tablets available without prior authorization.

metformin immediate-release solution ≥ 13 years of age and Riomet ER

- Documentation of the following is required for type 2 diabetes, prediabetes, or prevention of diabetes related to PCOS:
  - appropriate diagnosis; **and**

- one of the following:
  - medical necessity for the use of a liquid formulation; **or**
  - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin tablet formulation, or allergic reaction or adverse reaction to the metformin tablet formulation that is not class specific (i.e., nausea, diarrhea); **and**
- for Riomet ER, medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin immediate-release solution formulation.

- Documentation of the following is required for gestational diabetes:
  - appropriate diagnosis; **and**
  - one of the following:
    - medical necessity for the use of a liquid formulation; **or**
    - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin tablet formulation, or allergic reaction or adverse reaction to the metformin tablet formulation that is not class specific (i.e., nausea, diarrhea); **and**
  - for Riomet ER, medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin immediate-release solution formulation; **and**
  - inadequate response, adverse reaction, or contraindication to insulin therapy.
- Documentation of the following is required for oligomenorrhea related to PCOS:
  - appropriate diagnosis; **and**
  - one of the following:
    - medical necessity for the use of a liquid formulation; **or**
    - medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin tablet formulation, or allergic reaction or adverse reaction to the metformin tablet formulation that is not class specific (i.e., nausea, diarrhea); **and**
  - for Riomet ER, medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin immediate-release solution formulation; **and**
  - inadequate response, adverse reaction, or contraindication to combined oral contraceptives.

miglitol

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with acarbose; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to acarbose; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to acarbose; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to acarbose; **and**
  - one of the following:
    - requested quantity is ≤ three tablets/day; **or**
    - clinical rationale for exceeding FDA-approved dosing.

SmartPA: Claims for miglitol within the quantity limit (as described above) will usually process at the pharmacy without a PA request if the member has a history of type 2 diabetes mellitus and paid MassHealth pharmacy claims for metformin and acarbose for at least 90 days within the last 120-day time period.†

Mounjaro

- Documentation of the following is required for the diagnosis of type 2 diabetes:
  - appropriate diagnosis; **and**
  - one of the following:

- inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with Byetta, liraglutide (generic Victoza), or Trulicity; **or**
- adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
- inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
- inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to Byetta, liraglutide (generic Victoza), or Trulicity; **and**

- the requested agent will not be used in combination with a GLP-1 receptor agonist; **and**
- if requested quantity exceeds quantity limits, clinical rationale for exceeding FDA-approved dosing.

- Documentation of the following is required for diagnosis of obesity or overweight:
  - appropriate diagnosis; **and**
  - member is ≥18 years of age; **and**
  - member weight (dated within the last 90 days); **and**
  - member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
  - the requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
  - one of the following:
    - both of the following:
      - one of the following weight-related comorbid conditions:
        - coronary heart disease or other atherosclerotic disease; **or**
        - dyslipidemia; **or**
        - hypertension; **or**
        - non-alcoholic steatohepatitis (NASH); **or**
        - obstructive sleep apnea; **or**
        - systemic osteoarthritis; **or**
        - type 2 diabetes mellitus; **and**
      - member BMI is ≥27 kg/m2 (dated within the last 90 days); **or**
    - member BMI is ≥30 kg/m2 (dated within the last 90 days); **and**
  - if requested quantity exceeds quantity limits, clinical rationale for exceeding FDA-approved dosing; **and**
  - one of the following:
    - if the member has received semaglutide, one of the following:
      - inadequate response to Wegovy as defined by all of the following:
        - member is adherent to Wegovy treatment (defined as ≥ 90 days of therapy within a 120-day time period)*; **and**
        - no weight loss over at least three months at the highest FDA-approved dose of Wegovy for obesity; **and**
        - member's current BMI is ≥ 27 kg/m2 (dated within the 90 days prior to initiation of Mounjaro); **or**
      - adverse reaction to semaglutide that cannot be managed or expected as part of GLP-1 receptor agonist therapy; **or**
    - if the member has not received semaglutide, both of the following:
      - one of the following;
        - inadequate response to liraglutide as defined by all of the following:
          - member is adherent to liraglutide treatment (defined as ≥ 90 days of therapy within a 120-day time period)*; **and**
          - no weight loss over at least three months at the highest FDA-approved dose of liraglutide for obesity; **and**
          - member's current BMI is ≥ 27 kg/m2 (dated within the 90 days prior to treatment initiation of Mounjaro); **or**
        - adverse reaction to liraglutide that cannot be managed or expected as part of GLP-1 receptor agonist therapy; **or**
        - contraindication to liraglutide; **and**
      - one of the following:
        - inadequate response to Wegovy as defined by all of the following:
          - member is adherent to Wegovy treatment (defined as ≥ 90 days of therapy within a 120-day time period)*; **and**
          - no weight loss over at least three months at the highest FDA-approved dose of Wegovy for obesity; **and**

        - member's current BMI is ≥ 27 kg/m2 (dated within the 90 days prior to treatment initiation of Mounjaro); **or**
      - adverse reaction to semaglutide that cannot be managed or expected as part of GLP-1 receptor agonist therapy; **or**
      - contraindication to semaglutide.
- For recertification for the diagnosis of obesity or overweight, documentation of the following is required:
  - member weight (dated within the last 90 days); **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - clinical rationale for continuation of therapy.
- Please note for the quantity limits listed above:
  - a 30 day supply should consist of one carton of four prefilled pens.

*Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to these agents.

Rezvoglar and Semglee

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 90 days of therapy within a 180-day time period) or adverse reaction with insulin glargine prefilled syringe or vial (branded or unbranded Lantus solostar or Lantus vial).

sitagliptin (generic Zituvio)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for the requested agent instead of Januvia; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to combination therapy of metformin used with each of the following: alogliptin, saxagliptin, Tradjenta; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to all of the following: alogliptin, saxagliptin, Tradjenta; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin and adverse reaction or contraindication to all of the following: alogliptin, saxagliptin, Tradjenta; **and**
  - if requested quantity exceeds quantity limits, clinical rationale for exceeding FDA-approved dosing.

Soliqua and Xultophy

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to Byetta, liraglutide (generic Victoza), or Trulicity; **and**
  - if requested quantity exceeds quantity limits, clinical rationale for exceeding FDA-approved dosing.
  - please note for the quanty limits listed above:
    - a 30 day supply should consist of:

- six prefilled pens (Soliqua)
- one carton of five prefilled pens (Xultophy)

SmartPA: Claims for Soliqua and Xultophy within the quantity limit (as described above) will usually process at the pharmacy without a PA request if the member has a history of type 2 diabetes mellitus and paid MassHealth pharmacy claims for metformin and Byetta, liraglutide (generic Victoza), or Trulicity for at least 90 days within the last 120-day time period.†

Steglatro

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with dapagliflozin, Invokana, or Jardiance; **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to dapagliflozin, Invokana, or Jardiance; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to dapagliflozin, Invokana, or Jardiance; **or**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to dapagliflozin, Invokana, and Jardiance; **and**
  - one of the following:
    - requested quantity is ≤ one tablet/day; **or**
    - clinical rationale for exceeding FDA-approved dosing.

SmartPA: Claims for Steglatro within the quantity limit (described above) will usually process at the pharmacy without a PA request if the member has a history of type 2 diabetes mellitus and paid MassHealth pharmacy claims for metformin and dapagliflozin, Invokana, or Jardiance for at least 90 days within the last 120-day time period.†

Tzield

- Documentation of the following is required for stage 2 type 1 diabetes mellitus:
  - appropriate diagnosis; **and**
  - member is ≥ eight years of age; **and**
  - appropriate dosing; **and**
  - prescriber is an endocrinologist or consult notes from specialist are provided; **and**
  - lab results documenting ≥ two islet autoantibodies; **and**
  - one of the following within the last three months:
    - fasting plasma glucose (FPG): 100 to 125 mg/dL; **or**
    - 2-hour plasma glucose (2-h PG): 140 to 199 mg/dL; **or**
    - A1C: 5.7% to 6.4%; **or**
    - 10% increase in A1C in ≤12 months; **and**
  - member has not been previously treated with Tzield.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 27 - Antiemetics, Appetite Stimulants, and Anabolics

Drug Category: Gastrointestinal

Medication Class/Individual Agents: Antiemetics/5-HT3 Receptor Antagonists, Appetite Stimulants, and Anabolics

I. Prior-Authorization Requirements

Antiemetics, Appetite Stimulants, and Anabolics – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aprepitant 125 mg powder for oral suspension	Emend	PA - > 6 units/28 days	A90
aprepitant 40 mg, 125 mg capsule		PA - > 2 units/28 days	A90
aprepitant 80 mg	Emend	PA - > 4 units/28 days	# , A90
aprepitant injectable emulsion	Cinvanti	PA	
aprepitant trifold pack	Emend	PA - > 2 packs/28 days	BP, A90
doxylamine / pyridoxine delayed-release	Diclegis	PA	BP, A90
doxylamine / pyridoxine extended-release	Bonjesta	PA	
dronabinol 2.5 mg	Marinol	PA - > 2 units/day	BP
dronabinol 5 mg, 10 mg	Marinol	PA - > 2 units/day	
fosaprepitant injection	Emend	PA - > 2 units/28 days	#
fosnetupitant / palonosetron injection	Akynzeo	PA - > 2 units/28 days	
megestrol 40 mg/mL suspension			A90
megestrol 625 mg/5 mL suspension		PA	A90
netupitant / palonosetron capsule	Akynzeo	PA - > 2 units/28 days	
oxandrolone		PA	
scopolamine transdermal patch	Transderm-Scop		BP, A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Granisetron oral formulations are FDA approved for the prevention/treatment of chemotherapy-induced and radiation-induced nausea and vomiting.
- Ondansetron is FDA approved for the prevention/treatment of postoperative, chemotherapy-induced, and radiation-induced nausea and vomiting.
- Netupitant/palonosetron is FDA approved for prevention of acute and delayed chemotherapy-induced nausea and vomiting (CINV).
- Rolapitant is FDA approved in combination with other antiemetic agents for prevention of delayed CINV.
- Dronabinol is an orally active cannabinoid that is FDA approved for the treatment of cancer chemotherapy induced nausea and vomiting in members with an inadequate response to conventional antiemetic treatments.
- Dronabinol is also FDA approved for the management of anorexia associated with weight loss in members with acquired immune deficiency syndrome (AIDS).
- Orally active cannabinoids are recommended by the National Comprehensive Cancer Network (NCCN) as an option for the treatment of breakthrough nausea and vomiting as an addition to the appropriate prophylactic regimen of conventional antiemetics that is based upon

Antiemetics, Appetite Stimulants, and Anabolics – 5-HT3 Receptor Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dolasetron	Anzemet	PA	
granisetron extended-release injection	Sustol	PA - > 2 units/28 days	
granisetron injection			
granisetron tablet		PA - > 2 units/28 days	A90
granisetron transdermal system	Sancuso	PA	
ondansetron injection			
ondansetron orally disintegrating tablet			A90
ondansetron solution		PA	A90
ondansetron tablet	Zofran		# , A90
palonosetron 0.25 mg/2 mL injection		PA - > 2 units/28 days	A90
palonosetron 0.25 mg/5 mL injection		PA - > 2 units/28 days	

Clinical Notes

emetogenicity of the chemotherapy regimen. The NCCN recommends that consideration can be given to the use of a cannabinoid in palliative care members; however, the NCCN recognizes that the use of cannabinoids in members with cancer-related anorexia has limited data to support this use.

- Oxandrolone is FDA approved for adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some members who, without definite pathophysiologic reasons, fail to gain or to maintain normal weight; to offset protein catabolism with prolonged corticosteroid administration; relief of bone pain associated with osteoporosis.
- For the treatment of nausea and vomiting of pregnancy, initial pharmacotherapy includes pyridoxine. The combination of doxylamine and pyridoxine could be used when pyridoxine monotherapy fails to improve symptoms.

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- AIDS-associated anorexia, cachexia, or weight loss
- Chemotherapy-induced nausea and vomiting (CINV)
- Nausea and vomiting of pregnancy (NVP)
- Osteoporosis-related bone pain
- Postoperative nausea and vomiting (PONV)
- Prevent weight loss/promote weight gain
- Radiation-induced nausea and vomiting (RINV)

Non-FDA-approved, for example:

- Anorexia of non-AIDS-related etiology or require appetite stimulation
- Appetite stimulation or relief from nausea/vomiting associated with a comorbid cancer diagnosis

- Nausea/vomiting of any etiology (not associated with chemotherapy or cyclic vomitting)
- PONV
- RINV
- Severe thermal burns

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Akynzeo, fosaprepitant injection, palonosetron, and Sustol injection > 2 units/28 days

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limit.

Anzemet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to to both of the following: granisetron tablet, ondansetron tablet or ODT.

aprepitant 40 mg capsule, 125 mg capsule, and trifold pack > 2 units/28 days

- Documentation of the following is required for the diagnosis of CINV:
  - appropriate diagnosis.
- Documentation of the following is required for the diagnosis of PONV:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limit.

aprepitant 80 mg capsule > 4 units/28 days

- Documentation of the following is required for the diagnosis of CINV:

- appropriate diagnosis.
- Documentation of the following is required for the diagnosis of PONV:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limit.

SmartPA: Claims for aprepitant (40 mg, 80 mg, 125 mg, trifold pack) above the established quantity limits will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims history of an antineoplastic medication in the last 60 days **or** has MassHealth medical claims for a CPT code for chemotherapy administration in the last 60 days.†

Bonjesta and doxylamine/pyridoxine delayed-release
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to combination therapy with doxylamine and pyridoxine; **and**
  - for Bonjesta, inadequate response or adverse reaction to doxylamine/pyridoxine delayed-release.

Cinvanti
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to oral aprepitant or fosaprepitant injection.

dronabinol capsule > 2 units/day
- Documentation of all of the following is required:
  - medical necessity for exceeding the quantity limit.

Emend 125 mg powder for oral suspension > 6 units/28 days
- Documentation of the following is required for the diagnosis of CINV:
  - appropriate diagnosis.
- Documentation of the following is required for the diagnosis of PONV:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limit.

SmartPA: Claims for Emend 125 mg powder for oral suspension above the established quantity limits will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims history of an antineoplastic medication in the last 60 days **or** has MassHealth medical claims for a CPT code for chemotherapy administration in the last 60 days.†

granisetron tablet > 2 units/day
- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - CINV; **or**
    - PONV; **or**
    - RINV; **and**
  - medical necessity for exceeding the quantity limit.

megestrol 625 mg/5 mL suspension
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to one or contraindication to both of the following: megestrol 40 mg/mL suspension, megestrol tablet.
- For recertification, documentation of the following is required:
  - positive response to therapy including weight gain or no net weight loss from baseline; **or**

- clinical rationale for continued therapy despite weight loss.

ondansetron solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the use of the solution formulation as noted by one of the following:
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **or**
    - clinical rationale why conventional formulations cannot be used; **or**
    - provider notes the appropriate dose cannot be achieved without splitting a tablet.

oxandrolone

- Documentation of all of the following is required for a diagnosis of promoting weight gain/preventing weight loss in adult members:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - significant weight loss as defined by one of the following:
    - body mass index (BMI) ≤ 20 kg/m^2; **or**
    - involuntary loss of ≥ 10% of premorbid body weight; **or**
    - involuntary loss of ≥ 5% of body weight within six months; **and**
  - inadequate response (defined by at least four weeks of therapy), adverse reaction, or contraindication to megestrol.
- Documentation of all of the following is required for a diagnosis of promoting weight gain/preventing weight loss in pediatric members:
  - appropriate diagnosis; **and**
  - member is < 18 years of age.
- Documentation of all of the following is required for a diagnosis of osteoporosis-related bone pain:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to two or contraindication to all of the following: acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), calcitonin.
- Documentation of the following is required for a diagnosis of severe thermal burns:
  - appropriate diagnosis.

Sancuso

- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - CINV; **or**
    - PONV; **or**
    - RINV; **and**
  - inadequate response, adverse reaction, or contraindication to ondansetron ODT.

IV. Pediatric Members

- ondansetron (Zofran) is FDA-approved for chemotherapy-associated nausea and vomiting in children ≥ four years of of age; however weight based dosing (I.V. product) is available for pediatric members ≥ six months of age.
- promethazine and prochlorperazine are FDA-approved for use in pediatric members ≥ two years of age.

Conventional Antiemetics (not all inclusive)

Antihistamines	Prokinetic	Phenothiazines	Anticholinergics
dimenhydrinate diphenhydramine hydroxyzine meclizine	metoclopramide	prochlorperazine promethazine	scopolamine trimethobenzamide

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 28 - Antifungal Agents - Topical

Drug Category: Dermatological

Medication Class/Individual Agents: Antifungal

I. Prior-Authorization Requirements

Antifungal Agents: Topical – Imidazoles			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
clotrimazole			*, A90
clotrimazole / betamethasone cream			A90
clotrimazole / betamethasone lotion		PA	A90
econazole 1% cream			A90
efinaconazole	Jublia	PA	
ketoconazole cream, shampoo			A90
ketoconazole foam	Extina	PA	A90
luliconazole	Luzu	PA	A90
miconazole			*, A90
miconazole / zinc oxide ointment	Vusion		BP, A90
oxiconazole cream	Oxistat	PA	A90
oxiconazole lotion	Oxistat	PA	
sertaconazole	Ertaczo		

Antifungal Agents: Topical – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ciclopirox 0.77% cream	Loprox		# , A90
ciclopirox 0.77% suspension	Loprox	PA	A90
ciclopirox 1% shampoo, 0.77% gel		PA	A90
ciclopirox 8% nail lacquer			A90
tavaborole	Kerydin	PA	A90
tolnaftate cream, powder			*, A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Dermatophyte infections routinely affect otherwise healthy individuals.
- Immunocompromised members are particularly susceptible to fungal infections.
- Topical antifungals are considered first-line therapy for most dermatophyte infections.
- Products are usually applied once or twice daily for two to four weeks (depending on the location).
- Combination products may prolong treatment and delay disease resolution.
- Onychomycosis requires 48 weeks of topical ciclopirox treatment.
- Ciclopirox nail lacquer demonstrates a minimally better cure rate versus placebo.

Antifungal Agents: Topical – Benzylamine			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
butenafine	Mentax		

Antifungal Agents: Topical – Allymines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
naftifine	Naftin	PA	A90

Antifungal Agents: Topical – Polyenes			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nystatin / triamcinolone cream, ointment			A90
nystatin cream, ointment, 100,000 powder			A90

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Onychomycosis – Jublia and tavaborole
- Seborrheic dermatitis – ciclopirox and ketoconazole
- Superficial tinea or candida (fungal) infections
- Vulvovaginal candidiasis – vaginal formulations only

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.

- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

ciclopirox gel

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (within the last 90 days) or adverse reaction to two different topical antifungals or contraindication to all topical antifungals available without PA; **and**
  - inadequate response (within the last 90 days), adverse reaction, or contraindication to ciclopirox cream.

SmartPA: Claims for ciclopirox gel will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two different topical antifungals available without PA and ciclopirox cream within the last 90 days.†

ciclopirox shampoo, ketoconazole foam, luliconazole, naftifine, oxiconazole

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (within the last 90 days) or adverse reaction to two different topical antifungals or contraindication to all topical antifungals available without PA.

SmartPA: Claims for ciclopirox shampoo, ketoconazole foam, luliconazole, naftifine, and oxiconazole will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two different topical antifungals available without PA within the last 90 days.†

ciclopirox suspension

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (within the last 90 days), adverse reaction, or contraindication to ciclopirox cream.

SmartPA: Claims for ciclopirox suspension will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for ciclopirox cream within the last 90 days.†

clotrimazole/betamethasone lotion

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (within the last 90 days), adverse reaction or contraindication to clotrimazole/betamethasone cream.

SmartPA: Claims for clotrimazole/betamethasone lotion will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for clotrimazole/betamethasone cream within the last 90 days.†

Jublia, tavaborole

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- one of the following:
  - inadequate response or adverse reaction to itraconazole or terbinafine oral tablets; **or**
  - medical necessity for topical formulation **and** inadequate response to 24 consecutive weeks of therapy or adverse reaction to ciclopirox nail solution; **or**
  - contraindication to all of the following: ciclopirox nail solution, itraconazole oral therapy and terbinafine oral tablets; **and**
- for tavaborole, medical records documenting inadequate response to 48 weeks of therapy, adverse reaction, or contraindication to Jublia.

tolnaftate liquid

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (within the last 90 days) or adverse reaction to two different topical antifungals or contraindication to all topical antifungals available without PA; **and**
  - inadequate response (within the last 90 days), adverse reaction, or contraindication to tolnaftate powder.

SmartPA: Claims for tolnaftate liquid will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two different topical antifungals available without PA and tolnaftate powder within the last 90 days.†

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria

Table 29 - Anti-Allergy and Anti-Inflammatory Agents - Ophthalmic

Drug Category: Anti-Allergy and Anti-Inflammatory Agents - Ophthalmic

Medication Class/Individual Agents: Anti-Allergy and Anti-Inflammatory Agents - Ophthalmic

I. Prior-Authorization Requirements

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – NSAIDs			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bromfenac 0.07%	Prolensa		BP, A90
bromfenac 0.075%	Bromsite	PA	A90
bromfenac 0.09%		PA	A90
diclofenac ophthalmic solution			A90
flurbiprofen ophthalmic solution			A90
ketorolac 0.4% ophthalmic solution	Acular LS		# , A90
ketorolac 0.45% ophthalmic solution	Acuvail		
ketorolac 0.5% ophthalmic solution	Acular		# , A90
nepafenac 0.1% ophthalmic suspension	Nevanac		
nepafenac 0.3% ophthalmic suspension	Ilevro	PA	

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – Mast Cell Stabilizers			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cromolyn ophthalmic			A90
lodoxamide	Alomide		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Nonpharmacologic treatments, such as allergen avoidance, cold compress, and lubrication to remove the allergen, may provide relief.
- Products containing vasoconstrictors may cause rebound redness if used more frequently than the recommended treatment duration.
- The dropper tip should not touch the eye in order to prevent contaminating the bottle.
- Remove contact lenses before instilling eye drops as some preservatives in ocular products may be absorbed by soft contact lenses.
- *FDA-approved ages:*
  - ≥ 18 years of age: bromfenac, cyclosporine 0.09%, dexamethasone, diclofenac, difluprednate, flurbiprofen, hydroxypropyl cellulose ophthalmic insert, loteprednol, prednisolone
  - ≥ 17 years of age: lifitegrast
  - ≥ 16 years of age: cyclosporine 0.05%
  - ≥ ten years of age: nepafenac
  - ≥ three years of age: azelastine, ketotifen, ketorolac tromethamine 0.4%, nedocromil
  - ≥ two years of age: alcaftadine, bepotastine, cetirizine, epinastine, fluorometholone, ketorolac tromethamine 0.5%, lodoxamide, olopatadine

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – Corticosteroids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dexamethasone intravitreal implant	Ozurdex		MB
dexamethasone ophthalmic insert	Dextenza		MB
dexamethasone ophthalmic suspension	Maxidex		
dexamethasone sodium phosphate ophthalmic solution			A90
difluprednate	Durezol		# , A90
fluorometholone	FML		# , A90
fluorometholone acetate	Flarex		
loteprednol 0.2%	Alrex		# , A90
loteprednol 0.25% suspension	Eysuvis	PA	
loteprednol 0.38% gel	Lotemax SM	PA	
loteprednol 0.5%	Lotemax		BP, A90
loteprednol 1% suspension	Inveltys	PA	
prednisolone acetate 0.12% ophthalmic suspension	Pred Mild		
prednisolone acetate 1% ophthalmic suspension	Pred Forte		BP, A90
prednisolone sodium phosphate ophthalmic solution			A90

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – Antihistamines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alcaftadine	Lastacaft		
bepotastine	Bepreve		BP, A90
cetirizine ophthalmic solution	Zerviate	PA	
ketotifen			*, A90

Clinical Notes

Pregnancy:

alcaftadine, cetirizine, lodoxamide, and nedocromil are pregnancy category B; the rest of the ophthalmic anti-allergy agents are pregnancy category C.

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
artificial tears			*, A90
cyclosporine 0.05% ophthalmic emulsion	Restasis		BP, A90
cyclosporine 0.09% ophthalmic solution	Cequa	PA	
cyclosporine 0.1% ophthalmic emulsion	Verkazia	PA	
cyclosporine 0.1% ophthalmic solution	Vevye	PA	
cyclosporine multidose 0.05% ophthalmic emulsion	Restasis Multidose	PA	
hydroxypropyl cellulose ophthalmic insert	Lacrisert		
lifitegrast	Xiidra	PA	
lotilaner	Xdemvy	PA	
naphazoline			*
naphazoline / pheniramine	Naphcon-A		A90
naphazoline / pheniramine	Opcon-A		A90
perfluorohexyloctane	Miebo	PA	
varenicline nasal spray	Tyrvaya	PA	

Ophthalmic Anti-Allergy and Anti-Inflammatory Agents – Mast Cell Stabilizer /Antihistamine			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
azelastine ophthalmic solution			A90
epinastine			A90
olopatadine ophthalmic solution			A90

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

* The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Perennial (chronic) or seasonal (short term) allergic conjunctivitis (Zerviate)
- Postoperative pain and inflammation following ocular surgery (bromfenac 0.09%, Bromsite, Ilevro, Inveltys, Lotemax SM)
- Keratoconjunctivitis sicca (KCS)/dry eyes (Cequa, Eysuvis, Miebo, Restasis Multidose, Tyrvaya, Vevye, Xdemvy, Xiidra)
- Vernal keratoconjunctivitis (Verkazia)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

bromfenac 0.09% and Bromsite

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- inadequate response or adverse reaction to bromfenac 0.07% opthalmic solution.

Cequa
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to cyclosporine 0.05% ophthalmic emulsion; **and**
  - requested quantity is ≤ two units/day.

SmartPA: Claims for Cequa will usually process at the pharmacy without a PA request for a quantity of ≤ two units/day if the member is ≥ 18 years of age and there is a history of paid MassHealth pharmacy claims for at least 90 out of the last 120 days for Cequa **or** if there is a history of paid claims for cyclosporine 0.05% ophthalmic solution in the last 90 days.†

Eysuvis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all topical corticosteroids for ophthalmic use available without PA; **and**
  - inadequate response, adverse reaction, or contraindication to cyclosporine 0.05% ophthalmic emulsion; **and**
  - requested duration is ≤ two weeks.

Ilevro
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ ten years of age; **and**
  - inadequate response or adverse reaction to nepafenac 0.1% ophthalmic suspension.

Inveltys and Lotemax SM (for postoperative pain and inflammation)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to loteprednol 0.5% ophthalmic gel, ointment, or suspension.

-
  -

Miebo and Tyrvaya
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: cyclosporine 0.05% ophthalmic emulsion and Xiidra; **and**
  - one of the following:
    - for Miebo, requested quantity is ≤ three mL/30 days; **or**
    - for Tyrvaya, requested quantity is ≤ 8.4 mL/30 days.

Restasis Multidose

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 16 years of age; **and**
  - medical necessity for use of multidose formulation instead of cyclosporine 0.05% ophthalmic emulsion (single use vial formulation); **and**
  - requested quantity is ≤ one unit/28 days.

Verkazia
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ four years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: azelastine ophthalmic solution, epinastine, ketotifen, olopatadine ophthalmic solution; **and**
  - inadequate response or adverse reaction to one or contraindication to all topical corticosteroids for ophthalmic use; **and**
  - requested quantity is ≤ four units/day.

Vevye
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: cyclosporine 0.05% ophthalmic emulsion, cyclosporine 0.09% ophthalmic emulsion, Xiidra, and Tyraya; **and**
  - requested quantity is ≤ two mL/50 days.

Xdemvy
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is an ophthalmologist or optometrist or consult notes from an ophthalmologist or optometrist are provided; **and**
  - requested quantity is ≤ ten mL for one course of therapy.

Xiidra
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 17 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to cyclosporine 0.05% ophthalmic emulsion; **and**
  - requested quantity is ≤ two units/day.

SmartPA: Claims for Xiidra will usually process at the pharmacy without a PA request for a quantity of ≤ two units/day if the member is ≥ 17 years of age and there is a history of paid MassHealth pharmacy claims for at least 90 out of the last 120 days for Xiidra **or** if there is a history of paid MassHealth pharmacy claims for cyclosporine 0.05% ophthalmic solution in the last 90 days.†

Zerviate for members ≥ three years of age
- Documentation of the following is required:
  - an appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to two or contraindication to all of the following: Alomide, azelastine ophthalmic solution, bepotastine, epinastine, ketotifen, Lastacaft, olopatadine ophthalmic solution; **or**
    - both of the following:

- diagnosis of vernal keratoconjunctivitis or atopic keratoconjunctivitis; **and**
- inadequate response or adverse reaction to one or contraindication to all of the following: azelastine ophthalmic solution, epinastine, ketotifen, olopatadine ophthalmic solution.

Zerviate for members ≥ two to < three years of age

- Documentation of the following is required:
  - an appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to two or contraindication to all of the following: Alomide, bepotastine, epinastine, Lastacaft, olopatadine ophthalmic solution; **or**
    - both of the following:
      - diagnosis of vernal keratoconjunctivitis or atopic keratoconjunctivitis; **and**
      - inadequate response or adverse reaction to one or contraindication to all of the following: bepotastine, epinastine, olopatadine ophthalmic solution.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 30 - Neuromuscular Blocker Agents

Drug Category: Muscle

Medication Class/Individual Agents: Neuromuscular Blockers

I. Prior-Authorization Requirements

Botulinum Toxins (Types A and B)				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** *Additional information:* • Due to the formation of antibodies, patients may develop resistance to Type A after repeated use. In these cases, Type B may be an alternative because antibodies to Type A and B do not cross-react. • Units of biological activity cannot be directly converted between Botulinum Types A and B. • There is also a difference in relative potencies between products distributed in North America and elsewhere. *Contraindications:* • Infection at the proposed injection site *Warnings:* • Recommended dose and frequency should not be exceeded. Risks with higher doses are unknown. • Hypersensitivity reactions • Pre-existing neuromuscular disorders • Dysphagia • Human albumin (both products contain albumin)
abobotulinumtoxinA	Dysport	PA		
incobotulinumtoxinA	Xeomin	PA		
onabotulinumtoxinA	Botox	PA		
rimabotulinumtoxinB	Myobloc	PA		

II. Therapeutic Uses

FDA-approved, for example:

- Blepharospasm–Botox, Xeomin

- Cervical dystonia–Botox, Dysport, Myobloc, Xeomin
- Lower limb spasticity–Botox, Dysport
- Migraine prophylaxis–Botox
- Neurogenic detrusor overactivity–Botox
- Overactive bladder–Botox
- Severe primary axillary hyperhidrosis in adults–Botox
- Sialorrhea–Myobloc, Xeomin
- Strabismus–Botox
- Upper limb spasticity–Botox, Dysport, Xeomin
- Urinary incontinence associated with neurologic conditions–Botox

non-FDA-approved, for example:

- Achalasia or esophageal dysphagia–Botox, Dysport
- Anal fissures–Botox, Dysport, Myobloc, Xeomin
- Anal stenosis, chronic constipation, or encopresis–Botox
- Gastroparesis–Botox, Dysport, Myobloc, Xeomin
- Migraine prophylaxis (concomitant therapy with a CGRP inhibitor)–Botox
- Migraine prophylaxis (dosing frequency every ten weeks)–Botox
- Myofascial pain syndrome–Botox
- Myofascial pelvic pain syndrome–Botox
- Severe primary axillary hyperhidrosis in pediatrics–Botox
- Severe palmar or plantar hyperhidrosis–Botox
- Sialorrhea–Botox
- Raynaud's phenomenon–Botox

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member’s condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member’s current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Botox

- Documentation of all of the following is required for achalasia or esophageal dysphagia:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - one of the following:
    - member has failed a surgical option; **or**
    - member is not a surgical candidate or is unwilling to undergo surgical procedure; **and**
  - initial requested dose is ≤ 100 units no more frequently than every six months.
- Documentation of all of the following is required for anal fissures:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical nifedipine, topical nitroglycerin.
- Documentation of all of the following is required for anal stenosis, chronic constipation, or encopresis:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all laxatives; **and**
  - inadequate response to dietary changes (e.g., increased intake of fluids and fiber) and/or behavior modification (e.g., biofeedback training, toilet training); and
  - initial requested dose is ≤ 100 units no more frequently than every three months.
- Documentation of all of the following is required for blepharospasm associated with dystonia, cervical dystonia, limb spasticity, and strabismus:
  - appropriate diagnosis; **and**
  - appropriate dosing for requested indication (member's weight must be provided).
- Documentation of all of the following is required for gastroparesis:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response, adverse reaction, or contraindication to metoclopramide; **and**
  - inadequate response or adverse reaction to one or contraindication to all antiemetics.
- Documentation of all of the following is required for migraine prophylaxis:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist, pain medicine/anesthesiology physician, or physical medicine/rehabilitation physician, or consult notes from a specialist are provided; **and**
  - headache frequency of ≥ 15 days/30 days; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: atenolol, metoprolol, nadolol, propranolol, timolol; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: amitriptyline, topiramate, valproic acid, venlafaxine; **and**
  - appropriate dosing for requested indication; **and**
  - for a dosing frequency of every ten weeks, both of the following:
    - member received initial positive response to therapy; **and**
    - member is experiencing a "wearing-off" or efficacy after a dose increase to 195 units; **and**
  - for concomitant therapy with a CGRP inhibitor, a partial, but incomplete, response to Botox used as monotherapy.
- Documentation of all of the following is required for myofascial pain syndrome:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: cyclobenzaprine, gabapentin or pregabalin, local anesthetic, SNRI, TCA agent; **and**
  - approriate dosing (up to a total dose of 200 units)**.**
- Documentation of all of the following is required for myofascial pelvic pain syndrome:

- appropriate diagnosis; **and**
- inadequate response or adverse reaction to two or contraindication to all of the following: gabapentin or pregabalin, muscle relaxant, SNRI, TCA agent, vaginal diazepam; **and**
- approriate dosing (up to a total dose of 300 units)**.**

- Documentation of all of the following is required for neurogenic bladder dysfunction or neurogenic detrusor overactivity in adults:
  - appropriate diagnosis; **and**
  - prescriber is a urologist or consult notes from a urologist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following classes:
    - two anticholinergic medications; **or**
    - one anticholinergic medication and one cholinergic agent; **or**
    - one anticholinergic medication and one alpha blocker; **or**
  - appropriate dosing for requested indication.
- Documentation of all of the following is required for neurogenic bladder dysfunction or neurogenic detrusor overactivity in pediatrics:
  - appropriate diagnosis; **and**
  - prescriber is a urologist or consult notes from a urologist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following classes:
    - one anticholinergic medication; **or**
    - one beta-3 adrenergic receptor agonist; **and**
  - appropriate dosing for requested indication.
- Documentation of all of the following is required for overactive bladder:
  - appropriate diagnosis; **and**
  - prescriber is a urologist or consult notes from a urologist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: two anticholinergic medications or one anticholinergic medication and one beta-3 adreneric receptor agonist; **and**
  - appropriate dosing for requested indication.
- Documentation of all of the following is required for Raynaud's Phenomenon:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: a calcium channel blocker (amlodipine or nifedipine), fluoxetine, losartan, a PDE type 5 inhibitor, a topical nitrate; **and**
  - requested dose is ≤ 200 units/90 days.
- Documentation of all of the following is required for severe primary axillary hyperhidrosis in adults:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided; **and**
  - inadequate response, adverse reaction, or contraindication to aluminum chloride solution; **and**
  - appropriate dosing for requested indication.
- Documentation of all of the following is required for severe primary axillary hyperhidrosis in pediatrics:
  - appropriate diagnosis; **and**
  - member is 12 to ≤ 18 years of age; **and**
  - prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided; **and**
  - inadequate response, adverse reaction, or contraindication to aluminum chloride solution; **and**
  - appropriate dosing for requested indication.
- Documentation of all of the following is required for severe palmar or plantar hyperhidrosis:
  - appropriate diagnosis; **and**
  - prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided; **and**
  - inadequate response, adverse reaction, or contraindication to aluminum chloride solution; **and**
  - appropriate dosing for requested indication.

- Documentation of all of the following is required for sialorrhea:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: atropine, glycopyrrolate, hyoscyamine, scopolamine, a tricyclic antidepressant; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: Myobloc, Xeomin; **and**
  - appropriate dosing (40 to 100 units every three to six months).

SmartPA: Claims for Botox ≤ 600 units will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for cerebral palsy and if MassHealth pharmacy claims indicate at least 70 days have passed since the last paid claim for Botox.†

Dysport

- Documentation of all of the following is required for achalasia or esophageal dysphagia:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - one of the following:
    - member has failed a surgical option; **or**
    - member is not a surgical candidate or is unwilling to undergo surgical procedure; **and**
  - initial requested dose is ≤ 250 units no more frequently than every six months.
- Documentation of all of the following is required for anal fissures:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical nifedipine, topical nitroglycerin.
- Documentation of all of the following is required for cervical dystonia, upper limb spasticity and lower limb spasticity:
  - appropriate diagnosis; **and**
  - appropriate dosing for requested indication (member's weight must be provided).
- Documentation of all of the following is required for gastroparesis:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response, adverse reaction, or contraindication to metoclopramide; **and**
  - inadequate response or adverse reaction to one or contraindication to all antiemetics.

Myobloc

- Documentation of all of the following is required for anal fissures:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical nifedipine, topical nitroglycerin.
- Documentation of all of the following is required for cervical dystonia:
  - appropriate diagnosis; **and**
  - appropriate dosing for requested indication (member's weight must be provided).
- Documentation of all of the following is required for gastroparesis:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response, adverse reaction, or contraindication to metoclopramide; **and**
  - inadequate response or adverse reaction to one or contraindication to all antiemetics.
- Documentation of all of the following is required for sialorrhea:

- appropriate diagnosis; **and**
- inadequate response or adverse reaction to two or contraindication to all of the following: atropine, glycopyrrolate, hyoscyamine, scopolamine, a TCA agent; **and**
- appropriate dosing for requested indication (member's weight must be provided).

Xeomin

- Documentation of all of the following is required for anal fissures:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical nifedipine, topical nitroglycerin.
- Documentation of all of the following is required for blepharospasm, cervical dystonia, and upper limb spasticity:
  - an appropriate diagnosis; **and**
  - appropriate dosing for requested indication (member's weight must be provided).
- Documentation of all of the following is required for gastroparesis:
  - appropriate diagnosis; **and**
  - prescriber is a gastroenterologist or surgeon or consult notes from a gastreoenterologist or surgeon are provided; **and**
  - inadequate response, adverse reaction, or contraindication to metoclopramide; **and**
  - inadequate response or adverse reaction to one or contraindication to all antiemetics.
- Documentation of all of the following is required for sialorrhea:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: atropine, glycopyrrolate, hyoscyamine, scopolamine, a TCA agent; **and**
  - appropriate dosing for requested indication (member's weight must be provided).

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 31 - Cerebral Stimulants and Miscellaneous Agents

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Cerebral Stimulant

I. Prior-Authorization Requirements

Cerebral Stimulants and Miscellaneous Agents – Short-and Intermediate-Acting Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphetamine salts	Adderall	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
amphetamine sulfate		PA	
amphetamine sulfate orally disintegrating tablet	Evekeo ODT	PA	
dexmethylphenidate	Focalin	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg tablet		PA	
dextroamphetamine 5 mg, 10 mg tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
dextroamphetamine 5 mg, 10 mg, 15 mg capsule	Dexedrine Spansule	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
dextroamphetamine solution		PA - < 3 years or ≥ 21 years and PA > 40 mL/day	
methamphetamine	Desoxyn	PA	
methylphenidate chewable tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
methylphenidate oral solution	Methylin oral solution	PA - < 3 years or ≥ 21 years and PA > 30 mL/day	#
methylphenidate sustained-release tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
methylphenidate-Ritalin	Ritalin	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Concurrent therapy with long-acting agents will require PA for quantities > two units/day (all agents combined). Concurrent therapy with a short- or intermediate-acting agent and a long-acting agent will also require PA for quantities > three units/day (all agents combined). Cerebral stimulant solutions will require PA for quantities > 40 mL/day (all agents combined). Individual drug quantity limits may also apply (see reference table below for individual drug quantity limits and dose consolidation options).

FDA-approved indications:

- Attention Deficit Hyperactivity Disorder (ADHD)
- Narcolepsy
- Binge-eating disorder (lisdexamfetamine)

Approved medications for ADHD according to age:

- ≥ six years of age: all cerebral stimulants, atomoxetine, clonidine extended-release 0.1 mg tablet, guanfacine extended-release, viloxazine
- ≥ three to < six years of age: short-acting dextroamphetamine/amphetamine, short- and

Cerebral Stimulants and Miscellaneous Agents – Long-Acting Amphetamine Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphetamine extended-release 1.25 mg/mL oral suspension		PA	
amphetamine extended-release 2.5 mg/mL oral suspension	Dyanavel XR	PA	
amphetamine extended-release chewable tablet	Dyanavel XR	PA	
amphetamine extended-release orally disintegrating tablet	Adzenys XR-ODT	PA	
amphetamine salts extended-release-Adderall XR	Adderall XR	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
amphetamine salts extended-release-Mydayis	Mydayis	PA	
dextroamphetamine transdermal	Xelstrym	PA	
lisdexamfetamine capsule	Vyvanse	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
lisdexamfetamine chewable tablet	Vyvanse	PA	BP

Cerebral Stimulants and Miscellaneous Agents – Long-Acting Methylphenidate Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dexmethylphenidate extended-release	Focalin XR	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
methylphenidate extended-release 72 mg tablet		PA	
methylphenidate extended-release chewable tablet	Quillichew ER	PA	
methylphenidate extended-release oral suspension	Quillivant XR	PA	
methylphenidate extended-release orally disintegrating tablet	Cotempla XR-ODT	PA	

Clinical Notes

intermediate-acting mixed amphetamine salts, dextroamphetamine and amphetamine sulfate

Approved medications for narcolepsy:

- Short- or intermediate-acting mixed amphetamine salts, dextroamphetamine, and methylphenidate
- modafinil
- solriamfetol
- pitolisant

Precautionary use in:

- advanced arteriosclerosis, symptomatic cardiovascular disease, moderate-to-severe hypertension, hyperthyroidism, glaucoma, motor tics, Tourette syndrome, and seizure disorders
- psychologically agitated states, history of drug abuse
- MAO inhibitor use within 14 days

The American Academy of Pediatrics (AAP) suggests evidence is particularly strong for stimulant medications for elementary and school-aged children and adolescents. Adjunctive therapies (guanfacine extended-release and clonidine extended-release 0.1 mg tablet) may be considered if stimulant therapy is not fully effective or limited by side effects. Atomoxetine has also demonstrated efficacy in reducing core symptoms among school-aged children and adolescents (AAP, 2019).

Cerebral Stimulants and Miscellaneous Agents – Long-Acting Methylphenidate Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
methylphenidate extended-release, CD		PA	
methylphenidate extended-release-Aptensio XR	Aptensio XR	PA	
methylphenidate extended-release-Concerta	Concerta	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
methylphenidate extended-release-Jornay PM	Jornay PM	PA	
methylphenidate extended-release-Relexxii	Relexxii	PA	
methylphenidate transdermal	Daytrana	PA - < 3 years or ≥ 21 years and PA > 1 unit/day	BP
methylphenidate-Ritalin LA	Ritalin LA	PA	
serdexmethylphenidate / dexmethylphenidate	Azstarys	PA	

Cerebral Stimulants and Miscellaneous Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
atomoxetine	Strattera	PA - < 6 years	# , A90
clonidine extended-release 0.1 mg tablet		PA - < 3 years and PA > 4 units/day	A90
guanfacine extended-release	Intuniv	PA - < 3 years	# , A90
viloxazine	Qelbree	PA	

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Attention Deficit Hyperactivity Disorder (ADHD)
- Narcolepsy
- Binge-eating disorder (lisdexamfetamine)

Non-FDA-approved, for example:

- Autism spectrum disorder
- Binge-eating disorder (all other cerebral stimulant agents)
- Depressive condition (as adjunctive treatment)
- Excessive sleepiness or fatigue associated with a chronic medical condition such as: cancer-related fatigue, multiple sclerosis, Parkinson's disease
- Sleep disorder (hypersomnia, obstructive sleep apnea, shift work disorder)
- Traumatic brain injury

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency for all stimulants prescribed.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member’s condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member’s current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

All requests for cerebral stimulants at quantities above established quantity limits (per day)

- Documentation of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - medical necessity for an increased dosage that results in requiring quantities that exceed the determined limits (see reference table below for individual drug quantity limits and dose consolidation options)

All requests for cerebral stimulant in members ≥ 21 years of age (new to therapy)

- Documentation of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - individual drug quantity limits must be met first where applicable; **and**
  - clinically appropriate diagnosis including:
    - ADHD; **or**

- autism spectrum disorder; **or**
- binge eating disorder; **or**
- depressive condition (as adjunctive treatment); **or**
- excessive sleepiness or fatigue associated with a chronic medical condition such as: cancer-related fatigue, multiple sclerosis, Parkinson's disease; **or**
- narcolepsy; **or**
- sleep disorder (hypersomnia, obstructive sleep apnea, shift work disorder); **or**
- traumatic brain injury.

Please note, three-month provisional approval may be allowed for members who were stabilized on the requested medication during a recent hospitalization.

SmartPA: Claims for amphetamine salts, amphetamine salts ER, Daytrana, dextroamphetamine (5 mg and 10 mg tablet, 5 mg, 10 mg, and 15 mg capsule, or solution), dexmethylphenidate, dexmethylphenidate ER, lisdexamfetamine capsule, methylphenidate (Ritalin), methylphenidate ER (Concerta), methylphenidate oral solution, methylphenidate SR, methylphenidate chewable tablet within quantity limits will usually process at the pharmacy without a PA request if the member is ≥ 21 years of age and has a history of a paid MassHealth pharmacy claims for a CNS stimulant within the last 90 days, or if the member is ≥ 21 years of age and has an appropriate diagnosis in history.†

Adzenys XR-ODT, amphetamine extended-release 1.25 mg/mL oral suspension, amphetamine salts extended-release (generic Mydayis), Dyanavel XR, lisdexamfetamine chewable tablet, Xelstrym

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for amphetamine salts extended-release (generic Mydayis), member is ≥ 13 years of age; **and**
  - clinical rationale for use of the requested agent instead of amphetamine salts extended-release (generic Adderall XR); **and**
  - clinical rationale for use of the requested agent instead of lisdexamfetamine capsule; **and**
  - for Dyanavel XR suspension, one of the following:
    - requested quantity is ≤8 mL (20 mg)/day; **or**
    - clinical rationale for exceeding the FDA approved maximum dose.

amphetamine sulfate

- Documentation of the following is required for diagnosis of ADHD:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as ≥ seven days of therapy) or adverse reaction to one amphetamine immediate-release product available without PA; **or**
    - clinical rationale for use of the requested agent instead of amphetamine immediate-release products available without PA.
- Documentation of the following is required for diagnosis of narcolepsy:
  - appropriate diagnosis; **and**
  - medical records documenting the results of the sleep study used to confirm narcolepsy [polysomnogram (PSG) or Multiple Sleep Latency Test (MSLT)]; **and**
  - one of the following:
    - inadequate response (defined as ≥ seven days of therapy) or adverse reaction to one amphetamine immediate-release product available without PA; **or**
    - clinical rationale for use of the requested agent instead of amphetamine immediate-release products available without PA.

Azstarys, Cotempla XR-ODT, Jornay PM, methylphenidate extended-release (generic Aptensio XR, Ritalin LA), methylphenidate extended-release CD, Quillichew ER, Quillivant XR

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- clinical rationale for use of the requested agent instead of dexmethylphenidate extended-release; **and**
- clinical rationale for use of the requested agent instead of methylphenidate transdermal; **and**
- one of the following:
  - medical necessity for requested formulation instead of solid oral formulations as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **or**
  - clinical rationale for use of the requested agent instead of methylphenidate extended-release (generic Concerta); **and**
- for Quillivant XR, one of the following:
  - requested quantity is ≤ 12 mL (60 mg)/day; **or**
  - clinical rationale for exceeding the FDA approved maximum dose.

Please note, six-month provisional approval may be allowed for members who are stabilized on the requested medication and there is severe risk of harm.

clonidine extended-release 0.1 mg tablet exceeding quantity limits

- Documentation of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - medical necessity for an increased dosage that results in requiring quantities that exceed the determined limits

dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for requested strength instead of dextroamphetamine 5 mg and 10 mg tablets available without PA.

Evekeo ODT

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for requested formulation instead of solid oral formulations as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age.

methamphetamine

- Documentation of the following is required:
  - diagnosis of ADHD; **and**
  - medical records documenting an inadequate response (defined as ≥ seven days of therapy) or adverse reaction to all other stimulant and non-stimulant medications.

methylphenidate extended-release 72 mg tablet and Relexxii

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for the 45 mg, 63 mg and 72 mg tablets, clinical rationale for use of the requested agent instead of all of the following:
    - two methylphenidate extended-release (generic Concerta) tablets to achieve the requested dose (i.e., 27 mg and 18 mg, 27 mg and 36 mg, or 36 mg and 36 mg); **and**
    - dexmethylphenidate extended-release; **and**
    - methylphenidate transdermal; **and**
  - for the 18 mg, 27 mg, 36 mg, and 54 mg tablets clinical rationale for use of the requested agent instead of all of the following:
    - dexmethylphenidate extended-release; **and**
    - methylphenidate extended-release tablets (generic Concerta); **and**

- methylphenidate transdermal.

Qelbree

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - inadequate response (defined as ≥ seven days of therapy), adverse reaction, or contraindication to atomoxetine; **and**
  - appropriate dosing; **and**
  - one of the following:
    - for members < 18 years of age, one of the following:
      - for 100 mg capsule, requested quantity is ≤ one unit/day; **or**
      - for 150 mg and 200 mg capsule, requested quantity is ≤ two units/day; **or**
    - for members ≥ 18 years of age, one of the following:
      - for 100 mg capsule, requested quantity is ≤ one unit/day; **or**
      - for 150 mg and 200 mg capsule, requested quantity is ≤ three units/day.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions. Please note, one-month provisional approval may be allowed for members who are stabilized on the requested medication to avoid risk of destabilization.

Behavioral Health Medication Polypharmacy ***(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, and viloxazine] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:

- appropriate diagnoses; **and**
- treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
- prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation; **and**
- one of the following:
  - member has a seizure diagnosis only; **or**
  - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
  - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
  - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and** one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Cerebral Stimulant Polypharmacy ***(overlapping pharmacy claims for 2 or more cerebral stimulants [immediate-release and extended-release formulations of the same chemical entity are not included in this restriction and are counted as one cerebral stimulant agent] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current cerebral stimulants and corresponding diagnoses; **and**
    - inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to monotherapy trial with a methylphenidate product; **and**
    - inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to monotherapy trial with an amphetamine product; **and**
    - clinical rationale for cerebral stimulant polypharmacy.

Alpha$_2$ Agonist or Cerebral Stimulant for members < three years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**

- for an alpha$_2$ agonist, member has a cardiovascular diagnosis only; **or**

- all of the following:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - treatment plan including names of current alpha$_2$ agonist(s) and cerebral stimulant(s) and corresponding diagnoses; **and**
  - clinical rationale for use of alpha$_2$ agonist or cerebral stimulant in member < three years of age; **and**
  - for requests for an amphetamine product, inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to a methylphenidate product.

atomoxetine or viloxazine for members < six years of age

- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - if member is < three years of age, prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided.

Reference Table:

Please note in addition to individual drug quantity limits, concurrent therapy quantity limits may also apply

Drug Name	Availability	Individual Drug Quantity Limits
Short- and Intermediate-Acting Agents		
amphetamine sulfate	Tablet: 5, 10 mg	Three units/day
amphetamine sulfate (Evekeo ODT)	Tablet: 5, 10, 15, 20 mg	Three units/day
dexmethylphenidate (Focalin)	Tablet: 2.5, 5, 10 mg	Three units/day
dextroamphetamine	Tablet: 2.5, 5, 7.5, 10, 15, 20, 30 mg	Three units/day
dextroamphetamine (Dexedrine Spansule)	Capsule: 5, 10, 15 mg	Three units/day
dextroamphetamine oral solution	Solution: 5 mg/5 mL	40 mL/day
methamphetamine (Desoxyn)	Tablet: 5 mg	N/A
methylphenidate chewable tablet	Chewable Tablet: 2.5, 5, 10 mg	Three units/day
methylphenidate sustained-release tablet	Tablet: 10, 20 mg	Three units/day
methylphenidate (Ritalin)	Tablet: 5, 10, 20 mg	Three units/day
methylphenidate oral solution (Methylin)	Solution: 5 mg/5 mL, 10 mg/5 mL	30 mL/day
mixed amphetamine salts (Adderall)	Tablet: 5, 7.5, 10, 12.5, 15, 20, 30 mg	Three units/day
Long-Acting Agents		
amphetamine (Adzenys XR-ODT)	Tablet: 3.1, 6.3, 9.4, 12.5, 15.7, 18.8 mg	One unit/day
amphetamine (Dyanavel XR)	Suspension: 2.5 mg/mL	8 mL/day
amphetamine (Dyanavel XR)	Tablet: 5, 10, 15, 20 mg	One unit/day
dexmethylphenidate (Focalin XR)	Capsule: 5,10, 15, 20, 25, 30, 35, 40 mg	Two units/day
dextroamphetamine (Xelstrym)	Patch: 4.5, 9, 13.5, 18 mg	One unit/day

lisdexamfetamine (Vyvanse)	Capsule: 10, 20, 30, 40, 50, 60, 70 mg Chewable Tablet: 10, 20, 30, 40, 50, 60 mg	Two units/day
methylphenidate (Aptensio XR)	Capsule: 10, 15, 20, 30, 40, 50, 60 mg	One unit/day
methylphenidate (Concerta)	Tablet: 18, 27, 36, 54 mg	Two units/day
methylphenidate	Tablet: 72 mg	One unit/day
methylphenidate, CD	Capsule: 10, 20, 30, 40, 50, 60 mg	Two units/day
methylphenidate (Jornay PM)	Capsule: 20, 40, 60, 80, 100 mg	One unit/day
methylphenidate (Cotempla XR-ODT)	Tablet: 8.6, 17.3, 25.9 mg	One unit/day
methylphenidate (Quillichew ER)	Tablet: 20, 30, 40 mg	Two units/day
methylphenidate (Quillivant XR)	Suspension: 25 mg/5 mL	12 mL/day
methylphenidate (Relexxii)	Tablet: 45, 63 mg	One unit/day
methylphenidate (Ritalin LA)	Capsule: 10, 20, 30, 40, 60 mg	Two units/day
methylphenidate transdermal (Daytrana)	Patch: 10, 15, 20, 30 mg	One unit/day
mixed amphetamine salts (Adderall XR)	Capsule: 5, 10, 15, 20, 25, 30 mg	Two units/day
mixed amphetamine salts (Mydayis)	Capsule: 12.5, 25, 37.5, 50 mg	One unit/day
serdexmethylphenidate/dexmethylphenidate (Azstarys)	Capsule: 26.1/5.2, 39.2/7.8, 52.3/10.4 mg	One unit/day

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 32 - Serums, Toxoids, and Vaccines

Drug Category: Serums, Toxoids, and Vaccines

Medication Class/Individual Agents: Serums, Toxoids, and Vaccines

I. Prior-Authorization Requirements

Serums, Toxoids, and Vaccines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
adenovirus live vaccine delayed-release oral tablets			
BCG live vaccine	BCG Vaccine		
BCG live, intravesical			MB
chikungunya virus vaccine, live	Ixchiq		
cholera vaccine, live, oral	Vaxchora		
COVID EUA – October 3, 2023 for members ≥ 12 years of age	Novavax COVID-19 vaccine, adjuvanted		1
COVID-19 Moderna vaccine, COVID EUA – September 11, 2023 for members ≥ 6 months of age	Spikevax		1
COVID-19 Pfizer vaccine, COVID EUA – September 11, 2023 for members ≥ 6 months of age	Comirnaty		1
dengue tetravalent vaccine, live	Dengvaxia		
diphtheria / tetanus / acellular pertussis / poliovirus inactivated / haemophilus B conjugate / hepatitis B vaccine	Vaxelis		
diphtheria / tetanus / acellular pertussis / poliovirus inactivated / haemophilus B	Pentacel		1

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Administrative Schedule:

- PA requirements exist to ensure appropriate dosing of vaccines given in a series to adult members. The pharmacy may contact the MassHealth Drug Utilization Review program for review of the claim in the event that a dose is required that is not consistent with the current Advisory Council on Immunization Practices (ACIP) recommendations.
- For vaccinations that require a series of doses, the time interval between each dose can be increased from the recommended schedule but should not be decreased. The immunization series does not need to be restarted, regardless of the length of time from the last dose (exception: oral typhoid).
- If two live vaccines are administered separately, there should be an interval of at least 28 days in between
- Multiple inactivated vaccines can be administered at any time in relation to another

Side Effects:

- Usually minor (e.g., slight fever, rash, or soreness at the site of injection)
- Serious reactions are extremely rare

Serums, Toxoids, and Vaccines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
conjugate vaccine			
diphtheria / tetanus toxoids / acellular pertussis / hepatitis B, recombinant / poliovirus, inactivated vaccine	Pediarix		1
diphtheria / tetanus toxoids / acellular pertussis / poliovirus, inactivated vaccine	Kinrix		1
diphtheria / tetanus toxoids / acellular pertussis vaccine	Daptacel		1
diphtheria / tetanus toxoids / acellular pertussis vaccine	Infanrix		1
diphtheria / tetanus toxoids vaccine			1
haemophilus B conjugate vaccine-Acthib	Acthib		1
haemophilus B conjugate vaccine-Hiberix	Hiberix		1
haemophilus B conjugate vaccine-Pedvaxhib	Pedvaxhib		1
hepatitis A vaccine, inactivated - Havrix	Havrix		1
hepatitis A vaccine, inactivated-Vaqta	Vaqta		1
hepatitis A, inactivated / hepatitis B recombinant	Twinrix		1
hepatitis B recombinant vaccine	Engerix-B		1
hepatitis B recombinant vaccine	Prehevbrio		1
hepatitis B recombinant vaccine	Recombivax HB		1
hepatitis B recombinant vaccine, adjuvanted	Heplisav-B		1

Clinical Notes

Safety:

- Thimerosal has been removed or reduced to trace amounts in almost all of the vaccines routinely recommended for children six years of age and younger
- Current scientific evidence does not support the hypothesis that vaccines have a causal link to autism

Contraindications:

- Serious allergic reaction to previous dose of vaccine or vaccine component

Not Contraindications:

- Mild acute illness with or without fever
- Current antimicrobial therapy
- Mild to moderate local reaction (e.g., swelling, redness, soreness)
- Low-grade or moderate fever after previous dose
- Convalescent phase of illness
- Premature birth

Precautions:

- Moderate or severe acute illness with or without fever

Live Virus Vaccines (e.g., measles, mumps, rubella, varicella):

- Avoid use in immunocompromised members
- Administration should be deferred in the presence of active infections or inactive, untreated tuberculosis
- Pregnancy should be avoided for three months following vaccination

Report unexpected events after vaccinations to the Vaccine Adverse Event Reporting System (VAERS) at (800) 822-7967.

Serums, Toxoids, and Vaccines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
human papillomavirus 9-valent vaccine	Gardasil 9	PA - < 9 years and PA ≥ 46 years	1
influenza virus vaccine, adjuvanted	Fluad	PA - < 65 years	1
influenza virus vaccine, high dose	Fluzone	PA - < 65 years	1
influenza virus vaccine-Afluria	Afluria		1
influenza virus vaccine-Fluarix	Fluarix		1
influenza virus vaccine-Flublok	Flublok		1
influenza virus vaccine-Flucelvax	Flucelvax		1
influenza virus vaccine-Flulaval	Flulaval		1
influenza virus vaccine-Flumist	Flumist		1
influenza virus vaccine-Fluzone	Fluzone		1
japanese encephalitis vaccine	Ixiaro		
measles / mumps / rubella / varicella virus vaccine	Proquad		1
measles / mumps / rubella vaccine	M-M-R II Vaccine		1
measles / mumps / rubella vaccine	Priorix		
meningococcal group B vaccine-Bexsero	Bexsero		1
meningococcal group B vaccine-Trumenba	Trumenba		1
pentavalent meningococcal groups A, B, C, W and Y vaccine	Penbraya		
pneumococcal 13-valent conjugate vaccine	Prevnar 13		1
pneumococcal 15-valent conjugate vaccine	Vaxneuvance		
pneumococcal 20-valent conjugate vaccine	Prevnar 20		
pneumococcal 21-valent conjugate vaccine	Capvaxive		

Serums, Toxoids, and Vaccines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
pneumococcal 23-valent polysaccharide vaccine	Pneumovax		1
poliovirus vaccine, inactivated	Ipol		1
quadrivalent meningococcal conjugate vaccine-Menactra	Menactra		1
quadrivalent meningococcal conjugate vaccine-Menquadfi	Menquadfi		1
quadrivalent meningococcal conjugate vaccine-Menveo	Menveo		1
rabies virus vaccine-Imovax Rabies	Imovax Rabies		
rabies virus vaccine-Rabavert	Rabavert		
respiratory syncytial virus vaccine	Abrysvo	PA - < 60 years	1
respiratory syncytial virus vaccine suspension	Mresvia	PA - < 60 years	
respiratory syncytial virus vaccine, adjuvanted	Arexvy	PA - < 50 years	
rotavirus vaccine, live, oral	Rotarix		1
rotavirus vaccine, live, oral, pentavalent	Rotateq		1
smallpox / monkeypox vaccine, live	Jynneos		1
tetanus toxoid / diphtheria vaccine	Tenivac		1
tetanus toxoids / diphtheria / acellular pertussis / inactivated poliovirus vaccine	Quadracel		
tetanus toxoids / diphtheria / acellular pertussis vaccine	Adacel		1
tetanus toxoids /	Boostrix		1

Serums, Toxoids, and Vaccines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
diphtheria / acellular pertussis vaccine			
tick-borne encephalitis vaccine	Ticovac		
typhoid vaccine capsule	Vivotif Berna		
typhoid vaccine injection	Typhim VI		
varicella virus vaccine	Varivax		1
varicella zoster immune globulin, human	Varizig		
yellow fever vaccine	YF-Vax		
yellow fever vaccine, live	Stamaril		
zoster vaccine recombinant, adjuvanted	Shingrix	PA - < 50 years	

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

1 Product may be available through the Massachusetts Department of Public Health (DPH). Please check with DPH for availability. MassHealth does not pay for immunizing biologicals (i.e., vaccines) and tubercular (TB) drugs that are available free of charge through local boards of public health or through the Massachusetts Department of Public Health without PA (130 CMR 406.413(C)). In cases where free vaccines are available to providers for specific populations (e.g. children, high risk, etc.), MassHealth will reimburse the provider only for individuals not eligible for the free vaccines. Notwithstanding the above, MassHealth will pay pharmacies for seasonal flu vaccine serum without PA, if the vaccine is administered in the pharmacy.

II. Therapeutic Uses

FDA-approved, for example:

- Maternal use for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through six months of age – Abrysvo
- Prevention of diseases caused by human papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, and 58 – Gardasil-9
- Prevention of herpes zoster – Shingrix
- Prevention of influenza – Fluad and Fluzone High-Dose
- Prevention of LRTD caused by RSV in individuals ≥ 50 years of age – Arexvy
- Prevention of LRTD caused by RSV in individuals ≥ 60 years of age – Abrysvo

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Herpes zoster vaccine (Shingrix)

- Documentation of the following is required:
  - appropriate indication; **and**
  - one of the following:
    - member ≥ 50 years of age; **or**
    - member is ≥ 18 years of age and is at increased risk of herpes zoster due to immunodeficiency or immunosuppression caused by known disease or therapy.

SmartPA: Claims for Shingrix for ≤ two doses in all MassHealth pharmacy claims history will usually process at the pharmacy without a PA request if the member is ≥ 18 years of age, has a history of MassHealth medical claims indicative of immunodeficiency or immunosuppression (including history of autologous hematopoietic stem cell transplant, hematologic malignancy, renal transplant, solid tumor receiving chemotherapy, HIV-infection).†

Human papillomavirus 9-valent vaccine (Gardasil-9)

- Documentation of the following is required:
  - appropriate indication; **and**
  - member is ≥ 9 and < 46 years of age; **or**
  - member is ≥ 46 years of age who has already begun the sequence while within the appropriate age range.

Inactivated influenza virus vaccine, high-dose (Fluzone High-Dose), and influenza virus vaccine, adjuvanted (Fluad) in members < 65 years of age

- Documentation of the following is required:
  - appropriate indication; **and**
  - requested quantity of one dose/season; **and**
  - medical necessity for high-dose instead of standard formulation in members < 65 years of age.

Respiratory syncytial virus vaccine (Abrysvo) in members < 60 years of age

- Documentation of the following is required for prevention of LRTD caused by RSV in adults < 60 years of age:
  - appropriate indication; **and**
  - medical necessity for the requested agent in member < 60 years of age.
- Documentation of the following is required for maternal use for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through six months of age:
  - appropriate indication; **and**
  - vaccine will be administered between weeks 32 and 36 of pregnancy.

Respiratory syncytial virus vaccine, adjuvanted (Arexvy) in members < 50 years of age

- Documentation of the following is required:
  - appropriate indication; **and**
  - medical necessity for the requested agent in member < 50 years of age.

Respiratory syncytial virus vaccine suspension (Mresvia) in members < 60 years of age

- Documentation of the following is required:
  - appropriate indication; **and**
  - medical necessity for the requested agent in member < 60 years of age.

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 33 - Inflammatory Bowel Disease Agents

Drug Category: Inflammatory Bowel Disease Agents

Medication Class/Individual Agents: Inflammatory Bowel Disease Agents

I. Prior-Authorization Requirements

Inflammatory Bowel Disease Agents				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
balsalazide	Colazal		# , A90	**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** Guidelines from the American College of Gastroenterology (ACG) include the following recommendations: • Sulfasalazine is effective for treating symptoms of mild to moderate active Crohn's disease. • Controlled release budesonide should be used for induction of remission for patients with mild to moderate ileocecal Crohn's disease. • Oral corticosteroids can be used for short-term for alleviating symptoms in moderate-to-severe active Crohn's disease. • Thiopurines and methotrexate are effective and should be considered for steroid-sparing and maintenance of remission in Crohn's disease. • Anti-TNF agents (infliximab, adalimumab, certolizumab) should be used in Crohn's disease that is resistant to corticosteroids and Crohn's disease refractory to thiopurines and methotrexate. • For patients with moderate-to-severe active Crohn's disease, anti-integrin therapy (vedolizumab) should be considered for induction of symptomatic remission. • Ustekinumab should be given for moderate-to-severe Crohn's disease who failed previous treatment with corticosteroids, thiopurines, methotrexate, or anti-TNF agents or who have had no prior exposure to anti-TNF
budesonide 3 mg delayed-release capsule			A90	
budesonide extended-release capsule	Ortikos	PA		
budesonide extended-release tablet	Uceris		BP, A90	
budesonide rectal foam	Uceris	PA	A90	
hydrocortisone enema	Cortenema		# , A90	
hydrocortisone foam	Cortifoam			
hydrocortisone hemorrhoidal cream	Anusol-HC		# , A90	
mesalamine 0.375 gram extended-release capsule	Apriso		BP, A90	
mesalamine 1.2 gram delayed-release tablet	Lialda		BP, A90	
mesalamine 250 mg, 500 mg controlled-release capsule	Pentasa		BP, A90	
mesalamine 400 mg delayed-release capsule	Delzicol DR	PA	A90	
mesalamine 800 mg delayed-release tablet		PA	A90	
mesalamine enema	Rowasa		# , A90	
mesalamine kit	Rowasa Kit	PA	A90	
mesalamine suppository	Canasa		# , A90	
olsalazine	Dipentum			
sulfasalazine	Azulfidine		# , A90	
sulfasalazine delayed-release	Azulfidine EN-Tabs		# , A90	

	Clinical Notes
	agents. • Anti-TNF agents should be considered to treat severe active Crohn’s disease. • Infliximab may be administered to treat fulminant Crohn’s disease. • Infliximab is effective and should be considered in treating perianal fistulas. • Adalimumab and certolizumab may be effective and should be considered in treating perianal fistulas. • Thiopurines may be effective and should be considered in treating fistulizing Crohn’s disease. • Anti-TNF agents, vedolizumab, and ustekinumab should be used to maintain remission in Crohn's disease. • In mild active ulcerative proctitis, rectal 5-ASA therapies for induction and maintenance of remission is recommended. • In mild active left-sided ulcerative colitis, rectal 5-ASA enemas combined with oral 5-ASA is recommended for induction of remission. • In mild active left-sided ulcerative colitis without response to oral and rectal 5-ASA, oral budesonide MMX is recommended for induction of remission. • In mild to moderate active ulcerative colitis not responding to oral 5-ASA, oral budesonide MMX is recommended for induction of remission. • In mild active left-sided or extensive ulcerative colitis, oral 5-ASA is recommended for maintenance of remission. • In moderate active ulcerative colitis, oral budesonide MMX is recommended. • In moderate-to-severe active ulcerative colitis, anti-TNF agents (adalimumab, golimumab, infliximab), vedolizumab, and tofacitinib is recommended for induction of remission. • In moderate-to-severe active ulcerative colitis with failure to anti-TNF agents, vedolizumab and tofacitinib is recommended for induction of remission. • Anti-TNF agents, vedolizumab, and tofacitinib should be used to maintain remission. 1. Rubin DT, Ananthakrishnan AN; Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2019 Mar;114(3):384-413.

	Clinical Notes
	2. Lichtensterin GR, Loftus EV; Practice Parameters Committee of the American College of Gastroenterology. Management of Crohn's Disease in adults: American College of Gastroenterology, Practice Parameters Committee. Am J Gastroenterol. 2018 Apr;113(4):481-517.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Crohn's disease
- Ulcerative colitis

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

budesonide rectal foam

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response (defined by at least three weeks of therapy) or adverse reaction to one or contraindication to both of the following: hydrocortisone enema, hydrocortisone foam.

mesalamine 400 mg delayed-release capsule
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - both of the following:
      - member is ≥ 5 years of age; **and**
      - agent will be used for treatment of active ulcerative colitis; **or**
    - member is ≥ 18 years of age; **and**
  - one of the following:
    - both of the following:
      - member's current weight is ≥ 24 kg; **and**
      - inadequate response, adverse reaction, or contraindication to mesalamine 1.2 g delayed-release tablet (Lialda); **or**
    - member's current weight is < 24 kg; **and**
  - appropriate dosing.

mesalamine 800 mg delayed-release capsule
- Documentation of the following is required:
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication all mesalamine oral formulations available without PA; **and**
  - appropriate dosing.

mesalamine enema kit
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to mesalamine enema and mesalamine suppository.

Ortikos
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all budesonide oral formulations available without PA; **and**
  - one of the following:
    - member is ≥ 18 years of age; **or**
    - both of the following:
      - member is ≥ eight years of age; **and**
      - agent will be used for treatment of active Crohn's disease.

MassHealth Evaluation Criteria
Table 34 - Antibiotics - Ophthalmic

Drug Category: Ophthalmic

Medication Class/Individual Agents: Antibacterial Agents

I. Prior-Authorization Requirements

Antibiotics: Ophthalmic			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
azithromycin ophthalmic solution	Azasite	PA	BP
bacitracin ophthalmic ointment		PA	A90
besifloxacin ophthalmic suspension	Besivance		
ciprofloxacin ophthalmic ointment, solution	Ciloxan		# , A90
erythromycin ophthalmic ointment			A90
gatifloxacin ophthalmic solution	Zymaxid		# , A90
gentamicin ophthalmic ointment, solution			A90
levofloxacin ophthalmic solution		PA	A90
moxifloxacin ophthalmic solution, twice daily		PA	A90
moxifloxacin ophthalmic solution-Vigamox	Vigamox		# , A90
natamycin	Natacyn		
ofloxacin ophthalmic solution	Ocuflox		# , A90
sulfacetamide ophthalmic ointment, solution			A90
tobramycin ophthalmic ointment,	Tobrex		# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Mild bacterial conjunctivitis may be self-limiting and resolve spontaneously in immune-competent adults.
- Most ophthalmic antibiotics contain the preservative benzalkonium chloride. Certain patients may have an allergic reaction or experience dose limiting ocular irritation when using agents containing preservatives. Moxifloxacin ophthalmic solutions are preservative free.
- Treatment should last five to seven days for bacterial conjunctivitis, five days for corneal ulcers, and a few weeks for blepharitis.
- Systemic antibiotic treatment should be utilized for conjunctivitis due to Neisseria gonorrhoeae or Chlamydia trachomatis.
- Ointment may blur vision for up to 20 minutes but are preferred for corneal ulcers because it acts as a lubricant.
- Contact lens wearers may require a flouroquinolone due to the high incidence of pseudomonas infection.

Antibiotics: Ophthalmic			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
solution			

Antibiotics: Ophthalmic – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bacitracin / polymyxin B ophthalmic ointment			A90
gentamicin / prednisolone ophthalmic ointment	Pred-G	PA	
gentamicin / prednisolone ophthalmic suspension	Pred-G		
neomycin / bacitracin / polymyxin B / hydrocortisone ophthalmic ointment			A90
neomycin / bacitracin / polymyxin B ophthalmic ointment			A90
neomycin / polymyxin B / dexamethasone ophthalmic ointment, suspension	Maxitrol		# , A90
neomycin / polymyxin B / gramicidin			A90
neomycin / polymyxin B / hydrocortisone ophthalmic suspension		PA	A90
sulfacetamide / prednisolone sodium phosphate ophthalmic solution			A90
tobramycin / loteprednol ophthalmic suspension	Zylet		
tobramycin 0.3% / dexamethasone 0.05%, ophthalmic suspension	Tobradex ST		

Antibiotics: Ophthalmic – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tobramycin 0.3% / dexamethasone 0.1%, ophthalmic ointment, suspension	Tobradex		# , A90
trimethoprim / polymyxin B ophthalmic solution	Polytrim		# , A90

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Ocular infections involving the conjunctiva and/or cornea
  - bacterial conjunctivitis
  - bacterial keratitis/corneal ulcers
  - blepharitis/blepharoconjunctivitis
  - surgical prophylaxis

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested

medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

moxifloxacin ophthalmic solution, twice daily

Documentation of the following is required:
- appropriate diagnosis; **and**
- inadequate response or adverse reaction to moxifloxacin ophthalmic solution (Vigamox).

SmartPA: Claims for moxifloxacin ophthalmic solution, twice daily will usually process at the pharmacy without a PA request if the prescriber is an ophthalmologist.†

Single-entity agents: Azasite, bacitracin ophthalmic ointment, and levofloxacin ophthalmic solution
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all single-entity or combination ophthalmic antibiotic(s) products available without prior authorization.

SmartPA: Claims for levofloxacin ophthalmic solution will usually process at the pharmacy without a PA request if the prescriber is an ophthalmologist.†

Combination antibiotic/corticosteroid products: neomycin/polymyxin B/hydrocortisone ophthalmic suspension, and Pred-G ointment
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to an ophthalmic antibiotic/corticosteroid combination product available without prior authorization; **or**
    - inadequate response, adverse reaction, or contraindication to both a single-entity or combination ophthalmic antibiotic(s) and a single-entity ophthalmic corticosteroid agent available without prior authorization.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 35 - Antibiotics and Anti-Infectives - Oral and Inhaled

Drug Category: Infectious Disease Agents

Medication Class/Individual Agents: Antibiotics and Anti-Infectives

I. Prior-Authorization Requirements

Anti-Infectives: Oral and Inhaled – Not Otherwise Classified

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
albendazole			A90	• Metronidazole is available in 250 mg and 500 mg tablets, and 375 mg capsules. Due to a considerable cost difference, metronidazole 375 mg capsules require prior authorization (PA). • Linezolid is FDA-approved for the treatment of gram-positive coccal infections including methicillin-resistant *Staphylococcus aureus* (MRSA). The Centers for Disease Control and Prevention (CDC) recommends that clinicians reserve linezolid for more severe infections after consultation with an infectious disease specialist or for those patients who have not responded to other antibiotics. Community-acquired MRSA has responded to a number of other antibiotics, including doxycycline, clindamycin, minocycline, and TMP/sulfamethoxazole. Vancomycin continues to be first-line treatment for hospital-acquired MRSA infections. Due to a considerable cost difference, linezolid suspension requires PA.
artemether / lumefantrine	Coartem	PA - > 24 units/365 days		
atovaquone	Mepron		# , A90	
benznidazole				
clindamycin capsule, injection, oral solution	Cleocin		# , A90	
dapsone tablet			A90	
fidaxomicin	Dificid	PA		
fosfomycin			A90	
ivermectin tablet	Stromectol		#	
linezolid suspension	Zyvox	PA	BP, A90	
linezolid tablet	Zyvox		# , A90	
mebendazole		PA	A90	
methenamine	Hiprex		# , A90	
metronidazole 250 mg, 500 mg tablet			A90	
metronidazole 375 mg capsule	Flagyl	PA	A90	
metronidazole suspension	Likmez	PA		
nifurtimox	Lampit	PA		
nitazoxanide	Alinia	PA		
nitrofurantoin 25 mg/5 mL suspension	Furadantin	PA	A90	
nitrofurantoin 50 mg/5 mL suspension		PA	A90	
nitrofurantoin macrocrystals	Macrodantin		# , A90	
nitrofurantoin monohydrate / macrocrystals	Macrobid		# , A90	
praziquantel	Biltricide		BP, A90	
pyrantel pamoate	Reese's Pinworm			
pyrimethamine	Daraprim	PA	BP, A90	
quinine	Qualaquin		# , A90	
rifamycin	Aemcolo	PA		

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
rifaximin 200 mg	Xifaxan		
rifaximin 550 mg	Xifaxan	PA	
secnidazole	Solosec	PA	
tafenoquine	Krintafel	PA - > 2 units/365 days	
tedizolid tablet	Sivextro	PA	
tinidazole			A90
triclabendazole	Egaten	PA	
trimethoprim tablet			A90
vancomycin capsule	Vancocin		# , A90
vancomycin oral solution	Firvanq		BP, A90

Antibiotics: Oral and Inhaled – Aminoglycosides

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amikacin liposome inhalation	Arikayce	PA		
neomycin			*, A90	
paromomycin			A90	
tobramycin inhalation powder	Tobi Podhaler	PA		
tobramycin inhalation solution-Bethkis	Bethkis	PA	BP, A90	
tobramycin inhalation solution-Kitabis Pak	Kitabis Pak		BP, A90	
tobramycin inhalation solution-Tobi	Tobi		# , A90	

Antibiotics: Oral and Inhaled – Penicillins

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amoxicillin			A90	• Amoxicillin/clavulanate is available as immediate-release and extended-release formulations. The extended-release formulation requires PA. In addition, amoxicillin/clavulanate 125/31.25 mg/5 mL suspension requires PA. The immediate-release tablets, chewable tablets, and select strengths of suspension are available without PA.
amoxicillin / clavulanate 125/31.25 mg/5 mL suspension	Augmentin	PA		
amoxicillin / clavulanate chewable tablet, 200/28.5, 250/62.5, 400/57, 600/42.9 mg/5 mL suspension, tablet	Augmentin		# , A90	
amoxicillin / clavulanate extended-release	Augmentin XR	PA	A90	
ampicillin			A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
dicloxacillin			A90
penicillin V			A90

Antibiotics: Oral and Inhaled – Sulfonamides

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
sulfadiazine			A90	
sulfamethoxazole / trimethoprim suspension	Sulfatrim		# , A90	
sulfamethoxazole / trimethoprim tablet	Bactrim		#	

Antibiotics: Oral and Inhaled – Fluoroquinolones

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
ciprofloxacin 100 mg tablet		PA	A90	• Ciprofloxacin tablets are available in 100 mg, 250 mg, 500 mg, and 750 mg strengths. The 250 mg, 500 mg, and 750 mg strengths are significantly less costly. PA is required for ciprofloxacin 100 mg tablets.
ciprofloxacin injection, suspension, 250 mg, 500 mg, 750 mg tablet	Cipro		# , A90	
delafloxacin tablet	Baxdela	PA		
levofloxacin			A90	
moxifloxacin tablet			A90	
ofloxacin tablet		PA	A90	

Antibiotics: Oral and Inhaled – Tetracyclines

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
demeclocycline			A90	*Oral antibiotics for the treatment of acne or rosacea:* • Moderate acne can be managed with topical retinoids in combination with oral antibiotics and/or benzoyl peroxide. • Oral tetracyclines may be used for the management of papulopustular rosacea. • These agents are most useful for improving inflammatory papules and pustules, and may also reduce erythema.
doxycycline hyclate 100 mg capsule	Vibramycin		# , A90	
doxycycline hyclate 100 mg tablet pack	Lymepak	PA		
doxycycline hyclate 20 mg, 100 mg tablet			A90	
doxycycline hyclate 50 mg capsule			A90	
doxycycline hyclate 50 mg tablet		PA	A90	
doxycycline hyclate 75 mg, 150 mg tablet		PA	A90	
doxycycline hyclate delayed-		PA	A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
release 50 mg, 75 mg, 100 mg, 150 mg tablet			
doxycycline hyclate delayed-release 60 mg, 80 mg, 200 mg tablet	Doryx	PA	A90
doxycycline monohydrate 150 mg capsule		PA	A90
doxycycline monohydrate 150 mg tablet		PA	A90
doxycycline monohydrate 40 mg capsule		PA	A90
doxycycline monohydrate 50 mg, 100 mg capsule			A90
doxycycline monohydrate 50 mg, 75 mg, 100 mg tablet			A90
doxycycline monohydrate 75 mg capsule		PA	A90
doxycycline monohydrate suspension			A90
minocycline capsule			A90
minocycline extended-release 45 mg, 90 mg, 135 mg tablet		PA	A90
minocycline extended-release 55 mg, 65 mg, 80 mg, 105 mg, 115 mg tablet	Solodyn		BP, A90
minocycline tablet		PA	A90
omadacycline tablet	Nuzyra	PA	
tetracycline capsule			A90
tetracycline tablet		PA	A90

Antibiotics: Oral and Inhaled – Macrolides

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
azithromycin injection, suspension, tablet	Zithromax		# , A90	• Azithromycin is available as 250 mg and 500 mg tablets, 100 mg/5mL and 200 mg/5mL suspensions, and one gram powder packets. The tablet and suspension formulations are significantly less costly. PA is required for the one gram powder packet.
azithromycin powder packet	Zithromax	PA	A90	
clarithromycin			A90	
clarithromycin		PA	A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
extended-release				• Clarithromycin is available in extended-release and immediate-release formulations. The immediate-release formulation is available without PA.
erythromycin delayed-release capsule, tablet			A90	
erythromycin ethylsuccinate suspension	Eryped		# , A90	
erythromycin stearate tablet			A90	
erythromycin tablet			A90	

Antibiotics: Oral and Inhaled – Antitubercular Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
bedaquiline	Sirturo	PA		
cycloserine			A90	
ethambutol	Myambutol		# , A90	
ethionamide	Trecator			
isoniazid			A90	
pretomanid			A90	
pyrazinamide			A90	
rifabutin	Mycobutin		BP, A90	
rifampin	Rifadin		# , A90	
rifapentine	Priftin			

Antibiotics: Oral and Inhaled – Cephalosporins

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
cefaclor capsule			A90	• Cefadroxil tablet requires PA. Cefadroxil capsule and suspension are less-costly alternatives and are available without PA. • Cefaclor is available as extended-release and immediate-release formulations. The immediate-release formulation is available without PA. • Cefpodoxime suspension requires PA. Cefpodoxime tablets are less costly and available without PA. Cefdinir, another third-generation cephalosporin, comes in a suspension formulation that is available without PA. • Cephalexin capsules are available in 250 mg, 500 mg, and 750 mg strengths. The 250 mg and 500 mg capsules are significantly less costly. PA is required for cephalexin 750 mg capsules.
cefaclor extended-release		PA	A90	
cefaclor suspension		PA	A90	
cefadroxil capsule, suspension			A90	
cefadroxil tablet		PA	A90	
cefdinir			A90	
cefixime		PA	A90	
cefpodoxime suspension		PA	A90	
cefpodoxime tablet			A90	
cefprozil			A90	
cefuroxime axetil			A90	
cephalexin 250 mg, 500 mg capsule, suspension			A90	
cephalexin 750 mg capsule		PA	A90	

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Infections (site and location vary by indication for requested agent)

Non-FDA-approved, for example:

- Infections (site and location vary by indication for requested agent)

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Aemcolo

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response or adverse reaction to one of the following: ciprofloxacin, levofloxacin; **or**
    - inadequate response, adverse reaction, or contraindication to azithromycin; **or**
    - contraindication to fluoroquinolones and azithromycin; and

- inadequate response, adverse reaction, or contraindication to Xifaxan (rifaximin) 200 mg
- requested quantity is ≤ 12 tablets/three days.

amoxicillin/clavulanate extended-release, azithromycin powder packet, cefaclor extended-release, cefaclor suspension, cefadroxil tablet, cefpodoxime suspension, cephalexin 750 mg capsule, ciprofloxacin 100 mg tablet, clarithromycin extended-release, metronidazole 375 mg capsule, and tetracycline tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to one other clinically appropriate, less-costly antibiotic; **and**
  - medical necessity for the requested formulation instead of formulations available without PA.

Alinia suspension

- Documentation of all of the following is required for a diagnosis of giardiasis:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member is ≥ one year of age; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: metronidazole, tinidazole.
- Documentation of all of the following is required for a diagnosis of cryptosporidiosis:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member is ≥ one year of age.
- Documentation of all of the following is required for a diagnosis of Helicobacter pylori:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following:
    - clarithromycin-based triple therapy containing metronidazole: proton pump inhibitor, clarithromycin, and metronidazole; **and**
    - bismuth quadruple therapy: proton pump inhibitor, bismuth subsalicylate, metronidazole, and tertracycline.

Arikayce

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member has completed a minimum of six consecutive months of a multidrug background regimen therapy; **and**
  - requested agent will be used as part of a combination antibacterial drug regimen to treat nontuberculous mycobacteria (*Mycobacterium avium* complex) lung disease; **and**
  - prescriber is a specialist (e.g., pulmonologist, infectious disease specialist) or consult notes from a specialist are provided.

Augmentin 125/31.25 mg/5mL suspension

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member is < 12 weeks of age; **or**
    - requested dose is too difficult to measure using the 250/62.5 mg/5 mL formulation.

Baxdela tablet and Nuzyra tablet, for non-MRSA community acquired bacterial pneumonia (CABP)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication all of the following: amoxicillin, amoxicillin/clavulanate,

ampicillin/sulbactam, azithromycin, cefotaxime, cefpodoxime, ceftriaxone, cefuroxime, clarithromycin, doxycycline, levofloxacin, moxifloxacin.

Baxdela tablet and Nuzyra tablet for suspected or confirmed MRSA acute bacterial skin and skin structure infection (ABSSSI) or suspected or confirmed mixed pathogen (including MRSA) ABSSSI

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - culture is positive for MRSA and inadequate response or adverse reaction to one or contraindication to all of the following: sulfamethoxazole-trimethoprim, clindamycin, vancomycin IV, linezolid, doxycycline, minocycline; **or**
    - member has a history of past MRSA infection and inadequate response or adverse reaction to two or contraindication to all of the following: sulfamethoxazole-trimethoprim, clindamycin, vancomycin IV, linezolid, doxycycline, minocycline; **and**
  - for suspected or confirmed mixed pathogen infections (including MRSA), inadequate response, adverse reaction, or contraindication to one other antibiotic with gram negative coverage available without PA.

Baxdela tablet and Nuzyra tablet for suspected or confirmed mixed pathogen non-MRSA ABSSSI

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all antibiotics with appropriate coverage for pathogens available without PA.

cefixime

- Documentation of all of the following is required:
  - appropriate diagnosis (e.g., genitourinary tract infections, respiratory tract infections, skin and skin structure infections); **and**
  - for suspension, one of the following:
    - member is < 13 years of age; **or**
    - medical necessity for use of suspension formulation instead of the capsule formulation; **and**
  - for capsules, requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication (e.g., culture not susceptible) to both of the following: cefdinir, cefpodoxime; **or**
    - member is completing a course of therapy which was initiated while a hospital inpatient.

SmartPA: Claims for cefixime capsule will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a diagnosis of genitourinary tract infections, respiratory tract infections, or skin and skin structure infections, there is a history of at least one paid MassHealth pharmacy claim for cefdinir or cefpodoxime in the last 90 days and the current claim plus history ≤ one unit/day.†

SmartPA: Claims for cefixime suspension will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a diagnosis of genitourinary tract infections, respiratory tract infections, or skin and skin structure infections, member's age < 13 years of age, and there is a history of at least one paid MassHealth pharmacy claim for cefdinir or cefpodoxime in the last 90 days.†

Coartem > 24 units/365 days

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limit.

Dificid

- Documentation of all of the following is required:
  - diagnosis of clostridium difficile-associated diarrhea (CDAD) that is not considered to be fulminant disease; **and**
  - member is ≥ six months of age; **and**
  - appropriate dosing.

Doryx (doxycycline hyclate delayed-release 60 mg tablet), doxycycline hyclate 50 mg, 75 mg, and 150 mg tablet, doxycycline hyclate delayed-release 50 mg, 75 mg, 80 mg, 100 mg, 150 mg, and 200 mg tablet, doxycycline monohydrate 40 mg and 75 mg capsule, and doxycycline monohydrate 150 mg capsule and tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to one doxycycline hyclate or monohydrate formulation available without PA; **and**
  - medical necessity for the requested formulation instead of doxycycline formulations available without PA.

Egaten

- Documentation of all of the following is required:
  - diagnosis of Fascioliasis; **and**
  - member is ≥ six years of age; **and**
  - prescriber is an infectious disease specialist or consult notes from an infectious disease specialist regarding the use of the agent are provided; **and**
  - appropriate dosing.

Krintafel > 2 units/365 days

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is receiving the requested agent in combination with chloroquine therapy; **and**
  - medical necessity for exceeding the quantity limit.

Lampit

- Documentation of all of the following is required for pediatric members:
  - appropriate diagnosis; **and**
  - member is < 18 years of age; **and**
  - appropriate dosing based on member weight; **and**
  - requested duration is ≤ 60 days; **and**
  - for members ≥ two to < 13 years of age, inadequate response, adverse reaction, or contraindication to benznidazole.
- Documentation of all of the following is required for adult members:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing based on member weight; **and**
  - requested duration is ≤ 90 days; **and**
  - inadequate response, adverse reaction, or contraindication to benznidazole.
- For recertification, documentation of medical necessity for duration of therapy exceeding 60 days in pediatric members or 90 days in adult members.

Likmez

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:

- inadequate response, adverse reaction, or contraindication to metronidazole tablets; **or**
- medical necessity for use of the suspension formulation instead of the tablet formulation.

linezolid suspension and Sivextro tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for linezolid suspension, medical necessity for use of the suspension formulation instead of the tablet formulation; **and**
  - one of the following:
    - vancomycin-resistant enterococcus (VRE) infection or suspected VRE infection and one of the following:
      - for Sivextro and one of the following:
        - inadequate response, adverse reaction, or contraindication to linezolid; **or**
        - culture is resistant to linezolid (if cultures can be obtained); **or**
      - for linezolid suspension; **or**
    - culture is positive for methicillin-resistant *Staphylococcus aureus* (MRSA) and inadequate response or adverse reaction to one or contraindication to all of the following: clindamycin, doxycycline, linezolid, minocycline, sulfamethoxazole/trimethoprim, vancomycin IV; **or**
    - member has a history of past MRSA infection and inadequate response or adverse reaction to two or contraindication to all of the following: clindamycin, doxycycline, linezolid, minocycline, sulfamethoxazole/trimethoprim, vancomycin IV.

Lymepak

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ eight years of age and weighs ≥ 45 kg; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to all doxycycline formulations available without prior authorization; **and**
  - medical necessity for the requested formulation instead of doxycycline 100 mg formulations available without prior authorization.

mebendazole

- Documentation of all of the following is required for a diagnosis of pinworm:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: albendazole, pyrantel pamoate.
- Documentation of all of the following is required for a diagnosis of whipworm, hookworm, or roundworm:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to albendazole.

minocycline extended-release 45 mg, 90 mg, 135 mg tablet, and minocycline tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for minocycline immediate-release tablet, both of the following:
    - inadequate response to minocycline capsule; **and**
    - medical necessity for the requested formulation instead of minocycline capsules; **and**
  - for minocycline extended-release tablet formulations, inadequate response, adverse reaction, or contraindication to both of the following: minocycline capsules, minocycline extended-release tablet (generic Solodyn).

nitazoxanide tablet

- Documentation of all of the following is required for a diagnosis of giardiasis:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: metronidazole, tinidazole.
- Documentation of all of the following is required for a diagnosis of cryptosporidiosis:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - member is ≥ 12 years of age.
- Documentation of all of the following is required for a diagnosis of Helicobacter pylori:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following:
    - clarithromycin-based triple therapy containing metronidazole: proton pump inhibitor, clarithromycin, and metronidazole; **and**
    - bismuth quadruple therapy: proton pump inhibitor, bismuth subsalicylate, metronidazole, and tertracycline.

nitrofurantoin 25 mg/5 mL suspension and nitrofurantoin 50 mg/5 mL suspension

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - medical necessity for use of the suspension formulation instead of the capsule formulation.

ofloxacin

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one of the following: ciprofloxacin, levofloxacin, moxifloxacin.

pyrimethamine

- Documentation of all of the following is required for toxoplasmosis treatment:
  - appropriate diagnosis; **and**
  - appropriate dosing and frequency; **and**
  - requested agent will be used as combination therapy.
- Documentation of all of the following is required for primary prophylaxis of toxoplasmosis:
  - indication is for primary prophylaxis of toxoplasmosis; **and**
  - appropriate dose and frequency; **and**
  - inadequate response, adverse reaction, or contraindication to trimethoprim-sulfamethoxazole; **and**
  - one of the following:
    - CD-4 count is < 200 cells/mm^3; **or**
    - clinical rationale for prophylaxis; **and**
  - requested agent will be used as combination therapy.
- Documentation of all of the following is required for secondary prophylaxis of toxoplasmosis:
  - indication is for secondary prophylaxis of toxoplasmosis; **and**
  - appropriate dose and frequency; **and**
  - one of the following:
    - CD-4 count is < 200 cells/mm^3; **or**
    - clinical rationale for prophylaxis; **and**
  - requested agent will be used as combination therapy.

Sirturo

- Documentation of all of the following is required for a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB):
  - appropriate diagnosis; **and**
  - requested agent will be used in combination with at least two other antitubercular agents.
- Documentation of all of the following is required for a diagnosis of non-tuberculous mycobacteria (NTM):
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one antimicrobial regimen not requiring PA, or contraindication to all regimens that do not require PA; **and**
  - requested agent will be used in combination with at least one other antitubercular agent; **and**
  - appropriate dosing.

Solosec

- Documentation of all of the following is required for a diagnosis of bacterial vaginosis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: oral or vaginal metronidazole, oral or vaginal clindamycin, oral tinidazole.
- Documentation of all of the following is required for a diagnosis of trichomoniasis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: oral metronidazole, oral tinidazole.

Tobi Podhaler

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to tobramycin inhalation solution (Kitabis Pak, Tobi).

tobramycin inhalation solution (Bethkis)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to tobramycin inhalation solution (Kitabis Pak, Tobi).

Xifaxan 550 mg

- Documentation of all of the following is required for a diagnosis of hepatic encephalopathy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to lactulose; **and**
  - requested quantity is ≤ two tablets/day.
- Docuentation of all of the following is required for a diagnosis of irritable bowel syndrome with diarrhea:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: bile acid sequestrant, bismuth subsalicylate, bulk-forming agent, diphenoxylate/atropine, loperamide, tricyclic antidepressant (TCA).
- Documentation of all of the following is required for a diagnosis of small intestinal bacterial overgrowth (SIBO):

- appropriate diagnosis; **and**
- member is ≥ 12 years of age; **and**
- inadequate response or adverse reaction to one or contraindication to all of the following: amoxicillin-clavulanate, ciprofloxacin, doxycycline, metronidazole, neomycin, norfloxacin, tetracycline, trimethoprim/sulfamethoxazole; **and**
- appropriate dosing (550 mg three times daily for 14 days).

SmartPA: Claims for Xifaxan 550 mg (≤ two tablets/day) will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a diagnosis of hepatic encephalopathy, member's age is ≥ 18 years of age, and a history of paid MassHealth pharmacy claims for lactulose.†

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plan.

MassHealth Evaluation Criteria
Table 36 - Drug and Alcohol Cessation Agents

Drug Category: Central Nervous System Agents

Medication Class/Individual Agents: Alcohol/Drug Cessation Agents

I. Prior-Authorization Requirements

Drug and Alcohol Cessation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acamprosate			A90
buprenorphine / naloxone film	Suboxone PD	PA - > 90 days (> 24 mg/day and ≤ 32 mg/day)	BP
buprenorphine / naloxone film	Suboxone PD	PA - > 32 mg/day	BP
buprenorphine / naloxone film ≤ 24 mg/day	Suboxone PD		BP
buprenorphine / naloxone sublingual tablet		PA - > 90 days (> 24 mg/day and ≤ 32 mg/day)	
buprenorphine / naloxone sublingual tablet		PA - > 32 mg/day	
buprenorphine / naloxone sublingual tablet ≤ 24 mg/day			
buprenorphine / naloxone sublingual tablet-Zubsolv	Zubsolv	PA	
buprenorphine extended-release injection-Brixadi	Brixadi	PA	
buprenorphine extended-release injection-Sublocade	Sublocade PD		
buprenorphine sublingual tablet		PA	
disulfiram			A90
lofexidine	Lucemyra	PA	
nalmefene	Opvee	PA	
naloxone 3 mg nasal spray	Rivive		
naloxone 4 mg nasal spray	Narcan		
naloxone 4 mg nasal spray			
naloxone 5 mg / 0.5 mL syringe	Zimhi		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Prescribing:

- Following the passage of the Consolidated Appropriations Act of 2023, and effective immediately, all practitioners who have a current DEA registration that includes Schedule III authority may now prescribe buprenorphine for Opioid Use Disorder in their practice if permitted by applicable state law. This also removes other federal requirements associated with the Drug Addiction and Treatment Act of 2000 (DATA 2000) that instituted discipline restrictions, patient limits, and certification related to provision of counseling.

FDA Approved Uses:

- Buprenorphine and buprenorphine/naloxone are Schedule III controlled substances approved for treatment of opioid dependence. These agents are not FDA-approved for pain management.
- Naltrexone injection is FDA-approved for the treatment of opioid and alcohol dependence in members who are abstinent at treatment initiation.

Contraindications:

- acamprosate: those who have had a hypersensitivity reaction to acamprosate in the past and severe renal impairment (creatinine clearance ≤ 30 mL/min)

Drug and Alcohol Cessation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
naloxone 8 mg nasal spray	Kloxxado PD		
naloxone syringe kit	Lifems Naloxone	PA	
naloxone vial, 0.4 mg/mL syringe, 2 mg/2 mL syringe			
naltrexone injection	Vivitrol PD		
naltrexone tablet		PA - < 6 years	A90

Clinical Notes

- buprenorphine: hypersensitivity to buprenorphine
- buprenorphine/naloxone: hypersensitivity to buprenorphine and/or to naloxone
- disulfiram: recent use of metronidazole, paraldehyde, alcohol, or alcohol-containing products, myocardial disease or coronary occlusion, psychoses and hypersensitivity to disulfiram or other thiuram derivatives
- naltrexone: current use of or dependence on opioids, acute withdrawal, those who have failed a naloxone challenge test or have a positive urine screen for opioids, acute hepatitis, or liver failure and sensitivity to naltrexone or any component of the product

Warnings/Precautions:

- acamprosate: does not eliminate or diminish withdrawal symptoms
- buprenorphine: acute alcoholism, adrenal cortical insufficiency, delirium tremens, CNS depression, respiratory depression, head injury, dependence, large doses of narcotics, hypotension
- buprenorphine/naloxone: respiratory depression, CNS depression, CNS depressants, acute abdominal conditions, acute alcoholism, adrenal cortical insufficiency, concomitant CYP3A4 inhibitors, delirium tremens, elderly or debilitated members, dependence, hepatitis, allergic reactions, head injury and increased intracranial pressure, prostatic hypertrophy or urethral stricture, and opioid withdrawal effects
- disulfiram: diabetes mellitus, disulfiram-alcohol reaction, hepatic dysfunction; hypothyroidism, epilepsy, cerebral damage, renal impairment, rubber contact dermatitis and environmental or occupational exposure to ethylene dibromide or its vapors
- naltrexone: hepatotoxicity, hepatic impairment, history of suicide attempts, with or without depression, symptoms of withdrawal

Please see the following link to find out more information regarding buprenorphine/naloxone tablets and buprenorphine/naloxone film:

https://www.mass.gov/lists/masshealth-pharmacy-publications-and-notices-for-prescribers-and-other-providers-0

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	Clinical Notes
	In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions (see below).

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Management of opioid withdrawal symptoms
- Opioid dependence

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Brixadi

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**

- member has been initiated on treatment with a single dose of a transmucosal buprenorphine product or is already being treated with buprenorphine; **and**
- clinical rationale for use of Brixadi instead of Sublocade documented as one of the following:
  - inadequate response or adverse reaction to Sublocade that cannot be expected or managed as part of buprenorphine therapy; **or**
  - medical necessity for weekly dosing; **or**
  - documented low belly fat inhibiting proper Sublocade administration; **or**
  - documented low body fat with BMI below 8.5 and attestation that Sublocade administration would cause harm to the patient.

buprenorphine tablet ≤ 24 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for prescribing buprenorphine instead of buprenorphine/naloxone documented as one of the following:
    - medical records documenting naloxone allergy; **or**
    - current pregnancy (request must include anticipated date of delivery); **or**
    - member is breastfeeding; **or**
    - prescriber documents desire to avoid buprenorphine/naloxone due to moderate-to-severe hepatic impairment (i.e., Child-Pugh B to C).

buprenorphine tablet > 24 mg/day to ≤ 32 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for prescribing buprenorphine instead of buprenorphine/naloxone documented as one of the following:
    - medical records documenting naloxone allergy; **or**
    - current pregnancy (request must include anticipated date of delivery); **or**
    - member is breastfeeding; **or**
    - prescriber documents desire to avoid buprenorphine/naloxone due to moderate-to-severe hepatic impairment (i.e., Child-Pugh B to C); **and**
  - one of the following:
    - this is the lowest effective dose for the member; **or**
    - complete treatment plan.

buprenorphine tablet > 32 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for prescribing buprenorphine instead of buprenorphine/naloxone documented as one of the following:
    - medical records documenting naloxone allergy; **or**
    - current pregnancy (request must include anticipated date of delivery); **or**
    - member is breastfeeding; **or**
    - prescriber documents desire to avoid buprenorphine/naloxone due to moderate-to-severe hepatic impairment (i.e., Child-Pugh B to C); **and**
  - medical necessity for dosing greater than 32 mg/day as noted by CYP3A4 genotyping confirming member is a rapid CYP3A4 metabolizer.

buprenorphine/naloxone film and buprenorphine/naloxone tablet > 24 mg/day to ≤ 32 mg/day for > 90 days

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - this is the lowest effective dose for the member; **or**
    - complete treatment plan.

buprenorphine/naloxone film and buprenorphine/naloxone tablet > 32 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**

- medical necessity for dosing greater than 32 mg/day as noted by CYP3A4 genotyping confirming member is a rapid CYP3A4 metabolizer.

Lifems Naloxone

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale to establish medical necessity of the convenience kit formulation, as it pertains to the caregiver; **and**
  - requested quantity is ≤ 2 kits/year.

lofexidine

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to oral clonidine; **and**
  - requested dose is ≤ 0.72 mg four times daily; **and**
  - requested duration is ≤ 14 days.

Opvee

- Documentation of all of the following is required:
  - indication is opioid overdose prevention/reversal; **and**
  - medical necessity for the use of a long-acting formulation for overdose reversal; **and**
  - requested quantity is ≤ two inhalers/year.

Zubsolv ≤ 17.2 mg/4.3 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction to buprenorphine/naloxone film that is allergic in nature, or cannot be expected or managed during the course of buprenorphine therapy.

Zubsolv > 17.2 mg/4.3 mg/day to ≤ 22.8 mg/5.8 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction to buprenorphine/naloxone film that is allergic in nature, or cannot be expected or managed during the course of buprenorphine therapy; **and**
  - one of the following:
    - this is the lowest effective dose for the member; **or**
    - complete treatment plan.

Zubsolv > 22.8 mg/5.8 mg/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction to buprenorphine/naloxone film that is allergic in nature, or cannot be expected or managed during the course of buprenorphine therapy; **and**
  - medical necessity for dosing greater than 22.8/5.8 mg/day as noted by CYP3A4 genotyping confirming member is a rapid CYP3A4 metabolizer.

Behavioral Health Medication Polypharmacy ***(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, and viloxazine] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:

- one of the following:
  - member had a recent psychiatric hospitalization (within the last three months); **or**
  - member has a history of severe risk of harm to self or others; **or**
- all of the following:
  - appropriate diagnoses; **and**
  - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; and
  - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**
      - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
      - cross-titration/taper of mood stabilizer therapy; **or**
      - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
      - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
      - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, and one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

naltrexone for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**

- member has a history of severe risk of harm to self or others; **or**

- all of the following:
  - appropriate diagnosis; **and**
  - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
  - prescriber is a specialist (e.g. psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

†**Note**: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.
Please see the following link to find out more information regarding buprenorphine/naloxone tablets and buprenorphine/naloxone film: https://www.mass.gov/lists/masshealth-pharmacy-publications-and-notices-for-prescribers-and-other-providers-0.

MassHealth Evaluation Criteria
Table 37 - Respiratory Syncytial Virus (RSV) Prophylaxis Agents

Drug Category: Respiratory Tract Agents

Medication Class/Individual Agents: Individual Agent: Immunologic Agents

I. Prior-Authorization Requirements

RSV Prophylaxis Agents				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
nirsevimab-alip	Beyfortus	PA - ≥ 8 months of age		**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** **RSV Prophylaxis Agents Evaluation Criteria:** • Evaluation criteria are based on recommendations from the Massachusetts Chapter of the American Academy of Pediatrics (AAP). • Nirsevimab-alip and palivizumab are intended for the prophylaxis of respiratory syncytial virus (RSV) and not for the treatment of patients currently infected with RSV • In most regions of the Northern Hemisphere, the first dose of palivizumab should be administered at the beginning of November and the last dose should be administered at the beginning of March, which will provide protection into April. Polymerase chain reaction (PCR) testing for RSV uses a 3% threshold to determine the weekly percentage of tests positive and allows for a reasonable estimation of RSV season where RSV testing is not performed or reported throughout the year. This method (3% threshold) defines season onset as the first of two consecutive weeks when the weekly percentage of tests positive for RSV was >3%.
palivizumab	Synagis	PA		

II. Therapeutic Uses

FDA-approved, for example:

- prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of severe RSV disease

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Beyfortus in members ≥ eight months of age

- Documentation of all of the following is required:
  - appropriate indication; **and**
  - member is ≥ eight months to < 20 months of age; **and**
  - appropriate dosing; **and**
  - one of the following:
    - member is severely immunocompromised; **or**
    - cystic fibrosis with manifestations of severe lung disease; **or**
    - member is American Indian or Alaska Native descent; **or**
    - chronic lung disease of prematurity who require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the six-month period before start of the RSV season or bronchopulmonary dysplagia; **or**
    - congenital diaphragmatic hernia and comorbid chronic lung disease; **or**
    - Down syndrome and comorbid congenital heart disease, chronic lung disease, airway clearance issues, or prematurity; **or**
    - congenital abnormality of the airway or neuromuscular disease; **or**
    - congenital heart disease; **or**
    - underwent cardiopulmonary bypass procedure.

Synagis for chronic lung disease (CLD) of prematurity or bronchopulmonary dysplasia (BPD)

- Documentation of all of the following is required:
  - appropriate indication; **and**

- inadequate response, adverse reaction, or contraindication to Beyfortus; **and**
- one of the following:
  - member is < 12 months of age at the start of the RSV season and has all of the following:
    - diagnosis of CLD or BPD; **and**
    - gestational age < 32 weeks 0 days; **and**
    - a requirement for supplemental oxygen for at least the first 28 days after birth; **or**
  - member is < 24 months of age at the start of the RSV season and has all of the following:
    - diagnosis of CLD or BPD; **and**
    - gestational age < 32 weeks 0 days; **and**
    - a requirement for supplemental oxygen for at least the first 28 days after birth; **and**
    - member continues to require medical support within the six months prior to the start of the RSV season with chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen.

Synagis for prematurity

- Documentation of all of the following is required:
  - appropriate indication; **and**
  - member is < 12 months of age at the start of the RSV season with a gestational age < 29 weeks 0 days; **and**
  - inadequate response, adverse reaction, or contraindication to Beyfortus.

Synagis for congenital heart disease (CHD)

- Documentation of all of the following is required:
  - appropriate indication; **and**
  - inadequate response, adverse reaction, or contraindication to Beyfortus; **and**
  - member is < 12 months of age at the start of the RSV season and has all of the following:
    - hemodynamically significant CHD; **and**
    - one of the following:
      - moderate-to-severe pulmonary hypertension; **or**
      - member requires medication (s) to control congestive heart failure and will require cardiac surgical procedures; **or**
      - member has evidence of cyanotic heart disease and prescriber is a pediatric cardiologist or has consulted with a pediatric cardiologist.

MassHealth Evaluation Criteria
Table 38 - Antiretroviral/HIV Therapy

Drug Category: Anti-infectives

Medication Class/Individual Agents: Antiretroviral/HIV Therapy

I. Prior-Authorization Requirements

Antiretroviral/HIV Therapy – Integrase Strand Transfer Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cabotegravir injection	Apretude PD		
cabotegravir tablet	Vocabria		
dolutegravir tablet	Tivicay	PA - > 1 unit/day	
dolutegravir tablet for oral suspension	Tivicay PD		
raltegravir	Isentress		BP

Antiretroviral/HIV Therapy – Protease Inhibitors (PI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
atazanavir	Reyataz		# , A90
darunavir	Prezista		# , A90
fosamprenavir	Lexiva	PA	A90
lopinavir / ritonavir	Kaletra		# , A90
nelfinavir	Viracept		
ritonavir packet	Norvir		
ritonavir tablet	Norvir PD		BP, A90
tipranavir	Aptivus		

Antiretroviral/HIV Therapy – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
abacavir / dolutegravir / lamivudine	Triumeq PD		
abacavir / lamivudine	Epzicom		# , A90
abacavir / lamivudine / zidovudine	Trizivir		# , A90
atazanavir / cobicistat	Evotaz		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Cabotegravir injection:

- Cabotegravir injection is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired human immunodeficiency virus type 1 (HIV-1) infection. Individuals must have a negative HIV-1 test prior to PrEP initiation and must be tested with each subsequent injection due to reports of drug-resistant HIV-1 variants when used by individuals with undiagnosed HIV-1 infection.

Fostemsavir:

- Fostemsavir in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

Ibalizumab-uiyk:

- Ibalizumab-uiyk, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug

Antiretroviral/HIV Therapy – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bictegravir / emtricitabine / tenofovir alafenamide	Biktarvy PD		
cabotegravir / rilpivirine	Cabenuva PD		
darunavir / cobicistat	Prezcobix PD		
darunavir / cobicistat / emtricitabine / tenofovir alafenamide	Symtuza PD		
dolutegravir / lamivudine	Dovato PD		
dolutegravir / rilpivirine	Juluca PD		
doravirine / lamivudine / tenofovir disoproxil fumarate	Delstrigo PD		
efavirenz / emtricitabine / tenofovir	Atripla		# , A90
efavirenz 400 mg / lamivudine 300 mg / tenofovir disoproxil fumarate 300 mg	Symfi Lo	PA	A90
efavirenz 600 mg / lamivudine 300 mg / tenofovir disoproxil fumarate 300 mg	Symfi	PA	A90
elvitegravir / cobicistat / emtricitabine / tenofovir alafenamide	Genvoya PD		
elvitegravir / cobicistat / emtricitabine / tenofovir disoproxil fumarate	Stribild		
emtricitabine / rilpivirine / tenofovir alafenamide	Odefsey PD		
emtricitabine / rilpivirine / tenofovir disoproxil fumarate	Complera		BP
emtricitabine / tenofovir alafenamide	Descovy PD		

Clinical Notes

resistant HIV-1 infection failing their current antiretroviral regimen.

Maraviroc Black Box Warning:

- Hepatotoxicity has been reported with maraviroc use. Evidence of a systemic allergic reaction (e.g., pruritic rash, eosinophilia, or elevated IgE) prior to the development of hepatotoxicity may occur. Members with signs or symptoms of hepatitis or allergic reaction following use of maraviroc should be evaluated immediately.

Maraviroc Warnings:

- Caution should be used when administering maraviroc to members with preexisting liver dysfunction or who are co-infected with viral hepatitis B or C.
- More cardiovascular events including myocardial ischemia and/or infarction were observed in members who received maraviroc. Use with caution in members at increased risk of cardiovascular events.

Antiretroviral/HIV Therapy – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
emtricitabine / tenofovir disoproxil fumarate	Truvada		# , A90
lamivudine / tenofovir disoproxil fumarate	Cimduo	PA	
lamivudine / zidovudine	Combivir		# , A90

Antiretroviral/HIV Therapy – Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
doravirine	Pifeltro PD		
efavirenz			A90
etravirine	Intelence		BP, A90
nevirapine			A90
nevirapine extended-release		PA	A90
rilpivirine	Edurant		BP

Antiretroviral/HIV Therapy – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
cobicistat	Tybost		
tesamorelin	Egrifta SV	PA	

Antiretroviral/HIV Therapy – Nucleoside Analog Reverse Transcriptase Inhibitors (NRTI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
abacavir	Ziagen		# , A90
didanosine			A90
emtricitabine	Emtriva		BP, A90
lamivudine 10 mg/mL solution	Epivir		# , A90
lamivudine 150 mg, 300 mg tablet	Epivir		# , A90
stavudine			A90
zidovudine	Retrovir		# , A90

Antiretroviral/HIV Therapy – Fusion Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
enfuvirtide	Fuzeon		

Antiretroviral/HIV Therapy – gp120 Attachment Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fostemsavir	Rukobia PD	PA	

Antiretroviral/HIV Therapy – CCR5 Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
maraviroc solution	Selzentry	PA	
maraviroc tablet	Selzentry	PA	A90

Antiretroviral/HIV Therapy – Capsid Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
lenacapavir	Sunlenca	PA	

Antiretroviral/HIV Therapy – CD4-Directed Post-Attachment Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ibalizumab-uiyk	Trogarzo	PA	

Antiretroviral/HIV Therapy – Nucleotide Analog Reverse Transcriptase Inhibitors (NtRTI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tenofovir disoproxil fumarate powder	Viread	PA - ≥ 13 years	A90
tenofovir disoproxil fumarate tablet	Viread	PA - > 1 unit/day	# , A90

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- HIV-associated visceral adipose tissue accumulation (VAT) lipodystrophy (Egrifta)
- HIV infection (Cimduo, efavirenz/lamivudine/tenofovir disoproxil fumarate, fosamprenavir, maraviroc, nevirapine extended-release, Rukobia, Senlenca, tenofovir disoproxil fumarate, Tivicay, Trogarzo)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Cimduo

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member is ≥ 18 years of age; **or**
    - member is < 18 years of age and weighs ≥ 35 kg; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents as defined by one of the following:
    - significant psychiatric diagnosis leading to documented difficulty with adherence; **or**
    - homeless members who may have difficulty storing larger amounts of medications; **or**
    - difficulty with adherence leading to complications; **or**
    - child/adolescent member or a member with developmental issues without adequate supports to properly manage their own HIV

regimen; **and**
- concurrent antiretroviral therapy with at least one other antiretroviral; **and**
- requested quantity is ≤ one unit/day.

efavirenz 400 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member is ≥ 18 years of age; **or**
    - member is < 18 years of age and weighs ≥ 35 kg; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents as defined by one of the following:
    - significant psychiatric diagnosis leading to documented difficulty with adherence; **or**
    - homeless members who may have difficulty storing larger amounts of medications; **or**
    - difficulty with adherence leading to complications; **or**
    - child/adolescent member or a member with developmental issues without adequate supports to properly manage their own HIV regimen; **and**
  - requested quantity is ≤ one unit/day.

efavirenz 600 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - member is ≥ 18 years of age; **or**
    - member is < 18 years of age and weighs ≥ 40 kg; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents as defined by one of the following:
    - significant psychiatric diagnosis leading to documented difficulty with adherence; **or**
    - homeless members who may have difficulty storing larger amounts of medications; **or**
    - difficulty with adherence leading to complications; **or**
    - child/adolescent member or a member with developmental issues without adequate supports to properly manage their own HIV regimen; **and**
  - requested quantity is ≤ one unit/day.

Egrifta SV
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dose and frequency; **and**
  - antiretroviral therapy for ≥ 60 days within the last 90 days; **and**
  - other potential causes of VAT accumulation/central obesity have been ruled out; **and**
  - one of the following:
    - for male member, waist circumference is currently > 102 cm; **or**
    - for female member, waist circumference is currently > 88 cm; **and**
  - member has failed lifestyle modification with diet and exercise.
- For recertification, documentation of a decrease in waist circumference from baseline is required.

fosamprenavir

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to an antiretroviral regimen containing one of the following protease inhibitors: atazanavir, darunavir, ritonavir; **and**
  - concurrent antiretroviral therapy with at least one other antiretroviral; **and**
  - appropriate dosing.

maraviroc
- Documentation of the following is required:
  - appropriate diagnosis.

SmartPA: Claims for maraviroc will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for HIV disease. †

nevirapine extended-release
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to nevirapine immediate-release formulation.

Rukobia and Sunlenca for HIV-1 infection
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - ongoing detectable viremia; **and**
  - antiretroviral-experienced with documented historical or baseline resistance, intolerability, and/or contraindication to antiretroviral; **and**
  - failing current antiretroviral regimen due to resistance, intolerance or safety considerations; **and**
  - concurrent antiretroviral therapy with at least one other antiretroviral; **and**
  - appropriate dosing; **and**
  - for Rukobia, requested quantity is ≤ two units/day.

tenofovir disoproxil fumarate tablet > one unit/day
- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - HIV infection; **or**
    - Chronic Hepatitis B; **and**
  - medical necessity for exceeding the quantity limit.

Tivicay > one unit/day
- For members <18 years of age, documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - concurrent therapy with efavirenz, fosamprenavir/ritonavir, Aptivus (tipranavir)/ritonavir, rifampin, or carbamazepine.
- For members ≥18 years of age, documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - concurrent therapy with efavirenz, fosamprenavir/ritonavir, Aptivus (tipranavir)/ritonavir, rifampin, or carbamazepine; **or**
    - integrase strand transfer inhibitor (INSTI)-associated resistance substitutions or clinically suspected INSTI-resistance.

Trogarzo
- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- member is ≥ 18 years of age; **and**
- ongoing detectable viremia; **and**
- resistance to at least one agent from each of the following three classes of antiretrovirals: NRTI, NNRTI, PI; **and**
- concurrent antiretroviral therapy with at least one other antiretroviral; **and**
- appropriate dosing; **and**
- inadequate response or adverse reaction to one or contraindication to both of the following: Rukobia, Sunlenca.

Viread powder ≥ 13 years of age

- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - HIV infection; **or**
    - Chronic Hepatitis B; **and**
  - swallowing disorder or condition affecting ability to swallow tablets (i.e., dysphagia).

SmartPA: Claims will usually process at the pharmacy without a PA for members ≥ 13 years of age request if the member has a history of paid MassHealth pharmacy claims of the requested medication for at least 90 days out of the last 120 days.†

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 39 - Influenza Prophylaxis and Treatment Agents

Drug Category: Anti-infectives

Medication Class/Individual Agents: Antiviral/Influenza

I. Prior-Authorization Requirements

Influenza Prophylaxis and Treatment Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
baloxavir	Xofluza	PA	
oseltamivir 30mg	Tamiflu	PA - > 20 units/ claim and PA > 40 units/ 365 days	#
oseltamivir 45 mg and 75 mg	Tamiflu	PA - > 10 units/ claim and PA > 20 units/ 365 days	#
oseltamivir suspension	Tamiflu	PA - > 180 mL/ claim and PA > 360 mL/ 365 days	#
zanamivir	Relenza	PA - < 5 years and PA > 20 inhalations/ claim and PA > 40 inhalations/ 365 days	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Contraindications:

- Zanamivir: hypersensitivity to any component of the product including lactose (milk proteins)

Warnings:

- Zanamivir: airway disease (e.g., COPD, asthma)
- Oseltamivir: hereditary fructose intolerance (with suspension), renal impairment, self-injury and delirium, and serious skin reactions

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

II. Therapeutic Uses

FDA-approved, for example:

- Influenza Type A and B (oseltamivir ≥ two weeks of age; Relenza ≥ seven years of age; Xofluza ≥ 12 years of age)
- Prophylaxis of Influenza Type A and B (oseltamivir ≥ one year of age; Relenza ≥ five years of age; Xofluza ≥ 12 years of age)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available)

require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Prophylaxis

oseltamivir and Relenza

- Documentation of all of the following is required for prophylaxis requests above the quantity limit:
  - if the request is for Relenza, member is five years of age or older; **and**
  - one of the following:
    - member is a resident in an institutional setting; **or**
    - both of the following:
      - one of the following:
        - member with likely exposure to others with confirmed, probable, or suspected influenza infection and are at risk of developing influenza-related complications with at least one risk factor, including:
          - members ≥ 65 years of age; **or**
          - members ≤ five years of age; **or**
          - members < 19 years of age who are receiving long-term aspirin therapy; **or**
          - residents of nursing homes or chronic care facilities; **or**
          - pregnant members and members up to two weeks postpartum; **or**
          - members with chronic medical conditions including:
            - chronic pulmonary disease (e.g., asthma, chronic obstructive pulmonary disease, cystic fibrosis); **or**
            - cardiovascular disease (except isolated hypertension); **or**
            - renal dysfunction; **or**
            - hepatic dysfunction; **or**
            - chronic metabolic or endocrine disease (e.g., diabetes mellitus, mitochondrial disease); **or**
            - hemoglobinopathies (e.g., sickle cell disease); **or**
            - immunosuppression, including HIV infection, organ or hematopoietic cell transplantation, malignancy (if prescriber notes immunosuppression is a concern), and inflammatory disorders treated with immunosuppressants; **or**
            - neurologic conditions that compromise handling of respiratory secretions (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, neuromuscular disorders); **or**
        - members from certain racial and ethnic minority groups are at increased risk for hospitalization with flu, including non-Hispanic Black members, Hispanic or Latino members, and American Indian or Alaska Native members; **or**
        - members who are morbidly obese (body mass index ≥ 40); **or**
      - members who work in institutions caring for individuals at high risk of serious complications of influenza infection during

an institutional outbreak; **and**

- one of the following:
  - requested dose and duration is consistent with current CDC recommendations; **or**
  - medical necessity for going above standard dosing or duration recommendations.

SmartPA: Claims for oseltamivir above quantity limits and Relenza above quantity limits (in members ≥ five years) will usually process at the pharmacy without a PA if MassHealth pharmacy claims data indicate the member is currently in an institutional setting.†

Treatment

oseltamivir and Relenza

- Documentation of all of the following is required for treatment requests above the quantity limit:
  - if the request is for Relenza, member is seven years of age or older; **and**
  - one of the following:
    - member is a resident in an institutional setting; **or**
    - all of the following:
      - member with confirmed, probable, or suspected influenza; **and**
      - member is at high risk for developing serious influenza-related complications with at least one risk factor (see above); **and**
      - one of the following:
        - requested dose and duration is consistent with current CDC recommendations; **or**
        - medical necessity for going above standard dosing or duration recommendations.

SmartPA: Claims for oseltamivir above quantity limits and Relenza above quantity limits (in members ≥ five years) will usually process at the pharmacy without a PA if MassHealth pharmacy claims data indicate the member is currently in an institutional setting.†

Xofluza

- Documentation of all of the following is required for prophylaxis or treatment requests:
  - member is 12 years of age or older; **and**
  - one of the following:
    - member with confirmed, probable, or suspected influenza; **or**
    - member with exposure to an individual with confirmed influenza infection; **and**
  - medical necessity for the use of single-dose preparation instead of treatment course with oseltamivir capsules; **and**
  - appropriate dosing; **and**
  - one of the following:
    - for the 20 mg tablet, requested quantity is ≤ two tablets per treatment; **or**
    - for the 40 mg and 80 mg tablets, requested quantity is ≤ one tablet per treatment.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 40 - Respiratory Agents - Oral

Drug Category: Respiratory Tract Agents

Medication Class/Individual Agents: Respiratory Agents - Oral

I. Prior-Authorization Requirements

Oral Respiratory Agents – Leukotriene Modifiers			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
montelukast granules	Singulair	PA	M90
montelukast tablet, chewable tablet	Singulair		# , M90
zafirlukast	Accolate	PA	M90
zileuton	Zyflo	PA	
zileuton extended-release		PA	

Oral Respiratory Agents – Selective Phosphodiesterase 4 [PDE4] Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
roflumilast tablet	Daliresp	PA	M90

Oral Respiratory Agents – Pulmonary Fibrosis Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nintedanib	Ofev	PA	
pirfenidone	Esbriet	PA	A90

Oral Respiratory Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
theophylline			M90

Oral Respiratory Agents – Short-Acting Beta Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
albuterol syrup, tablet			A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Contraindications:

- All agents: hypersensitivity to any component
- roflumilast tablet:
  - moderate-to-severe liver impairment
- zileuton:
  - active liver disease
  - persistent liver enzyme elevations three or more times the upper limit of normal

Warnings:

- montelukast
  - Should not be used to treat an acute asthma attack: member should have short-acting beta-agonist
  - Should not be abruptly substituted for steroids
  - Neuropsychiatric events (e.g., agitation, aggressive behavior, depression, suicidal ideation, etc.) have been reported with use of this agent
  - Eosinophilic conditions (e.g., vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy) may present in asthmatic members taking montelukast)
  - Chewable tablets contain phenylalanine
- nintedanib

	Clinical Notes
	• Do not use in moderate or severe liver impairment • Increased risk of bleeding • Increased risk of gastrointestinal perforation • pirfenidone • Liver enzyme elevations three times the upper limit of normal • Photosensitivity reaction or rash • roflumilast tablet • Should not be used to treat an acute asthma attack • May be associated with unexplained weight loss • Use with potential cytochrome P450 enzyme inducers may decrease roflumilast concentrations • Psychiatric events including suicidality have been reported with this agent. Use with caution in those with history of depression and/or suicidal thoughts • zafirlukast • Liver disease • Not for reversal of bronchospasm in acute asthma • zileuton • Alcohol intake of substantial quantities • Liver disease • Not for reversal of bronchospasm in acute asthma • Neuropsychiatric events (e.g., sleep disorders and behavior changes) have been reported with use of this agent

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- asthma (montelukast, zafirlukast, zileuton extended-release, Zyflo)
- allergic rhinitis (montelukast)
- chronic obstructive pulmonary disease (roflumilast tablet)
- exercise-induced bronchospasm (montelukast)
- chronic fibrosing interstitial lung diseases with a progressive phenotype (Ofev)
- idiopathic pulmonary fibrosis (Ofev, pirfenidone)
- systemic sclerosis-associated interstitial lung disease (Ofev)

Non-FDA-approved, for example:

- eosinophilic esophagitis (montelukast)

- urticaria (montelukast)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

montelukast granules

- Documentation of the following is required for the diagnosis of allergic rhinitis:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to one oral second-generation antihistamine (i.e., loratadine, cetirizine, fexofenadine); **and**
  - inadequate response (defined as ≥ 14 days of therapy), adverse reaction, or contraindication to one intranasal antihistamine or intranasal corticosteroid; **and**
  - medical necessity for the granule formulation as noted by one of the following:
    - member is < two years of age; **or**
    - inadequate response or adverse reaction to montelukast chewable tablets; **and**
  - requested quantity is ≤ one unit/day.
- Documentation of the following is required for the diagnosis of asthma:
  - appropriate diagnosis; **and**
  - medical necessity for the granule formulation as noted by one of the following:
    - member is < two years of age; **or**
    - inadequate response or adverse reaction to montelukast chewable tablets; **and**
  - requested quantity is ≤ one unit/day.
- Documentation of the following is required for the diagnosis of eosinophilic esophagitis:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 60 days of therapy) or adverse reaction to one or contraindication to all proton pump inhibitors; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to both of the following: topical budesonide, topical fluticasone.

- Documentation of the following is required for the diagnosis of Exercise-Induced Bronchospasm (EIB):
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: one short-acting beta agonist inhaler (albuterol or levalbuterol), low dose inhaled corticosteroid-formoterol; **and**
  - medical necessity for the granule formulation as noted by one of the following:
    - member is < two years of age; **or**
    - inadequate response or adverse reaction to montelukast chewable tablets; **and**
  - requested quantity is ≤ one unit/day.
- Documentation of the following is required for the diagnosis of urticaria:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all second-generation antihistamines; **and**
  - medical necessity for the granule formulation as noted by one of the following:
    - member is < two years of age; **or**
    - inadequate response or adverse reaction to montelukast chewable tablets.

Ofev and pirfenidone for idiopathic pulmonary fibrosis
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - for pirfenidone 267 mg, requested quantity is ≤ nine units/day; **or**
    - for pirfenidone 534 mg, requested quantity is ≤ three units/day; **or**
    - for pirfenidone 801 mg, requested quantity is ≤ three units/day; **or**
    - for Ofev, requested quantity is ≤ two units/day.

Ofev for chronic fibrosing interstitial lung diseases with a progressive phenotype
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ two units/day.

Ofev for systemic sclerosis-associated interstitial lung disease
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: cyclophosphamide, mycophenolate; **and**
  - requested quantity is ≤ two units/day.

roflumilast tablet
- Documentation of the following is required:
  - diagnosis of Chronic Obstructive Pulmonary Disease (COPD); **and**
  - inadequate response (within the last four months) or adverse reaction to one or contraindication to all long-acting bronchodilator (long-acting beta-agonist, long-acting anticholinergic); **and**
  - inadequate response (within the last four months) or adverse reaction to one or contraindication to all inhaled corticosteroids; **and**
  - requested quantity is ≤ one unit/day.

SmartPA: Claims for roflumilast 500 mg tablet (≤ one unit/day) will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a diagnosis of chronic obstructive pulmonary disease and the member has a history of paid MassHealth pharmacy claims within the last 120 days for a combination long-acting beta agonist/inhaled corticosteroid or a long-acting bronchodilator and an inhaled corticosteroid.†

zafirlukast

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - requested quantity is ≤ two units/day.

SmartPA: Claims for zafirlukast (≤ two units/day) will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for a diagnosis of asthma, or paid MassHealth pharmacy claims for a short/long acting inhaled beta agonist for ≥ 90 days of therapy in the last 120 days, or paid MassHealth pharmacy claims for an inhaled corticosteroid in the last 90 days.†

zileuton extended-release

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one or contraindication to both of the following: montelukast, zafirlukast; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to Zyflo; **and**
  - requested dose is ≤ 1,200 mg twice daily.

Zyflo

- Documentation of the following is required:
  - diagnosis of asthma; **and**
  - inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to one or contraindication to both of the following: montelukast, zafirlukast; **and**
  - requested dose is ≤ 600 mg four times daily.

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 41 - Antibiotics - Topical

Drug Category: Dermatological

Medication Class/Individual Agents: Antibiotics

I. Prior-Authorization Requirements

Topical Antibacterials			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bacitracin			*, A90
bacitracin / polymyxin B topical ointment	double antibiotic ointment		*, A90
chlorhexidine gluconate			*, A90
gentamicin topical cream, ointment			A90
hydrogen peroxide			*, A90
iodine			*, A90
isopropyl alcohol			*, A90
mafenide	Sulfamylon		# , A90
mupirocin cream		PA	A90
mupirocin ointment	Centany		A90
mupirocin ointment			A90
neomycin / bacitracin / polymyxin B topical ointment	triple antibiotic ointment		*, A90
ozenoxacin	Xepi	PA	
povidone			*, A90
silver sulfadiazine			A90
silver sulfadiazine-Silvadene	Silvadene		# , A90

Vaginal Antibiotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
clindamycin vaginal cream-Cleocin	Cleocin		# , A90
clindamycin vaginal cream-Clindesse	Clindesse	PA	
clindamycin vaginal gel	Xaciato	PA	
clindamycin vaginal	Cleocin Vaginal Ovule		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Warnings and Precautions:

- Contact with eyes should be avoided.
- Contact with mucosal surfaces should be avoided with mupirocin 2% ointment.
- If severe local irritation occurs, product should be discontinued.
- Prolonged use may result in overgrowth of nonsusceptible microorganisms, including fungi.
- Mupirocin 2% ointment contains polyethylene glycol. This product should be avoided if large quantities of polyethylene glycol could potentially be absorbed, especially in those with moderate-to-severe renal impairment or open wounds with damaged skin (other formulations do not contain polyethylene glycol).

Vaginal Antibiotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
suppository			
metronidazole 0.75% vaginal gel			A90
metronidazole 0.75% vaginal gel-Vandazole	Vandazole	PA	
metronidazole 1.3% vaginal gel	Nuvessa	PA	

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

* The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Bacterial vaginosis - Clindesse, Nuvessa, Vandazole, Xaciato
- Treatment of impetigo - mupirocin cream, Xepi
- Infected traumatic lesions - mupirocin cream

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Clindesse, Nuvessa, Vandazole, Xaciato

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: oral metronidazole tablets, metronidazole 0.75% vaginal gel available without PA; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: clindamycin vaginal cream, Cleocin Vaginal Ovule; **and**
  - appropriate dosing.

mupirocin cream for impetigo or infected traumatic lesions

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to mupirocin ointment; **and**
  - requested quantity is ≤ one package/30 days.

Xepi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two months of age; **and**
  - medical records documenting an inadequate response or adverse reaction to one or contraindication to both of the following: mupirocin cream, mupirocin ointment; **and**
  - requested quantity is ≤ one package/30 days.

MassHealth Evaluation Criteria
Table 42 - Immune Suppressants - Topical

Drug Category: Topical Agents

Medication Class/Individual Agents: Immune Suppressants

I. Prior-Authorization Requirements

Dermatological Immune Suppressants				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
crisaborole	Eucrisa PD	PA		**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** *Topical Immunosuppressants:* • Crisaborole is a topical phosphodiesterase 4 inhibitor that is FDA-approved for the treatment of mild to moderate atopic dermatitis in members three months of age and older. • Ruxolitinib cream is a topical Janus kinase inhibitor that is FDA-approved for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised members 12 years of age and older.
pimecrolimus	Elidel		BP, A90	
roflumilast cream, foam	Zoryve	PA		
ruxolitinib cream	Opzelura	PA		
tacrolimus topical			A90	
tapinarof	Vtama	PA		

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Atopic dermatitis (eczema)

- Plaque psoriasis
- Seborrheic dermatitis
- Vitiligo

Non-FDA-approved, for example:

- Alopecia areata
- Seborrheic dermatitis

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Eucrisa

- Documentation of all of the following is required:
  - diagnosis of atopic dermatitis; **and**
  - member is ≥ three months of age; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical corticosteroids, topical calcineurin inhibitors; **and**
  - one of the following:
    - requested quantity is 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit.

SmartPA: Claims for ≤ 60 grams/30 days of Eucrisa will usually process at the pharmacy without a PA request if the member is ≥ three months of age, has a history of MassHealth medical claims for atopic dermatitis, and has a history of a paid MassHealth pharmacy claim for one topical corticosteroid or one topical calcineurin inhibitor.†

Opzelura

- Documentation of all of the following is required for a diagnosis of atopic dermatitis:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response or adverse rection to one or contraindication to both of the following: topical corticosteroids, topical

calcineurin inhibitors; **and**
- inadequate response, adverse reaction or contraindication to Eucrisa; **and**
- one of the folowing:
  - requested quantity is 60 grams/30 days; **or**
  - medical necessity for exceeding the quantity limit.

- Documentation of all of the following is required for a diagnosis of vitiligo:
  - appropriate diagnosis; **and**
  - prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - total body surface area (BSA) to be treated is ≤ 10%; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: topical corticosteroids and topical calcineurin inhibitors; **and**
  - one of the following:
    - requested quantity is 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit.

- Documentation of all of the following is required for a diagnosis of alopecia areata:
  - appropriate diagnosis; **and**
  - prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response or adverse reaction to one topical corticosteroid, or contraindication to all topical corticosteroids; **and**
  - inadequate response or adverse reaction to one intralesional corticosteroid, or contraindication to all intralesional corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Olumiant, Xeljanz, Xeljanz XR.

Vtama
- Documentation of all of the following is required:
  - diagnosis of plaque psoriasis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: topical corticosteroids, topical calcineurin inhibitors, vitamin D analogs; **and**
  - one of the following:
    - requested quantity is 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit.

Zoryve cream
- Documentation of all of the following is required:
  - diagnosis of plaque psoriasis; **and**
  - member is ≥ six years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: topical calcineurin inhibitors, topical corticosteroids, vitamin D analogs; **and**
  - one of the following:
    - requested quantity is 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit.

Zoryve foam
- Documentation of all of the following is required for the diagnosis of seborrheic dermatitis:

- appropriate diagnosis; **and**
- member is ≥ nine years of age; **and**
- inadequate response or adverse reaction to two or contraindication to all of the following: topical antifungals, topical corticosteroids, topical calcineurin inhibitors; **and**
- one of the following:
  - requested quantity is 60 grams/30 days; **or**
  - medical necessity for exceeding the quantity limit.

- Documentation of all of the following is required for the diagnosis of plaque psoriasis:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: topical calcineurin inhibitors, topical corticosteroids, vitamin D analogs; **and**
  - one of the following:
    - requested quantity is 60 grams/30 days; **or**
    - medical necessity for exceeding the quantity limit.

†**Note**: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 43 - Pulmonary Hypertension Agents

Drug Category: Cardiovascular Agents

Medication Class/Individual Agents: Peripheral Vasodilators and Pulmonary Hypertension Agents

I. Prior-Authorization Requirements

Pulmonary Hypertension Agents – Phosphodiesterase Type 5 Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
sildenafil 20 mg tablet	Revatio	PA	A90
sildenafil oral suspension-Liqrev	Liqrev	PA	
sildenafil oral suspension-Revatio	Revatio	PA	BP, A90
tadalafil suspension	Tadliq	PA	
tadalafil tablet-Adcirca	Adcirca	PA	A90

Pulmonary Hypertension Agents – Soluble Guanylate Cyclase Stimulators			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
riociguat	Adempas	PA	

Pulmonary Hypertension Agents – Prostanoids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
epoprostenol-Flolan	Flolan		
epoprostenol-Veletri	Veletri	PA	
iloprost	Ventavis	PA	
treprostinil inhalation powder	Tyvaso DPI	PA	
treprostinil inhalation solution	Tyvaso	PA	
treprostinil injection	Remodulin	PA	BP

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report (2019)[1]

- For treatment naïve patients with WHO FC II and III, initial combination therapy with ambrisentan and tadalafil is suggested to improve 6-minute walk distance (6MWD). For patients unwilling or unable to tolerate combination therapy, monotherapy with an endothelin receptor antagonist (ERA), phosphodiesterase-5 (PDE-5) inhibitor, or riociguat is recommended.
- For treatment naïve patients in WHO FC IV, initiation of a parenteral prostanoid agent is recommended. For patients who are unwilling or unable to manage parenteral therapy, a combination of an inhaled prostanoid with an oral PDE-5 inhibitor and an ERA is recommended.
- For WHO FC III or IV patients who have an inadequate response to established PAH-specific monotherapy, the addition of a second class of PAH therapy is recommended to improve exercise capacity.

World Health Organization Functional Classification (WHO-FC) of Patients With PH[2]

Pulmonary Hypertension Agents – Prostanoids			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
treprostinil tablet	Orenitram	PA	

Pulmonary Hypertension Agents – Endothelin Receptor Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ambrisentan	Letairis	PA	A90
bosentan	Tracleer	PA	BP, A90
macitentan	Opsumit	PA	

Pulmonary Hypertension Agents – Combination Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
macitentan / tadalafil	Opsynvi	PA	

Pulmonary Hypertension Agents – Prostacyclin Receptor Agonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
selexipag	Uptravi	PA	

Pulmonary Hypertension Agents – Activin Signaling Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
sotatercept-csrk	Winrevair	PA	

Clinical Notes

- Class I: Patients with no symptoms, and for whom ordinary physical activity does not cause fatigue, palpitation, dyspnea, or anginal pain.
- Class II: Patients who are comfortable at rest but who have symptoms with less-than-ordinary physical activity resulting in slight limitations of physical activity.
- Class III: Patients who are comfortable at rest but have symptoms with less-than-ordinary effort resulting in marked limitations of physical activity.
- Class IV: Patients who have symptoms at rest. These patients manifest signs of heart failure.

Key symptoms of PAH include fatigue, dizziness and fainting (near syncope).

[1] *Klinger JR, Elliott CG, Levine DJ, Bossone E, Duvall L, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report.* ***Chest. 2019 Mar;155(3):565-586****. doi: 10.1016/j.chest.2018.11.030. Epub 2019 Jan 17. Erratum in:* ***Chest. 2021 Jan;159(1):457****. PMID: 30660783.*

[2] *Barst RJ, McGoon M, Torbicki A, et al. Diagnosis and differential assessment of pulmonary arterial hypertension.* ***J Am Coll Cardiol 2004; 43:40S-47S.***

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Treatment of chronic thromboembolic pulmonary hypertension (CTEPH)
- Treatment of WHO Group 1 pulmonary arterial hypertension (PAH)
- Pulmonary hypertension associated with interstitial lung disease (PH, ILD)

Non-FDA-approved, for example:

- Raynaud phenomenon

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Adempas (riociguat)

- Documentation of the following is required for a diagnosis of CTEPH:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - persistent or recurrent CTEPH after surgical treatment, or CTEPH is inoperable; **and**
  - requested quantity is ≤ three tablets/day; **and**
  - one of the following:
    - no recent paid pharmacy claims for tadalafil or sildenafil; **or**
    - agent will not be coadministered with a PDE-5 inhibitor.
- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: sildenafil, tadalafil; **and**
  - requested quantity is ≤ three tablets/day; **and**
  - one of the following:
    - no recent paid pharmacy claims for tadalafil or sildenafil; **or**
    - agent will not be coadministered with a PDE-5 inhibitor.

SmartPA: Claims for Adempas will usually process at the pharmacy without a PA request if there is a history of paid claims of the requested agent, or if the member is ≥ 18 years of age, has a history of MassHealth medical claims for PAH, the prescriber is a pulmonologist or cardiologist, there is a history of paid MassHealth pharmacy claims for sildenafil 20 mg tablets or tadalafil 20 mg tablets, there is no history of paid MassHealth pharmacy claims for sildenafil 20 mg tablet and tadalafil 20 mg tablet within the last 30

days, and there is no history of paid MassHealth pharmacy claims for sildenafil 20 mg tablet and tadalafil 20 mg tablet for ≥ 15 days of therapy within the last 30 days, and the requested quantity is ≤ three tablets/day.†

ambrisentan, bosentan, and Opsumit (macitentan)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - one of the following:
    - for ambrisentan and Opsumit, requested quantity is ≤ one tablet/day; **or**
    - for bosentan tablet, requested quantity is ≤ two tablets/day; **or**
    - for bosentan for suspension, all of the following:
      - member is < 13 years of age; **and**
      - prescriber must provide member's current weight; **and**
      - requested quantity is ≤ four tablets/day.

SmartPA: Claims for ambrisentan, bosentan tablet, and Opsumit will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent, or if the member has a history of MassHealth medical claims for PAH, the prescriber is a pulmonologist or cardiologist, and the requested quantity is ≤ one tablet/day (ambrisentan and Opsumit) or ≤ two tablets/day (bosentan tablet).†

SmartPA: Claims for bosentan for suspension will usually process at the pharmacy without a PA request if the member is < 13 years of age, has a history of MassHealth medical claims for PAH, the prescriber is a pulmonologist or cardiologist, and the requested quantity is ≤ four tablets/day.†

epoprostenol (generic Veletri)

- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - inadequate response, adverse reaction, or contraindication to Flolan.

SmartPA: Claims for epoprostenol (generic Veletri) will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent.†

Liqrev, and sildenafil oral suspension (generic Revatio)

- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - one of the following:
    - no recent paid pharmacy claims for Adempas; **or**
    - requested agent will not be administered with Adempas; **and**
  - one of the following:
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets); **or**
    - member utilizes tube feeding; **or**
    - member is <13 years of age; **or**
    - medical necessity for the requested formulation instead of sildenafil tablets; **and**
  - for Liqrev, medical necessity for use instead of sildenafil oral suspension (generic Revatio).
  - For recertification for a diagnosis of PAH, documentation of continuation to meet the criteria for use of the suspension instead of the tablet formulation as noted by one of the following:
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed; **or**
    - member utilizes tube feeding; **or**

- member is <13 years of age; **or**
- medical necessity for the requested formulation instead of tablets.

- Documentation of the following is required for a diagnosis of Raynaud phenomenon:
  - appropriate diagnosis; **and**
  - one of the following:
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets); **or**
    - member utilizes tube feeding; **or**
    - member is <13 years of age; **or**
    - medical necessity for the requested formulation instead of sildenafil tablets; **and**
  - for Liqrev, medical necessity for use instead of sildenafil oral suspension (generic Revatio); **and**
  - one of the following:
    - inadequate response or adverse reaction to one, or contraindication to all of the following: amlodipine, nifedipine, topical nitroglycerin; **or**
    - PDE5 inhibitor is being used for the healing of digital ulcers.

Opsynvi
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - medical necessity for use of the combination product instead of the commercially available separate agents; **and**
  - requested quantity is ≤ one tablet/day; **and**
  - one of the following:
    - no recent paid pharmacy claims for Adempas; **or**
    - agent will not be coadministered with Adempas.

Orenitram (treprostinil), treprostinil injection, and Ventavis (iloprost)
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - inadequate response, adverse reaction, or contraindication to epoprostenol (generic Veletri) or Flolan; **and**
  - for Ventavis, requested quantity is ≤ nine ampules/day.

SmartPA: Claims for Orenitram, treprostinil injection, and Ventavis will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent, or if the member has a history of MassHealth medical claims for PAH, member has a history of paid MassHealth pharmacy claims for epoprostenol (generic Veletri) or Flolan, the prescriber is a pulmonologist or cardiologist, and, if the request is for Ventavis, the requested quantity is ≤ nine ampules/day.†

sildenafil 20 mg tablet
- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - one of the following:
    - no recent paid pharmacy claims for Adempas; **or**
    - requested agent will not be administered with Adempas.

- Documentation of the following is required for a diagnosis of Raynaud phenomenon:
  - appropriate diagnosis; **and**

- one of the following:
  - inadequate response or adverse reaction to one, or contraindication to all of the following: amlodipine, nifedipine, topical nitroglycerin; **or**
  - PDE5 inhibitor is being used for the healing of digital ulcers.

SmartPA: Claims for sildenafil 20 mg tablets will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for PAH, there is no history of paid claims for Adempas within the last 30 days, and there is no history of paid MassHealth pharmacy claims for Adempas for ≥ 15 days of therapy within the last 30 days.†

tadalafil

- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - one of the following:
    - no recent paid pharmacy claims for Adempas; **or**
    - agent will not be co-administered with Adempas; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to sildenafil 20 mg tablets; **or**
    - member is treatment naïve and the requested agent will be used in combination with ambrisentan.

- Documentation of the following is required for a diagnosis of Raynaud phenomenon:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to one, or contraindication to all of the following: amlodipine, nifedipine, topical nitroglycerin; **or**
    - PDE5 inhibitor is being used for the healing of digital ulcers; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to sildenafil (generic Revatio); **or**
    - medical necessity for use of the requested agent instead of sildenafil (generic Revatio).

SmartPA: Claims for tadalafil 20 mg tablet will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for PAH, the prescriber is a pulmonologist or cardiologist, there is a history of paid MassHealth pharmacy claims for sildenafil 20 mg tablet, there is no history of paid MassHealth pharmacy claims for Adempas within the last 30 days, and there is no history of paid MassHealth pharmacy claims for Adempas for ≥ 15 days of therapy within the last 30 days.†

Tadliq

- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - one of the following:
    - no recent paid pharmacy claims for Adempas; **or**
    - agent will not be co-administered with Adempas; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to sildenafil 20 mg tablets; **or**
    - member is treatment naïve and the requested agent will be used in combination with ambrisentan; **and**
  - one of the following:
    - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets); **or**
    - member utilizes tube feeding; **or**
    - member is <13 years of age; **or**

- medical necessity for the requested formulation instead of tadalafil tablets.
- For recertification for a diagnosis of PAH, documentation of continuation to meet the criteria for use of the suspension instead of the tablet formulation as noted by one of the following:
  - member has severe dysphagia and is currently utilizing only formulations that can easily be swallowed; **or**
  - member utilizes tube feeding; **or**
  - member is <13 years of age; **or**
  - medical necessity for the requested formulation instead of tablets.

Tyvaso (treprostinil inhalation solution), Tyvaso DPI (treprostinil inhalation powder)

- Documentation of the following is required for a diagnosis of PAH:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - inadequate response, adverse reaction, or contraindication to epoprostenol (generic Veletri) or Flolan; **and**
  - for Tyvaso DPI, medical records documenting an inadequate response, adverse reaction, or contraindication to Tyvaso inhalation solution.
- Documentation of the following is required for a diagnosis of PH-ILD:
  - appropriate diagnosis; **and**
  - prescriber is a pulmonologist or cardiologist, or prescriber provides consultation notes from a pulmonologist or cardiologist regarding the diagnosis; **and**
  - for Tyvaso DPI, medical records documenting an inadequate response, adverse reaction, or contraindication to Tyvaso inhalation solution.

SmartPA: Claims for Tyvaso will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent, or if the member has a history of MassHealth medical claims for PAH, member has a history of paid MassHealth pharmacy claims for epoprostenol (generic Veletri) or Flolan, and the prescriber is a pulmonologist or cardiologist. †

Uptravi (selexipag)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - requested quantity is ≤ two tablets/day; **and**
  - for Uptravi vial, the member is stabilized on Uptravi tablets and is temporarily unable to take oral medications.

SmartPA: Claims for Uptravi tablets will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent.†

Winrevair

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided; **and**
  - member is on stable background therapy for PAH; **and**
  - member's current weight.
- For recertification, prescriber must provide medical records documenting positive response to therapy (including, but not limited to improvement in walk distance, dyspnea, functional class, exercise capacity, or hemodynamic parameters such as NT-proBNP or pulmonary vascular resistance).

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 44 - Hepatitis Antiviral Agents

Drug Category: Anti-infectives

Medication Class/Individual Agents: Hepatitis antivirals

I. Prior-Authorization Requirements

Hepatitis Antiviral Agents – Miscellaneous Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
adefovir	Hepsera	PA - > 1 unit/day	# , A90
entecavir solution	Baraclude	PA - > 20 mL/day	
entecavir tablet	Baraclude	PA - > 1 unit/day	# , A90
lamivudine 100 mg tablet		PA - > 1 unit/day	A90
peginterferon alfa-2a	Pegasys	PA	
ribavirin 200 mg capsule		PA	A90
ribavirin tablet			A90
tenofovir alafenamide	Vemlidy PD		
tenofovir disoproxil fumarate powder	Viread	PA - ≥ 13 years	A90
tenofovir disoproxil fumarate tablet	Viread	PA - > 1 unit/day	# , A90

Hepatitis Antiviral Agents – Combination Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
elbasvir / grazoprevir	Zepatier	PA	
glecaprevir / pibrentasvir	Mavyret PD	PA	
ledipasvir / sofosbuvir PD	Harvoni	PA	
sofosbuvir / velpatasvir PD	Epclusa	PA	
sofosbuvir / velpatasvir / voxilaprevir	Vosevi	PA	

Hepatitis Antiviral Agents – Single Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
sofosbuvir	Sovaldi	PA	

Clinical Notes

PLEASE SEE SECTION III BELOW FOR PREFERRED HEPATITIS C PRODUCT REFERENCE TABLE

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please note: For evaluation criteria where medical records and results of diagnostic tests assessing hepatic fibrosis and liver disease stage are required, staging information must clearly demonstrate early stage (e.g., Metavir Score F0-F2) or advanced stage (e.g., Metavir Score F3-F4) disease. If results are inconclusive, further diagnostic testing may be required.

Hepatitis B Virus (HBV) Nucleoside Analog Reverse Transcriptase Inhibitor:

- Tenofovir alafenamide is a prodrug of tenofovir FDA-approved for the treatment of chronic HBV infection in adults with compensated liver disease. No dosage adjustment is required in members with mild, moderate, or severe renal impairment.

Hepatitis C Virus (HCV) Combination Products:

- Elbasvir/grazoprevir is a once-daily combination of

	Clinical Notes
	elbasvir, an HCV NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor. Elbasvir/grazoprevir with or without ribavirin is indicated for the treatment of members with chronic HCV genotypes 1 or 4 infection including those with compensated cirrhosis. The FDA-approved treatment duration is 12 or 16 weeks depending on HCV genotype, prior treatment history, and for members HCV with genotype 1a infection, the presence of certain NS5A polymorphisms at baseline. • Glecaprevir/pibrentasvir is a once-daily combination of glecaprevir, an HCV NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor. It is indicated for the treatment of chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection in members three years and older, including members with renal impairment. It is also approved for adults with HCV genotype 1 who have been previously treated with an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. The recommended treatment duration is eight, 12, or 16 weeks depending on genotype, prior treatment history, and cirrhosis status. • Ledipasvir/sofosbuvir is a once-daily combination of ledipasvir, an HCV NS5A inhibitor, and sofosbuvir, an HCV NS5B polymerase inhibitor, that is FDA-approved for the treatment of chronic HCV genotype 1, 4, 5, or 6 infection. The FDA-approved treatment duration is eight, 12 or 24 weeks depending on prior treatment history, cirrhosis status, and baseline viral load. Eight weeks of treatment can be considered for treatment-naïve adults with HCV genotype 1 without cirrhosis and baseline HCV viral load <6 million IU/mL. • Ombitasvir/paritaprevir/ritonavir/dasabuvir includes fixed-dose ombitasvir, an HCV NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor and ritonavir, a CYP3A inhibitor co-packaged with dasabuvir, an HCV non-nucleoside NS5B palm polymerase inhibitor. Ombitasvir/paritaprevir/ritonavir/dasabuvir with or without ribavirin is indicated for the treatment of members with chronic HCV genotype 1 infection including those with compensated cirrhosis. The FDA-approved treatment duration is 12 or 24 weeks depending on prior treatment history and cirrhosis status. • Sofosbuvir/velpatasvir is a once-daily combination of sofosbuvir, an HCV NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, that is FDA

	Clinical Notes
	approved for the treatment of chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection. The FDA-approved treatment duration is 12 weeks regardless of the presence or absence of cirrhosis. The addition of ribavirin is recommended in members with decompensated cirrhosis. • Sofosbuvir/velpatasvir/voxilaprevir is a once-daily combination of sofosbuvir, an HCV NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor. It is indicated for the treatment of chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection in adults who have been previously treated with an HCV regimen containing an NS5A inhibitor. It is also indicated for the treatment of chronic HCV genotype 1a or 3 infection in adults who have been previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. The FDA-approved treatment duration is 12 weeks. The following regimens are not recommended by treatment guidelines for routine use in the treatment of hepatitis C.[1] Requests for these regimens will be reviewed on a case-by-case basis taking into consideration medical necessity for use over a standard of care regimen (e.g., regimen containing a combination product recommended for routine use). • Peginterferon alfa as monotherapy or in combination with other HCV antivirals • Sovaldi (sofosbuvir) plus peginterferon alfa and ribavirin • Sovaldi (sofosbuvir) plus ribavirin [1] AASLD-IDSA. HCV guidance: Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed December 16, 2019.

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Hepatitis B (chronic) – adefovir, entecavir, lamivudine, Pegasys, tenofovir disoproxil fumarate
- Hepatitis C – ledipasvir/sofosbuvir, Mavyret, ribavirin, sofosbuvir/velpatasvir, Vosevi, Zepatier

Note: The above list may not include all FDA-approved and Non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Preferred Hepatitis C Product Reference Table:

HCV GT	Treatment History	Cirrhosis Status	Preferred Regimen(s) (listed in alphabetical order)[1]
GT1	Naïve	Non-cirrhotic	• ledipasvir/sofosbuvir x eight weeks (if viral load < six million IU/mL) • Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT1 (cont.)	Naïve	Cirrhotic (CTP A)	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT1 (cont.)	Experienced (PEG/RBV)	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT1 (cont.)	Experienced (PEG/RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks

GT1 (cont.)	Experienced (PI+PEG/RBV)	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks
GT1 (cont.)	Experienced (SOF+PEG/RBV or SOF+RBV)	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks (GT 1b)[2]
GT1 (cont.)	Experienced (SOF+PEG/RBV or SOF+RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks (GT 1b)[2]
GT1 (cont.)	Experienced (SOF+SMV)	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks (GT 1b)[2]
GT1 (cont.)	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 16 weeks (no prior PI) • Vosevi x 12 weeks
GT2	Naïve or experienced (PEG/RBV)	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT2 (cont.)	Naïve	Cirrhotic (CTP A)	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT2 (cont.)	Experienced (PEG/RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks
GT2 (cont.)	Experienced (SOF+RBV)	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks[2]
GT2 (cont.)	Experienced (SOF+RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks[2]
GT2 (cont.)	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Vosevi x 12 weeks
GT3	Naïve	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT3 (cont.)	Naïve	Cirrhotic (CTP A)	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks (plus RBV[2] if Y93H substitution is present)
GT3 (cont.)	Experienced (PEG/RBV)	Non-cirrhotic	• Mavyret x 16 weeks • sofosbuvir/velpatasvir x 12 weeks (plus RBV[2] if Y93H substitution is present)

GT3 (cont.)	Experienced (PEG/RBV)	Cirrhotic (CTP A)	• Mavyret x 16 weeks • sofosbuvir/velpatasvir +RBV x 12 weeks[2]
GT3 (cont.)	Experienced (SOF+PEG/RBV or SOF+RBV)	Non-cirrhotic or cirrhotic (CTP A)	• Mavyret x 16 weeks
GT3 (cont.)	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Vosevi x 12 weeks (plus RBV[2] if cirrhosis is present)
GT4, 5, or 6	Naïve or experienced (PEG/RBV)	Non-cirrhotic	• Mavyret x eight weeks • sofosbuvir/velpatasvir x 12 weeks
GT4, 5, or 6 (cont.)	Naïve or experienced (PEG/RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • sofosbuvir/velpatasvir x 12 weeks
GT4, 5, or 6 (cont.)	Experienced (SOF+PEG/RBV or SOF+RBV)	Non-cirrhotic	• Mavyret x eight weeks • Vosevi x 12 weeks[2]
GT4, 5, or 6 (cont.)	Experienced (SOF+PEG/RBV or SOF+RBV)	Cirrhotic (CTP A)	• Mavyret x 12 weeks • Vosevi x 12 weeks[2]
GT4, 5, or 6 (cont.)	Experienced (NS5A inhibitor)	Non-cirrhotic or cirrhotic (CTP A)	• Vosevi x 12 weeks

CTP=Child Turcotte Pugh, DAA=direct-acting antiviral, eGFR=estimated glomerular filtration rate, GT=genotype, HCV=hepatitis C virus, PEG=peginterferon alfa, PI=protease inhibitor, RBV=ribavirin, SOF=sofosbuvir

Please note, pediatric dosing formulations of Brand name Epclusa and Harvoni are preferred. For all other strengths, generics are preferred.

[1]This Reference Table is intended for use as a reference only and does not guarantee prior authorization approval. PA requests for preferred regimens must meet PA criteria (see below for complete prior authorization criteria).

[2]Regimen is not FDA-approved in all clinical scenarios. Regimen is supported by the AASLD-IDSA treatment guidelines. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed December 16, 2019.

adefovir (> one unit/day), Baraclude solution (> 20 mL/day), entecavir tablets (> one unit/day), lamivudine solution (> 20 mL/day), and lamivudine 100 mg tablets (> one unit/day)

- Documentation of the following is required:
  - diagnosis of chronic hepatitis B; **and**
  - medical necsesity for exceeding the quantity limits.

ledipasvir/sofosbuvir

- Documentation of the following is required for treatment-naïve members without cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 4, 5, or 6; **and**
  - one of the following:
    - for genotype 1, member is ≥ three years of age; **or**
    - for genotype 4, 5, 6, member is ≥18 years of age and clinical rationale for use instead of sofosbuvir/velpatasvir or member is ≥ three and <18 years of age; **and**
  - appropriate dosing; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3); **and**

- one of the following:
  - for genotype 1, member is ≥ three and < 18 years of age and requested duration is 12 weeks; **or**
  - for genotype 1, member is ≥ 18 years of age and baseline viral load (within the last six months) < 6 million IU/mL and requested duration is eight weeks; **or**
  - both of the following:
    - for genotype 1, baseline viral load (within the last six months) ≥ 6 million IU/mL and requested duration is 12 weeks; **and**
    - clinical rationale for use instead of sofosbuvir/velpatasvir; **or**
  - for genotypes 4, 5, and 6, requested duration is 12 weeks.

- Documentation of the following is required for treatment-naïve members with compensated cirrhosis **or** treatment-experienced members (failed treatment with an interferon with or without ribavirin and/or protease inhibitor) without cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 4, 5, or 6; **and**
  - one of the following:
    - member is ≥ 18 years of age and clinical rationale for use instead of sofosbuvir/velpatasvir; **or**
    - member is ≥ three and < 18 years of age; **and**
  - appropriate dosing; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 12 weeks.

- Documentation of the following is required for treatment-experienced members (failed treatment with an interferon with or without ribavirin and/or protease inhibitor) with compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 4, 5, or 6; **and**
  - one of the following:
    - member is ≥ 18 years of age and clinical rationale for use instead of sofosbuvir/velpatasvir; **or**
    - member is ≥ three and < 18 years of age; **and**
  - appropriate dosing; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - one of the following:
    - for genotype 1, member is ≥ three and < 18 years of age and requested duration is 24 weeks; **or**
    - for genotype 1, member is ≥ 18 years of age and requested duration is 12 weeks and requested regimen includes ribavirin; **or**
    - for genotype 1, member is ≥ 18 years of age and requested duration is 24 weeks and prescriber provides clinical rationale for use of 24-week treatment with ledipasvir/sofosbuvir instead of 12-week treatment with ledipasvir/sofosbuvir and ribavirin; **or**
    - for genotype 4, 5, and 6, requested duration is 12 weeks.

- Documentation of the following is required for treatment-naïve or treatment-experienced members with decompensated cirrhosis (CTP class B or C) :
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**
  - clinical rationale for use instead of sofosbuvir/velpatasvir; **and**
  - decompensated cirrhosis; **and**

- member is not s/p liver or kidney transplant; **and**
- medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
- one of the following:
  - member is treatment-naïve or treatment-experienced (prior failure of peginterferon and ribavirin with or without an HCV protease inhibitor only) and one of the following:
    - requested regimen includes ribavirin and requested duration is 12 weeks; **or**
    - requested duration is 24 weeks and contraindication or prior intolerance to ribavirin; **or**
  - member is treatment-experienced (prior failure of sofosbuvir- or NS5A inhibitor-containing regimen) and both of the following:
    - requested regimen includes ribavirin; **and**
    - requested duration is 24 weeks.

Mavyret

- Documentation of the following is required for treatment-naïve members with or without compensated cirrhosis or the following off-label indications: Treatment-naïve members post-liver transplant, post-kidney transplant, or HCV-Negative Organ Recipients from HCV-Positive Donors with or without compensated cirrhosis (CTP class A):
  - member is ≥ three years of age; **and**
  - for tablets, requested quantity is ≤ three units/day; **and**
  - for packets of pellets, requested quantity is ≤ five units/day.

- Documentation of the following is required for treatment-experienced members (failed treatment with interferon, peginterferon, ribavirin only; sofosbuvir plus peginterferon and ribavirin only; or sofosbuvir plus ribavirin only) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - requested dose is three 100 mg/40 mg tablets once daily; **and**
  - for genotype 3, requested duration is 16 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - for genotype 1, 2, 4, 5, or 6, one of the following:
    - absence of cirrhosis and requested duration is eight weeks; **or**
    - compensated cirrhosis and requested duration is 12 weeks.

- Documentation of the following is required for treatment-experienced members (failed treatment with sofosbuvir plus simeprevir or a HCV protease inhibitor plus peginterferon alfa and ribavirin only) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1; **and**
  - member is ≥ three years of age; **and**
  - requested dose is three 100 mg/40 mg tablets once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 12 weeks.

- Documentation of the following is required for treatment-experienced members (failed treatment with an HCV NS5A inhibitor without an HCV protease inhibitor) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1; **and**
  - member is ≥ three years of age; **and**
  - requested dose is three 100 mg/40 mg tablets once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 16 weeks.

- Documentation of the following is required for requests noting prior failure with Mavyret or Vosevi:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - member has previously failed Mavyret or Vosevi; **and**
  - requested regimen includes glecaprevir/pibrentasvir three 100 mg/40 mg tablets once daily, sofosbuvir 400 mg once daily, and ribavirin; **and**
  - requested duration is 16 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - member does not have decompensated cirrhosis.

- Documentation of the following is required for treatment-experienced members (no prior NS5A failure) post-liver transplant with or without compensated cirrhosis (CTP class A):
  - diagnosis of hepatitis C and s/p liver transplant; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**
  - for members with compensated cirrhosis, requested regimen includes ribavirin; **and**
  - one of the following:
    - for genotype 1, 2, 4, 5, or 6 and requested duration is 12 weeks; **or**
    - for genotype 3 (prior failure of peginterferon/ribavirin with or without sofosbuvir) and requested duration is 16 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis).

- Documentation of the following is required for treatment-experienced members (no prior NS5A failure) post-kidney transplant with or without compensated cirrhosis (CTP class A):
  - diagnosis of hepatitis C and s/p kidney transplant; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**

- requested duration is 12 weeks; **and**
- medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
- stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis).

SmartPA: Claims for Mavyret tablet at a quantity of ≤ three units/day or Mavyret pellet packet at a quantity of ≤ five units/day will usually pay at the pharmacy without a PA request for members age ≥ three years of age if there are no paid MassHealth pharmacy claims for hepatitis C drug in all claims history, there are no paid MassHealth pharmacy claims for drugs suggestive of decompensated cirrhosis in all claims history, and there is no history of paid MassHealth pharmacy claims within the last 90 days for a drug that may lower DAA efficacy.

Pegasys for chronic hepatitis B
- Documentation of the following is required:
  - diagnosis of chronic hepatitis B.

ribavirin 200 mg capsule
- Documentation of the following is required:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype; **and**
  - medical necessity for requested capsule formulation instead of the 200 mg tablets.

sofosbuvir/velpatasvir
- Documentation of the following is required for treatment-naïve members with or without compensated cirrhosis or the following off-label indications: Treatment-naïve members post-liver transplant, post-kidney transplant, or HCV-Negative Organ Recipients from HCV-Positive Donors with or without compensated cirrhosis (CTP class A):
  - member is ≥ three years of age; **and**
  - requested quantity is ≤ one unit/day.

- Documentation of the following is required for treatment-experienced members (failed treatment with peginterferon alfa and ribavirin, with or without protease inhibitor) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 12 weeks; **and**
  - for members ≥ 18 years of age with genotype 3, one of the following:
    - absence of cirrhosis and one of the following:
      - testing results document absence of NS5A resistance-associated substitution Y93H; **or**
      - testing results document presence of NS5A resistance-associated substitution Y93H and requested regimen includes ribavirin; **or**
    - compensated cirrhosis and requested regimen includes ribavirin.

- Documentation of the following is required for treatment-naïve or treatment-experienced members with decompensated cirrhosis

(CTP class B or C) :

- diagnosis of hepatitis C; **and**
- hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
- decompensated cirrhosis (Child Pugh Class B or C); **and**
- member is not s/p liver or kidney transplant; **and**
- member is ≥ three years of age; **and**
- appropriate dosing; **and**
- medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
- one of the following:
  - member is treatment-naïve or treatment-experienced (prior failure of peginterferon and ribavirin with or without an HCV protease inhibitor only) and one of the following:
    - requested regimen includes ribavirin and requested duration is 12 weeks; **or**
    - requested duration is 24 weeks and contraindication or prior intolerance to ribavirin; **or**
  - member is treatment-experienced (prior failure of sofosbuvir- or NS5A inhibitor-containing regimen) and both of the following:
    - requested regimen includes ribavirin; **and**
    - requested duration is 24 weeks.

- Documentation of the following is required for treatment-experienced members post-liver transplant with or without cirrhosis (CTP class A, B or C) :
  - diagnosis of hepatitis C and s/p liver transplant; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - one of the following:
    - absence of cirrhosis or compensated cirrhosis and requested duration is 12 weeks; **or**
    - decompensated cirrhosis and both of the following:
      - requested regimen includes ribavirin; **and**
      - requested duration is 12 weeks (treatment-naïve) or 24 weeks (treatment-experienced).

- Documentation of the following is required for treatment-naïve members or treatment-experienced† members post-kidney transplant with or without compensated cirrhosis (CTP class A):
  - diagnosis of hepatitis C and s/p liver transplant; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ three years of age; **and**
  - appropriate dosing; **and**
  - requested duration is 12 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4).

SmartPA: Claims for generic sofosbuvir/velpatasvir, Epclusa 200 mg/50 mg tablet, Epclusa pellet packet, at a quantity of ≤ one unit/day will usually pay at the pharmacy without PA for members age ≥ three years of age if there are no paid MassHealth pharmacy claims for hepatitis C drug in all claims history, there are no paid MassHealth pharmacy claims for drugs suggestive of decompensated cirrhosis in all claims history, and there is no history of paid MassHealth pharmacy claims within the last 90 days for a drug that may lower DAA efficacy.

Sovaldi

- Documentation of the following is required for treatment-naïve members or treatment-experienced members with or without compensated cirrhosis (CTP A):
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 2 or 3; **and**
  - member is ≥ three years of age; **and**
  - clinical rationale for use instead of sofosbuvir/velpatasvir and Mavyret; **and**
  - appropriate dosing; **and**
  - requested duration is 12 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - one of the following:
    - for genotype 2, requested duration is 12 weeks; or
    - for genotype 3, requested duration is 24 weeks; **and**
  - requested regimen includes ribavirin.

Vosevi

- Documentation of the following is required for treatment-experienced members (failed treatment with an HCV NS5A inhibitor) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 400 mg/100 mg/100 mg once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 12 weeks; **and**
  - for genotype 3 and compensated cirrhosis, requested regimen includes ribavirin.

- Documentation of the following is required for treatment-experienced members (failed treatment with sofosbuvir without an HCV NS5A inhibitor) with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1a or 3; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 400 mg/100 mg/100 mg once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - requested duration is 12 weeks.

- Documentation of the following is required for requests noting prior failure with Mavyret or Vosevi:
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ 18 years of age; **and**

- medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
- stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
- member does not have decompensated cirrhosis; **and**
- one of the following:
  - both of the following:
    - member has previously failed Mavyret and requested regimen is 400 mg/100 mg/100 mg once daily for 12 week; **and**
    - for members with compensated cirrhosis, requested regimen includes ribavirin; **or**
  - both of the following:
    - member has previously failed Vosevi or Mavyret plus Sovaldi and requested regimen is 400 mg/100 mg/100 mg once daily plus ribavirin for 24 weeks; **and**
    - clinical rationale for use instead of Mavyret plus Sovaldi plus ribavirin.

- Documentation of the following is required for treatment-experienced (failed treatment with sofosbuvir or an HCV NS5A inhibitor) members post-liver transplant with or without compensated cirrhosis:
  - diagnosis of hepatitis C; **and**
  - one of the following:
    - genotype 1, 2, 3, 4, 5, or 6 and prior treatment failure with an HCV NS5A inhibitor; **or**
    - both of the following:
      - genotype 1 or 3 and prior treatment failure with sofosbuvir without an HCV NS5A inhibitor; **and**
      - clinical rationale for use instead of Mavyret; **or**
    - genotype 4, 5, or 6 and prior treatment failure with sofosbuvir without an HCV NS5A inhibitor; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 400 mg/100 mg/100 mg once daily; **and**
  - for members with compensated cirrhosis, requested regimen includes ribavirin; **and**
  - requested duration is 12 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis).

- Documentation of the following is required for treatment-experienced (failed treatment with sofosbuvir or an HCV NS5A inhibitor) members post-kidney transplant with or without compensated cirrhosis:
  - diagnosis of hepatitis C s/p kidney transplant; **and**
  - genotype 1, 2, 3, 4, 5, or 6; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 400 mg/100 mg/100 mg once daily; **and**
  - for members with compensated cirrhosis, requested regimen includes ribavirin; **and**
  - requested duration is 12 weeks; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis).

Zepatier

- Documentation of the following is required for HCV genotype 1 in treatment-naïve members or treatment-experienced members (failed treatment with peginterferon alfa and ribavirin only):

- diagnosis of hepatitis C; **and**
- hepatitis C virus genotype 1; **and**
- contraindication to all combination products FDA-approved for the treatment of hepatitis C virus genotype 1 infection; **and**
- member is ≥ 18 years of age; **and**
- requested dose is 50 mg/100 mg once daily; **and**
- medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
- stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
- member does not have decompensated cirrhosis; **and**
- one of the following:
  - for genotype 1a, testing results document absence of NS5A resistance-associated substitutions at amino acid positions 28, 30, 31, and 93, and requested duration is 12 weeks; **or**
  - for genotype 1a, testing results document presence of NS5A resistance-associated substitutions at amino acid positions 28, 30, 31, or 93, and requested regimen includes ribavirin and requested duration is 16 weeks; **or**
  - for genotype 1b, requested duration is 12 weeks.

- Documentation of the following is required for HCV genotype 1 in treatment-experienced members (failed treatment with a HCV protease inhibitor plus peginterferon alfa and ribavirin only):
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 1; **and**
  - contraindication to all combination products FDA-approved for the treatment of hepatitis C virus genotype 1 infection; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 50 mg/100 mg once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**
  - member does not have decompensated cirrhosis; **and**
  - requested regimen includes ribavirin; **and**
  - one of the following:
    - for genotype 1a, testing results document absence of NS5A resistance-associated substitutions at amino acid positions 28, 30, 31, and 93, and requested duration is 12 weeks; **or**
    - for genotype 1a, testing results document presence of NS5A resistance-associated substitutions at amino acid positions 28, 30, 31, or 93, and requested duration is 16 weeks; **or**
    - for genotype 1b, requested duration is 12 weeks.

- Documentation of the following is required for HCV genotype 4 in treatment-naïve or treatment-experienced members (failed treatment with peginterferon alfa and ribavirin only):
  - diagnosis of hepatitis C; **and**
  - hepatitis C virus genotype 4; **and**
  - contraindication to all combination products FDA-approved for the treatment of hepatitis C virus genotype 4 infection; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is 50 mg/100 mg once daily; **and**
  - medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4); **and**
  - stage of liver disease is early stage (e.g., Metavir Score F0 to F2), or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis); **and**

- member does not have decompensated cirrhosis; **and**
- one of the following:
  - member is treatment-naïve, and requested duration is 12 weeks; **or**
  - member has a history of relapse to prior peginterferon alfa and ribavirin treatment, and requested duration is 12 weeks; **or**
  - member has a history of on-treatment virologic failure (failure to suppress or breakthrough) while on peginterferon alfa and ribavirin treatment, requested regimen includes ribavirin, and requested duration is 16 weeks.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria

Table 45 - Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents

Drug Category: Blood Disorder Agents

Medication Class/Individual Agents: Hematopoietic Agents

I. Prior-Authorization Requirements

Sickle Cell Disease Agents - P-Selectin Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
crizanlizumab-tmca	Adakveo	PA	MB

Sickle Cell Disease Agents - Gene Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
exagamglogene autotemcel for sickle cell disease	Casgevy PD	PA	CO, MB
lovotibeglogene autotemcel	Lyfgenia	PA	CO, MB

Sickle Cell Disease Agents - Antimetabolites			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
hydroxyurea capsule	Droxia		
hydroxyurea tablet	Siklos	PA	

Sickle Cell Disease Agents - Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
l-glutamine	Endari	PA	

Sickle Cell Disease Agents - Hemoglobin S (HbS) Polymerization Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
voxelotor	Oxbryta	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Luspatercept-aamt is a subcutaneously (SC) administered erythroid maturation agent. It is a modified activin receptor type IIB fusion protein that acts as a ligand trap for members of the Transforming Growth Factor-Beta (TGF-beta) superfamily involved in the late stages of erythropoiesis (red blood cell production).
  - FDA-approved dosing: 1 to 1.25 mg/kg SC every three weeks
  - This agent should be administered by a medical professional.
  - Luspatercept-aamt should be discontinued if one does not experience a decrease in transfusion burden after nine weeks of treatment at the maximum dose level or if unacceptable toxicity occurs at any time.
- L-glutamine is an oral agent indicated to reduce acute complications in children ≥ five years of age and adults with sickle cell disease (SCD).
- Guidelines from the British Society for Haematology and the National Heart, Lung, and Blood Institute (NHLBI) recommend the use of hydroxyurea for adults with SCD who have experienced three or more moderate to severe pain crises in a 12-month period, pain or chronic anemia interfering with daily activities or with severe or

Beta Thalassemia Agents - Erythroid Maturation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
luspatercept-aamt	Reblozyl	PA	MB

Beta Thalassemia Agents - Gene Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betibeglogene autotemcel	Zynteglo PD	PA	CO, MB

Clinical Notes

recurrent episodes of acute chest syndrome (ACS). In addition, they give a strong recommendation for use in children nine-to-42 months of age and a moderate recommendation for children and adolescents > 42 months of age regardless of disease severity.

- NHLBI recommends aiming for target ANC ≥ 2,000/uL. Maintain PLT count ≥ 80,000/uL. If neutropenia or thrombocytopenia occurs, hold hydroxyurea and monitor complete blood count with WBC differential weekly. When blood counts have recovered, reinstitute hydroxyurea at 5 mg/kg/day and if warranted, increase by 5 mg/kg/day increments every eight weeks until mild myelosuppression (ANC 2,000 to 4,000/uL to a maximum dose of 35 mg/kg/day).
- NHLBI notes that a clinical response to hydroxyurea may take three-to-six months. A six-month trial on the maximum tolerated dose is required prior to considering discontinuation due to treatment failure.[1]
- Crizanlizumab-tmca is the first humanized anti-P-selectin monoclonal antibody FDA-approved to reduce the frequency of vasoocclusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease.
  - It is given as an intravenous (IV) infusion at a dose of 5 mg/kg at week 0, week 2 and then every four weeks.
  - This agent should be administered by a medical professional.
- Voxelotor is an oral HbS polymerization inhibitor indicated for the treatment of SCD in adults and pediatric patients four years of age and older.
- Betibeglogene autotemcel is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of adult and pediatric patients with β-thalassemia who require regular red blood cell (RBC) transfusions This agent is a one-time intravenous (IV) infusion designed to deliver a functional copy of human β-globin gene (βA-T87Q-globin) into a patient's own hematopoietic stem cells (HSC). Given the risk of serious adverse reactions, this agent is administered only by qualified treatment centers.
  - MassHealth Drug Utilization Review will be reaching out to prescribers after administration to verify clinical effectiveness and at ongoing intervals for long-term monitoring of sustained response. For additional information regarding betibeglogene autotemcel,

	Clinical Notes
	please see the Acute Hospital Carve-Out Drugs List found at **www.mass.gov/druglist**. • Exagamglogene autotemcel is an autologous, ex vivo CRISPR/Cas9 gene-editing therapy indicated for the treatment of sickle cell disease in patients 12 years of age and older with recurrent vaso-occlusive crises (VOCs). This agent is a one-time IV infusion that works to edit the erythroid-specific enhancer region of *BCL11A* in the $CD34^+$ hematopoietic stem and progenitor cells (HSPCs) to reduce erythroid-specific expression of *BCL11A* and thereby increase levels of fetal hemoglobin (HbF). Given the risk of serious adverse reactions, this agent is administered only by qualified treatment centers. • MassHealth Drug Utilization Review will be reaching out to prescribers after administration to verify clinical effectiveness and at ongoing intervals for long-term monitoring of sustained response. For additional information regarding exagamglogene, please see the Acute Hospital Carve-Out Drugs List found at **www.mass.gov/druglist**. 1.Yawn BP, Buchanan GR, Afenyi-Annan AN, Ballas SK, Hassell KL, James AH, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. JAMA. 2014 Sep 10;312(10):1033-48.

CO Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Beta thalassemia (Reblozyl, Zynteglo)
- Myelodysplastic syndromes associated anemia (Reblozyl)
- Sickle cell disease (Adakveo, Casgevy, l-glutamine, Lyfgenia, Oxbryta, Siklos)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Adakveo

- Documentation of all of the following is required:
  - diagnosis of sickle cell disease; **and**
  - member is ≥ 16 years of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member has experienced ≥ two sickle cell crises in the previous 12 months; **and**
  - member's current weight; **and**
  - inadequate response to hydroxyurea at the maximally tolerated dose for at least three months; **or**
  - adverse reaction or contraindication to hydroxyurea.
- For recertification, documentation of positive response to therapy (e.g., decrease in VOCs, reduction in need for pain management, decrease in hospitalizations) is required.

Casgevy

- Documentation of all of the following is required:
  - diagnosis of sickle cell disease; **and**
  - copy of genetic test confirming diagnosis of SCD; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - history of ≥ two sickle cell crises per year in the last two years; **and**
  - one of the following:
    - inadequate response to hydroxyurea therapy at the maximally tolerated dose for at least three months*; **or**
    - adverse reaction or contraindication to hydroxyurea; **and**
  - appropriate dosing and treatment dates; **and**
  - infusion will take place in a qualified treatment facility; **and**
  - member is clinically stable and eligible for HSCT; **and**
  - member does not have active HIV, HBV, or HCV infection; **and**

- member has not received any prior SCD gene therapy.

* Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to these agents.

l-glutamine

- Documentation of all of the following is required:
  - diagnosis of sickle cell disease; **and**
  - member is ≥ five years of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member has experienced ≥ two sickle cell crises in the previous 12 months; **and**
  - member's current weight; **and**
  - inadequate response, adverse reaction, or contraindication to hydroxyurea.

Lyfgenia

- Documentation of all of the following is required:
  - diagnosis of sickle cell disease; **and**
  - copy of genetic test confirming diagnosis of SCD; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member is ≥ 12 years of age; **and**
  - history of ≥ two sickle cell crises per year in the last two years; **and**
  - one of the following:
    - inadequate response to hydroxyurea therapy at the maximally tolerated dose for at least three months*; **or**
    - adverse reaction or contraindication to hydroxyurea; **and**
  - medical necessity for use of requested agent instead of Casgevy; **and**
  - member does not have HIV infection; **and**
  - member does not have α-thalassemia trait (-α3.7/-α3.7); **and**
  - appropriate dosing and treatment dates; **and**
  - infusion will take place in a qualified treatment facility; **and**
  - member is clinically stable and eligible for HSCT; **and**
  - member has not received any prior SCD gene therapy.

* Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to these agents.

Oxbryta

- Documentation of all of the following is required:
  - diagnosis of sickle cell disease; **and**
  - member is ≥ four years of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member has experienced at least one sickle cell crisis in the previous 12 months; **and**
  - one of the following:
    - inadequate response to hydroxyurea therapy at the maximally tolerated dose for at least three months; **or**
    - adverse reaction or contraindication to hydroxyurea; **and**
  - member has a baseline hemoglobin level ≤ 10.5 g/dL (lab work should be drawn within the last 60 days); **and**
  - for Oxbryta 300 mg tablet for oral suspension, medical necessity for the requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **and**

- appropriate dosing.
- For recertification, documentation of positive response to therapy (e.g., decrease in VOCs, Hb increase of at least one g/dL from baseline, reduction in laboratory markers associated with hemolysis) is required.

Reblozyl for beta thalassemia
- Documentation of all of the following is required:
  - medical records and genetic testing supporting diagnosis of transfusion-dependent beta thalassemia; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist supporting the use of the requested agent are provided; **and**
  - member's current weight.
- For recertification, documentation of positive response to therapy (e.g., decrease in transfusion requirements) is required.

Reblozyl for myelodysplastic syndromes associated anemia
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist supporting the use of the requested agent are provided; **and**
  - member's current weight.
- For recertification, documentation of positive response to therapy (e.g., decrease in transfusion requirements) is required.

Siklos
- Documentation of all of the following is required:
  - diagnosis of sickle cell disease; **and**
  - member is ≥ two years of age; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member's current weight; **and**
  - medical necessity for the requested formulation as noted by one of the following:
    - member is < 13 years of age; **or**
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow.

Zynteglo
- Documentation of all of the following is required:
  - diagnosis of transfusion-dependent beta thalassemia; **and**
  - copy of genetic test confirming diagnosis; **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - member is < 51 years of age; **and**
  - appropriate dosing and treatment dates; **and**
  - member does not have pre-existing HIV, HBV, or HCV infection; **and**
  - member has required ≥ 100 mL/kg/year of pRBC or ≥ eight transfusions within the last 12 months; **and**
  - infusion will take place in a qualified treatment center; **and**
  - member is clinically stable and eligible for HSCT.

MassHealth Evaluation Criteria
Table 46 - Urinary Dysfunction Agents

Drug Category: Renal and Urinary

Medication Class/Individual Agents: Urinary Dysfunction Agents

I. Prior-Authorization Requirements

Urinary Dysfunction Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bethanechol			A90
darifenacin		PA - > 1 unit/day	A90
desmopressin-DDAVP	DDAVP		# , A90
desmopressin-Nocdurna	Nocdurna	PA	
fesoterodine	Toviaz		# , A90
flavoxate			A90
mirabegron extended-release	Myrbetriq		BP, A90
oxybutynin extended-release tablet	Ditropan XL		# , A90
oxybutynin gel	Gelnique		BP
oxybutynin immediate-release 2.5 mg tablet		PA	A90
oxybutynin immediate-release 5 mg tablet, syrup			A90
oxybutynin solution		PA	A90
oxybutynin transdermal system	Oxytrol		
solifenacin suspension	Vesicare LS	PA	
solifenacin tablet	Vesicare		# , A90
tolterodine extended-release	Detrol LA		# , A90
tolterodine immediate-release	Detrol		# , A90
trospium extended -release		PA	A90
trospium immediate-release			A90
vibegron	Gemtesa	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- First-line treatment options according to the 2019 American Urological Association guidelines for overactive bladder activity are behavioral therapy.
- Pharmacological treatments recommended for overactive bladder include antimuscarinic agents or B-3 adrenergic receptor agonists, either monotherapy or in combination of one agent from each class. Literature does not support use of one specific agent over another.
- First-line pharmacological therapy for neurogenic detrusor overactivity includes anticholinergic agents. Fesoterodine, mirabegron, and solifenacin are all approved therapies for NDO in pediatric members.
- Once daily dosing with extended-release agents tend to have less antimuscarinic side effects than the immediate-release products.

References:

1. Lightner DJ, Gomelsky A, Souter L et al: Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline amendment 2019. J Urol 2019; 202:

	Clinical Notes
	558. Available from: https://www.auanet.org/guidelines/guidelines/overactive-bladder-(oab)-guideline . 2. The Committee for Establishment of the Clinical Guidelines for Nocturia of the Neurogenic Bladder Society (2010), Clinical guidelines for nocturia. International Journal of Urology, 17: 397–409.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Neurogenic detrusor overactivity
- Nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void
- Overactive bladder with symptoms of urinary frequency, urgency, or incontinence

Non-FDA-approved, for example:

- Postoperative pain related to catheter placement

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to,

documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

darifenacin > one unit/day
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - clinical rationale why the dose cannot be consolidated; **or**
    - clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA.

Gemtesa, and trospium extended-release
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: darifenacin, fesoterodine, mirabegron extended-release, oxybutynin extended-release tablet, solifenacin, tolterodine extended-release; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - for requested quantity > 1 unit/day, one of the following:
      - clinical rationale why the dose cannot be consolidated; **or**
      - clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA.

SmartPA: Claims for Gemtesa, and trospium extended-release for a quantity of ≤ one unit/day will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims within the last 365 days for two of the following: darifenacin, fesoterodine, mirabegron extended-release, oxybutynin extended-release tablet, solifenacin, tolterodine extended-release. †

Nocdurna
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response or adverse reaction to desmopressin acetate tablets; **or**
    - medical necessity for the sublingual tablet instead of the tablet formulation available without prior authorization; **and**
  - appropriate dosing; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - for requested quantity > one unit/day, one of the following:
      - clinical rationale why the dose cannot be consolidated; **or**
      - clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA.

SmartPA: Claims for Nocdurna for a quantity of ≤ one unit/day will usually process at the pharmacy without a PA request if the member is ≥ 18 years of age and has a history of paid MassHealth pharmacy claims within the last 365 days for desmopressin tablets. †

oxybutynin 2.5 mg immediate-release tablet, oxybutynin solution
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**

- medical necessity for use of the requested agent instead of formulations available without prior authorization; **and**
- appropriate dosing; **and**
- for oxybutynin 2.5 mg immediate-release tablet, one of the following:
  - requested quantity is ≤ three units/day; **or**
  - for requested quantity > three units/day, one of the following:
    - clinical rationale why the dose cannot be consolidated; **or**
    - clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA.

Oxytrol for Women

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - an intolerable adverse reaction to Oxytrol (oxybutynin transdermal system); **and**
  - one of the following:
    - requested quantity is ≤ eight patches/28 days; **or**
    - for requested quantity > eight patches/28 days, clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA; **and**
  - one of the following:
    - an intolerable adverse reaction to oral extended-release oxybutynin; **or**
    - medical necessity for the use of transdermal formulation as noted by one of the following:
      - member utilizes tube feeding (G-tube/J-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow.

Vesicare LS

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a urologist or consult notes from a urology office are provided; **and**
  - one of the following:
    - member is ≥ two years of age and < five years of age; **or**
    - inadequate response, adverse reaction, or contraindication to oxybutynin syrup; **and**
  - appropriate dosing.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 47 - Antifungal Agents - Oral and Injectable

Drug Category: Anti-infectives

Medication Class/Individual Agents: Antifungal Agents - Oral and Injectable

I. Prior-Authorization Requirements

Oral and Injectable Antifungal Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphotericin B			
amphotericin B lipid complex	Abelcet		
amphotericin B liposome	Ambisome		#
anidulafungin	Eraxis		
caspofungin	Cancidas		#
clotrimazole troche			A90
fluconazole	Diflucan		# , A90
flucytosine	Ancobon		BP, A90
griseofulvin suspension, tablet			A90
ibrexafungerp	Brexafemme	PA	
isavuconazonium	Cresemba	PA	
itraconazole 100 mg capsule	Sporanox		# , A90
itraconazole 65 mg capsule	Tolsura	PA	
itraconazole solution	Sporanox		BP, A90
ketoconazole tablet			A90
micafungin	Mycamine		#
miconazole buccal tablet	Oravig	PA	
nystatin oral suspension			A90
oteseconazole	Vivjoa	PA	
posaconazole injection	Noxafil	PA	BP
posaconazole powder for oral suspension	Noxafil	PA	
posaconazole suspension	Noxafil	PA	A90
posaconazole tablet	Noxafil		# , A90
rezafungin	Rezzayo	PA	
terbinafine tablet			A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Please see below criteria update based on the Centers for Disease Control and Prevention (CDC) recommendations regarding voriconazole suspension and tablet.

- Terbinafine is only FDA-approved for the treatment of onychomycosis of the toenail and fingernail due to dermatophytes.
- Certain azole antifungals have medication specific adverse events:
  - Fluconazole is associated with alopecia.
  - Itraconazole is associated with aldosterone-like effects and should be avoided in patients with a history of heart failure.
  - Voriconazole is associated with abnormal vision and rash.
- Voriconazole is an effective agent for *aspergillus, scedosporium,* and *fusarium* infections.
- Isavuconazonium and posaconazole are the only azole antifungals with activity against zygomycosis (mucormycosis) infections.
- Azole antifungals are potent inhibitors of various CYP450 enzymes:

Cytochrome P-450 Metabolism of Oral Antifungals

Oral and Injectable Antifungal Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
voriconazole injection, 200 mg tablet	Vfend		#
voriconazole suspension, 50 mg tablet	Vfend	PA	A90

Clinical Notes

Agent	2C19	2C9	3A4	1A2	2A6	2E1	2D6
fluconazole	X(S)	X(S)	X(M)				
itraconazole			X(S)				
voriconazole	X(W)	X(W)	X(M)				
posaconazole			X(S)				
ketoconazole			X(S)	X(M)	X(M)	X(M)	
clotrimazole			X(M)				
terbinafine			X(S)				X(S)
isavuconazole			X(M)				

S=Strong, M=Moderate, W=Weak

- Hepatic function abnormalities are associated with the azole class, including terbinafine, and as such, careful monitoring of liver function tests are recommended in all patients receiving these agents. Specific monitoring recommendations include:
  - isavuconazonium: at initiation and during course of treatment
  - itraconazole: for all patients being treated for longer than one month
  - posaconazole: at the start of and during the course of therapy
  - terbinafine: before initiation and should be repeated if

	Clinical Notes
	used for > six weeks • voriconazole: at initiation and during course of treatment

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Aspergillosis, blastomycosis, and histoplasmosis – Tolsura
- invasive Aspergillus infections – Cresemba, voriconazole suspension, 50 mg tablet
- prevention of invasive Aspergillus and Candida infections – posaconazole injection, posaconazole oral suspension
- candidemia – Rezzayo, voriconazole suspension, 50 mg tablet
- disseminated candidiasis – voriconazole suspension, 50 mg tablet
- esophageal candidiasis – voriconazole suspension, 50 mg tablet
- fungal infections caused by Fusarium and Scedosporium – voriconazole suspension, 50 mg tablet
- invasive candidiasis – Rezzayo
- oropharyngeal candidiasis – Oravig, posaconazole oral suspension
- recurrent vulvovaginal candidiasis – Brexafemme, Vivjoa
- vulvovaginal candidiasis – Brexafemme
- zygomycosis (mucormycosis) – Cresemba

Non FDA-approved, for example:

- Aspergillus endophthalmitis and keratitis – voriconazole suspension, 50 mg tablet
- esophageal candidiasis – posaconazole oral suspension
- fungal infections caused by Fusarium and Scedosporium – Cresemba
- oropharyngeal candidiasis – voriconazole suspension, 50 mg tablet
- prevention of invasive Aspergillus and Candida infections – voriconazole suspension, 50 mg tablet
- zygomycosis (mucormycosis) – posaconazole injection, posaconazole oral suspension

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90

or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.

- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Brexafemme

- Documentation of the following is required for the treatment of acute vulvovaginal candidiasis:
  - appropriate diagnosis; **and**
  - member is post-menarchal; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to oral fluconazole; **or**
    - Candida species is fluconazole-resistant.
- Documentation of the following is required for the treatment of recurrent vulvovaginal candidiasis:
  - appropriate diagnosis; **and**
  - results from a potassium hydroxide (KOH) test to confirm diagnosis; **and**
  - member has had ≥ 3 acute VVC episodes within the last 12 months; **and**
  - requested quantity is ≤ 24 tablets for one course of therapy; **and**
  - member is post-menarchal; **and**
  - one of the following:
    - inadequate response (defined as ≥ 24 weeks of therapy or recurrence of infection while on maintenance therapy), adverse reaction, or contraindication to oral fluconazole; **or**
    - candida species is fluconazole-resistant.

Cresemba

- Documentation of the following is required for the treatment of aspergillus infections:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: posaconazole, voriconazole; **and**
  - for the injectable formulation, medical necessity for the injectable formulation instead of oral capsule formulation.
- Documentation of the following is required for the treatment of zygomycosis (mucormycosis):
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - for the injectable formulation, medical necessity for use of the IV formulation instead of oral capsule formulation; **and**
  - inadequate response, adverse reaction, or contraindication to posaconazole.

SmartPA: Claims for Cresemba capsule will usually process at the pharmacy without a PA request for members who are ≥ 18 years of age with a history of MassHealth medical claims for zygomycosis (mucormycosis) within the last 365 days.†

Oravig

- Documentation of the following is required for the diagnosis of oropharyngeal candidiasis:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**

- inadequate response, adverse reaction, or contraindication to both of the following: clotrimazole troches, nystatin suspension.

posaconazole injection

- Documentation of the following is required for the prevention of invasive aspergillus and candida fungal infections:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - medical necessity for use of the injectable formulation instead of oral formulations; **and**
  - member has a diagnosis of one of the following:
    - hematologic malignancy (e.g., acute myelogenous leukemia, myelodysplastic syndromes) with neutropenia; **or**
    - hematopoietic stem cell transplantation (HSCT); **or**
    - graft-versus-host disease (GVHD).
- Documentation of the following is required for the treatment of invasive aspergillosis fungal infections:
  - appropriate diagnosis; **and**
  - member is ≥ 13 years of age; **and**
  - medical necessity for use of the IV formulation instead of oral formulations.
- Documentation of the following is required for the treament of zygomycosis (mucormycosis):
  - appropriate diagnosis; **and**
  - member is ≥13 years of age; **and**
  - medical necessity for use of the IV formulation instead of oral formulations.

posaconazole oral suspension

- Documentation of the following is required for the prevention of invasive aspergillus and candida fungal infections:
  - appropriate diagnosis; **and**
  - member is ≥ 13 years of age; **and**
  - member has a diagnosis of one of the following:
    - hematologic malignancy (e.g., acute myelogenous leukemia, myelodysplastic syndromes) with neutropenia; **or**
    - hematopoietic stem cell transplantation (HSCT); **or**
    - graft-versus-host disease (GVHD).
- Documentation of the following is required for the treatment of esophageal candidiasis:
  - appropriate diagnosis; **and**
  - member is ≥ 13 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: oral fluconazole, itraconazole, voriconazole.
- Documentation of the following is required for the treatment of oropharyngeal candidiasis:
  - appropriate diagnosis; **and**
  - member is ≥ 13 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: oral fluconazole, itraconazole.
- Documentation of the following is required for the treatment of zygomycosis (mucormycosis):
  - appropriate diagnosis; **and**
  - member is ≥ 13 years of age.

SmartPA: Claims for posaconazole oral suspension will usually process at the pharmacy without a PA request for members who are ≥ 13 years of age with a history of MassHealth medical claims for zygomycosis (mucormycosis) within the last 365 days.†

posaconazole powder for oral suspension

- Documentation of the following is required for the prevention of invasive aspergillus and candida fungal infections:
  - member has a diagnosis of one of the following:
    - hematologic malignancy (e.g., acute myelogenous leukemia, myelodysplastic syndromes) with neutropenia; **or**
    - hematopoietic stem cell transplantation (HSCT); **or**
  - member is ≥ 18 years of age; **and**

- prescriber is an infectious disease specialist or consult notes from a specialist are provided; **and**
- inadequate response, adverse reaction, contraindication, or Candida isolate is resistant to ALL of the following: anidulafungin, caspofungin, micafungin; **and**
- requested quantity is ≤ six vials for one course of therapy.

Rezzayo

- Documentation of all of the following is required:
  - member has a diagnosis of one of the following:
    - candidemia; **or**
    - invasive candidiasis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is an infectious disease specialist or consult notes from a specialist are provided; **and**
  - inadequate response, adverse reaction, contraindication, or Candida isolate is resistant to all of the following: anidulafungin, caspofungin, micafungin; **and**
  - requested quantity is ≤ six vials for one course of therapy.

Tolsura

- Documentation of the following is required for the treatment of aspergillosis, blastomycosis, and histoplasmosis:
  - appropriate diagnosis; **and**
  - medical necessity for the 65 mg capsule instead of the 100 mg capsule.

Vivjoa

- Documentation of the following is required for the treatment of recurrent vulvovaginal candidiasis:
  - appropriate diagnosis; **and**
  - results from a potassium hydroxide (KOH) test to confirm diagnosis; **and**
  - member has had ≥ three acute VVC episodes within past 12 months; **and**
  - requested quantity is ≤ 18 capsules for one course of therapy; **and**
  - one of the following:
    - member is ≥ 12 years of age and not of reproductive potential; **or**
    - member is post-menopausal; **and**
  - one of the following:
    - inadequate response (defined as ≥ 24 weeks of therapy or recurrence of infection while on maintenance therapy), adverse reaction, or contraindication to oral fluconazole; **or**
    - Candida species is fluconazole resistant.

voriconazole suspension, 50 mg tablet

- Documentation of the following is required for the prevention of invasive aspergillus and candida fungal infections:
  - member has a diagnosis of one of the following:
    - hematologic malignancy (e.g., acute myelogenous leukemia, myelodysplastic syndromes) with neutropenia; **or**
    - hematopoietic stem cell transplantation (HSCT); **or**
    - graft-versus-host disease (GVHD).
- Documentation of the following is required for the treatment of aspergillus, scedosporium, and fusarium infections:
  - appropriate diagnosis.
- Documentation of the following is required for the treatment of aspergillus endophthalmitis and keratitis:
  - appropriate diagnosis.
- Documentation of the following is required for the treatment of candidemia and disseminated candidiasis infections:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to oral fluconazole.

- Documentation of the following is required for the treatment of esophageal candidiasis:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: oral fluconazole, itraconazole.
- Documentation of the following is required for the treatment of oropharyngeal candidiasis:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: oral fluconazole, itraconazole, posaconazole.

SmartPA: Claims for voriconazole suspension or 50 mg tablet will usually process at the pharmacy without a PA request for members with a history of MassHealth medical claims for aspergillus within the last 365 days.†

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 48 - Antiparkinsonian Agents

Drug Category: CNS Agents

Medication Class/Individual Agents: Antiparkinsonian Agents

I. Prior-Authorization Requirements

Antiparkinsonian Agents – Dopamine Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
apomorphine film	Kynmobi	PA	
apomorphine injection	Apokyn		#
bromocriptine 2.5 mg, 5 mg	Parlodel		# , A90
pramipexole	Mirapex		# , A90
pramipexole extended-release	Mirapex ER	PA	A90
ropinirole			A90
ropinirole extended-release			A90
rotigotine transdermal system	Neupro	PA - > 1 unit/day	BP

Antiparkinsonian Agents – Monoamine Oxidase (MAO) Type-B Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
rasagiline	Azilect	PA - > 1 unit/day	A90
safinamide	Xadago	PA	
selegiline capsule, tablet			A90
selegiline orally disintegrating tablet	Zelapar	PA	

Antiparkinsonian Agents – Catechol-O-Methyl Transferase (COMT) Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
entacapone	Comtan		# , A90
opicapone	Ongentys	PA	
tolcapone	Tasmar	PA	A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- There is no universal first choice in the treatment of Parkinson’s disease. Clinical and lifestyle characteristics of the member should be taken into account.
- Most patients will develop motor complications over time and will require levodopa therapy. Adjuvant medications may help to reduce motor complications and raise quality of life in late stage Parkinson’s disease.
- Anticholinergics are poorly tolerated in the elderly and should be avoided.

Antiparkinsonian Agents – Dopamine Analogues			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
carbidopa	Lodosyn		# , A90
carbidopa / levodopa enteral suspension	Duopa	PA	
carbidopa / levodopa extended-release capsule	Rytary	PA	
carbidopa / levodopa extended-release tablet			A90
carbidopa / levodopa orally disintegrating tablet		PA	A90
carbidopa / levodopa tablet	Sinemet		# , A90
levodopa	Inbrija	PA	

Antiparkinsonian Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amantadine extended-release capsule	Gocovri	PA	
amantadine extended-release tablet	Osmolex ER	PA	
amantadine immediate-release capsule, solution, tablet			A90
carbidopa / levodopa / entacapone	Stalevo		# , A90
istradefylline	Nourianz	PA	A90

Antiparkinsonian Agents – Anticholinergic Medications			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
benztropine			A90
trihexyphenidyl			A90

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Drug-induced extrapyramidal symptoms (Gocovri, Osmolex ER)
- Parkinson's disease
- Parkinson's disease psychosis (Nuplazid)

Non-FDA-approved, for example:

- Restless leg syndrome (pramipexole extended-release)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

carbidopa/levodopa orally disintegrating tablet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is unable to swallow pills or use a conventional formulation; **and**
  - member is not currently receiving other oral formulations.

Duopa

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member has a PEG tube; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to carbidopa/levodopa immediate-release tablet formulation.

Gocovri

- Documentation of the following is required for a diagnosis of Parkinson's disease:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: carbidopa/levodopa, dopamine agonist, monoamine oxidase-type B (MAO B) inhibitor, anticholinergic agent; **and**
  - for the 68.5 mg capsule, member has moderate or severe renal impairment; **and**
  - one of the following:
    - for 68.5 mg capsule, requested quantity is ≤ one unit/day; **or**
    - for 137 mg capsule, requested quantity is ≤ f two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral solution); **and**
  - medical necessity for use of amantadine extended-release capsules instead of amantadine extended-release tablets.
- Documentation of the following is required for a diagnosis of Parkinson's disease with dyskinesia while on levodopa-based therapy:
  - appropriate diagnosis; **and**
  - member is experiencing dyskinesia while on levodopa-based therapy; **and**
  - member is concurrently taking carbidopa/levodopa; **and**
  - for the 68.5 mg capsule, member has moderate or severe renal impairment; **and**
  - one of the following:
    - for 68.5 mg capsule, requested quantity is ≤ one unit/day; **or**
    - for 137 mg capsule, requested quantity is ≤ two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral solution); **and**
  - medical necessity for use of amantadine extended-release capsules instead of amantadine extended-release tablets.
- Documentation of the following is required for a diagnosis of Parkinson's disease with "off" episodes while on carbidopa/levodopa therapy:
  - appropriate diagnosis; **and**
  - member is experiencing “off” symptoms with carbidopa/levodopa therapy despite maximizing dose; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to carbidopa/levodopa in combination with all of the following: dopamine agonist, catechol-o-methyl transferase (COMT) inhibitor, MAO B inhibitor; **and**
  - for the 68.5 mg capsule, member has moderate or severe renal impairment; **and**
  - one of the following:
    - for 68.5 mg capsule, requested quantity is ≤ one unit/day; **or**
    - for 137 mg capsule, requested quantity is ≤ two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral solution); **and**
  - medical necessity for use of amantadine extended-release capsules instead of amantadine extended-release tablets.
- Documentation of the following is required for a diagnosis of drug-induced extrapyramidal symptoms:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all anticholinergic agents; **and**
  - for the 68.5 mg capsule, member has moderate or severe renal impairment; **and**
  - one of the following:
    - for 68.5 mg capsule, requested quantity is ≤ one unit/day; **or**
    - for 137 mg capsule, requested quantity is ≤ two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral solution); **and**
  - medical necessity for use of amantadine extended-release capsules instead of amantadine extended-release tablets.

Inbrija and Kynmobi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is experiencing "off" symptoms with carbidopa/levodopa therapy despite maximizing dose; **and**
  - medical records documenting an inadequate response or adverse reaction to carbidopa/levodopa immediate-release used as needed for "off" symptoms; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to carbidopa/levodopa in combination with all of the following: dopamine agonist, COMT inhibitor, MAO B inhibitor; **and**
  - one of the following:
    - for Inbrija**,** requested dose is 84 mg (two 42 mg capsules) up to five times per day as needed for "off" symptoms; **or**
    - for Kynmobi, requested quantity is ≤ five units/day.

Neupro > one unit/day and rasagiline > one unit/day

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is concurrently taking carbidopa/levodopa; **and**
  - medical records documenting titration to doses exceeding the quantity limit.

Nourianz

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is experiencing "off" symptoms with carbidopa/levodopa therapy despite maximizing dose; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to carbidopa/levodopa in combination with all of the following: dopamine agonist, COMT inhibitor, MAO B inhibitor; **and**
  - requested quantity is ≤ one unit/day.

Ongentys and tolcapone

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is concurrently taking carbidopa/levodopa; **and**
  - for Ongentys, an inadequate response, adverse reaction, or contraindication to entacapone.
  - for tolcapone, an inadequate response, adverse reaction, or contraindication to both of the following: entacapone, Ongentys.

SmartPA: Claims for Ongentys will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for Parkinson's disease, a history of paid MassHealth pharmacy claims for a carbidopa/levodopa product for at least 90 days within the last 120 days, and a history of paid MassHealth pharmacy claims for entacapone.†

SmartPA: Claims for tolcapone will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for Parkinson's disease, a history of paid MassHealth pharmacy claims for a carbidopa/levodopa product for at least 90 days within the last 120 days, and a history of paid MassHealth pharmacy claims for entacapone and Ongentys.†

Osmolex ER

- Documentation of the following is required for a diagnosis of Parkinson's disease:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: carbidopa/levodopa, dopamine agonist, MAO B inhibitor, anticholinergic agent; **and**
  - one of the following:
    - for tablet, requested quantity is ≤ one unit/day; **or**
    - for tablet dose pack, requested quantity is ≤ two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral

solution).

- Documentation of the following is required for a diagnosis of Parkinson's disease with dyskinesia while on levodopa-based therapy:
  - appropriate diagnosis; **and**
  - member is experiencing dyskinesia while on levodopa-based therapy; **and**
  - member is concurrently taking carbidopa/levodopa; **and**
  - one of the following:
    - for tablet, requested quantity is ≤ one unit/day; **or**
    - for tablet dose pack, requested quantity is ≤ two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release.
- Documentation of the following is required for a diagnosis of Parkinson's disease with "off" episodes while on carbidopa/levodopa therapy:
  - appropriate diagnosis; **and**
  - member is experiencing “off” symptoms with carbidopa/levodopa therapy despite maximizing dose; **and**
  - medical records documenting an inadequate response, adverse reaction, or contraindication to carbidopa/levodopa in combination with all of the following: dopamine agonist, COMT inhibitor, and MAO B inhibitor; **and**
  - one of the following:
    - for tablet, requested quantity is ≤ one unit/day; **or**
    - for tablet dose pack,requested quantity is ≤ two units/day; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release.
- Documentation of the following is required for a diagnosis of drug-induced extrapyramidal symptoms:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to all anticholinergic agents; **and**
  - medical necessity for use of amantadine extended-release instead of amantadine immediate-release (capsules, tablets, oral solution); **and**
  - one of the following:
    - for tablet, requested quantity is ≤ one unit/day; **or**
    - for tablet dose pack, requested quantity is ≤ two units/day.

pramipexole extended-release

- Documentation of the following is required for the diagnosis of Parkinson’s disease:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction or inadequate response to both of the following: pramipexole immediate-release, ropinirole extended-release.

- Documentation of the following is required for the diagnosis of Restless leg syndrome:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to both of the following: pramipexole immediate-release, ropinirole extended-release.

Rytary

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to the carbidopa/levodopa immediate-release tablet formulation; **and**
  - medical necessity for use instead of carbidopa/levodopa extended-release tablet.

Xadago

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- member is concurrently taking carbidopa/levodopa; **and**
- member is experiencing "off" symptoms with carbidopa/levodopa therapy; **and**
- medical records documenting an inadequate response or adverse reaction to selegiline and rasagiline; **and**
- requested quantity is ≤ one unit/day.

Zelapar

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is concurrently taking carbidopa/levodopa; **and**
  - member is unable to swallow pills or use a conventional formulation; **and**
  - member is not currently receiving other oral solid formulation; **and**
  - requested quantity is ≤ two units/day.

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 49 - Osteoporosis and Bone Metabolism Agents

Drug Category: Bone

Medication Class/Individual Agents: Osteoporosis and Bone Metabolism Agents

I. Prior-Authorization Requirements

Osteoporosis and Bone Metabolism Agents – Bisphosphonates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alendronate / cholecalciferol	Fosamax Plus D	PA	
alendronate effervescent tablet	Binosto	PA	
alendronate solution		PA	M90
alendronate tablet	Fosamax		# , M90
ibandronate injection		PA	MB
ibandronate tablet	Boniva		# , M90
pamidronate			MB
risedronate	Actonel	PA	M90
risedronate delayed-release	Atelvia	PA	BP, M90
zoledronic acid 4 mg			MB
zoledronic acid 5 mg	Reclast		MB

Osteoporosis and Bone Metabolism Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
abaloparatide	Tymlos	PA	
burosumab-twza	Crysvita	PA	
calcitonin salmon injection	Miacalcin	PA	
calcitonin salmon nasal spray			M90
denosumab-Prolia	Prolia	PA	
denosumab-Xgeva	Xgeva	PA	
estrogens, conjugated/bazed oxifene	Duavee	PA	
raloxifene	Evista		# , M90
romosozumab-aqqg	Evenity	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Pharmacologic treatment should be offered to men and women who have known osteoporosis and to those who have experienced fragility fractures.
- Pharmacologic treatment should be considered for men and women who are at risk for developing osteoporosis (patients with a T-score from –1.5 to –2.5, are receiving glucocorticoids, or are ≥ 62 years of age).
- The FDA recommends considering nonestrogen treatments prior to estrogen and/or hormone therapy for prevention of osteoporosis.
- While combination therapy may produce small increases in bone mineral density (BMD) compared to monotherapy, the impact of combination therapy on fracture rates is unknown. The potential side effects and additional costs should be weighed against potential gains.

Osteoporosis and Bone Metabolism Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
teriparatide 600 mcg/2.4 mL	Forteo	PA	BP
teriparatide 620 mcg/0.48 mL		PA	

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Paget's disease
- prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors and in multiple myeloma
- treatment of FGF23-related hypophosphatemia in tumor induced osteomalacia
- treatment of giant cell tumor of the bone
- treatment of hypercalcemia
- treatment of hypercalcemia of malignancy
- treatment of hypocalcemia with hypoparathyroidism
- treatment of moderate-to-severe vasomotor symptoms associated with menopause
- treatment of X-Linked hypophosphatemia
- treatment/prevention of glucocorticoid-induced osteoporosis
- treatment/prevention of postmenopausal osteoporosis in women and osteoporosis in men
- treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer
- treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name

Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Paget's Disease (calcitonin salmon injection)

- Documentation (including medical records) of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to alendronate; **or**
    - contraindication to oral bisphosphonates; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to pamidronate; **or**
    - inadequate response to an adequate trial or adverse reaction to zoledronic acid 5 mg; **or**
    - contraindication to IV bisphosphonates.

Paget's Disease (risedronate)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to an adequate trial or adverse reaction to alendronate.

Prevention of postmenopausal osteoporosis (Duavee)

- Documentation of all of the following is required:
  - indication of prevention of postmenopausal osteoporosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to one oral bisphosphonate; **or**
    - contraindication to all oral bisphosphonates; **and**
  - inadequate response, adverse reaction, or contraindication to all of the following: one menopausal hormonal agent available without PA, raloxifene, zoledronic acid 5 mg; **and**
  - requested quantity is ≤ one unit/day.

Prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors and in multiple myeloma, and treatment of hypercalcemia of malignancy (Xgeva)

- Documentation of all of the following is required:
  - diagnosis of one of the following:
    - prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors; **or**

- prevention of skeletal-related events secondary to multiple myeloma; **or**
- treatment of hypercalcemia of malignancy; **and**

- prescriber is an oncologist, hematologist, or orthopedic specialist or consult notes from an oncologist, hematologist, or orthopedic specialist are provided; **and**
- appropriate dosing.

Primary or hypogonadal osteoporosis with a high risk for fracture or postmenopausal osteoporosis with a high risk for fracture (teriparatide 600 mcg/2.4 mL, teriparatide 620 mcg/2.48 mL)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - bone mineral density indicating osteoporosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate; **or**
    - member is at very high risk for fracture indicated by at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - history of multiple fractures; **or**
      - history of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids); **or**
      - T-score less than −3.0; **or**
      - high risk for falls; **or**
      - history of injurious falls; **or**
      - very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm; **or**
    - contraindication to oral bisphosphonates; **and**
  - one of the following:
    - diagnosis of severe osteoporosis defined as at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - T-score less than −3.0; **or**
      - T-score of -2.5 or below plus a fragility fracture; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following: ibandronate injection, Prolia, zoledronic acid 5 mg; **and**
  - for teriparatide 620 mcg/2.48 mL, medical necessity for the requested formulation instead of teriparatide 600 mcg/2.4 mL.

Postmenopausal osteoporosis (calcitonin salmon injection), or postmenopausal osteoporosis with a high risk for fracture (Evenity, Tymlos)

- Documentation (including medical records) of all of the following is required:
  - appropriate diagnosis; **and**
  - bone mineral density indicating osteoporosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate; **or**
    - member is at very high risk for fracture indicated by at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - history of multiple fractures; **or**
      - history of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids); **or**
      - T-score less than −3.0; **or**
      - high risk for falls; **or**
      - history of injurious falls; **or**

        - very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm; **or**
      - contraindication to oral bisphosphonates; **and**
    - one of the following:
      - diagnosis of severe osteoporosis defined as at least one of the following:
        - history of fracture within the past 12 months; **or**
        - history of fractures while on osteoporosis therapy; **or**
        - T-score less than −3.0; **or**
        - T-score of -2.5 or below plus a fragility fracture; **or**
      - inadequate response or adverse reaction to one or contraindication to all of the following: ibandronate injection, Prolia, zoledronic acid 5 mg; **and**
    - inadequate response to an adequate trial, adverse reaction, or contraindication to teriparatide 600 mcg/2.4 mL; **and**
    - for calcitonin salmon injection, inadequate response, adverse reaction, or contraindication to calcitonin nasal spray.

Treatment of FDF23-related hypophosphatemia in tumor induced osteomalacia (Crysvita)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - phosphaturic mesenchymal tumor cannot be resected or localized; **and**
  - appropriate dosing.
- For recertification, documentation of positive response to therapy (defined as either improved member serum phosphorus concentration and/or radiographic improvement) is required.

Treatment of giant cell tumor of the bone (Xgeva)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - tumor or metastases are unresectable; **or**
    - surgical resection is likely to result in severe morbidity; **or**
    - surgery is not an option at this time; **and**
  - appropriate dose and frequency for giant cell tumor of the bone.

Treatment of hypercalcemia (calcitonin salmon injection)

- Documentation (including medical records) of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for calcitonin salmon injection.

Treatment of moderate-to-severe vasomotor symptoms associated with menopause (Duavee)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction to one or contraindication to all menopausal hormonal agents available without PA; **and**
  - requested quantity is ≤ one unit/day.

Treatment of osteoporosis (Fosamax Plus D)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the combination product instead of the individual agents.

Treatment of X-Linked hypophosphatemia (Crysvita)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ six months of age; **and**
  - member's current weight; **and**
  - appropriate dosing.
- For recertification, documentation of positive response to therapy (defined as either improved member serum phosphorus concentration and/or radiographic improvement) is required.

Treatment/prevention of glucocorticoid-induced osteoporosis (teriparatide 600 mcg/2.4 mL, teriparatide 620 mcg/2.48 mL)
- Documentation of all of the following is required:
  - appropriate diagnosis or chronic glucocorticoid use for at least three months in duration; **and**
  - bone mineral density indicating osteoporosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate; **or**
    - member is at very high risk for fracture indicated by at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - history of multiple fractures; **or**
      - history of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids); **or**
      - T-score less than −3.0; **or**
      - high risk for falls; **or**
      - history of injurious falls; **or**
      - very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm; **or**
    - contraindication to oral bisphosphonates; **and**
  - one of the following:
    - diagnosis of severe osteoporosis defined as at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - T-score less than −3.0; **or**
      - T-score of -2.5 or below plus a fragility fracture; **or**
    - inadequate response or adverse reaction to one or contraindication to all of the following: ibandronate injection, Prolia, zoledronic acid 5 mg; **and**
  - for teriparatide 620 mcg/2.48 mL, medical necessity for the requested formulation instead of teriparatide 600 mcg/2.4 mL.

Treatment/prevention of glucocorticoid-induced osteoporosis (risedronate, risedronate delayed-release)
- Documentation of all of the following is required:
  - appropriate diagnosis or chronic glucocorticoid use for at least three months in duration; **and**
  - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate.

Treatment/prevention of glucocorticoid-induced osteoporosis (Prolia)
- Documentation of all of the following is required:
  - appropriate diagnosis or chronic glucocorticoid use for at least three months in duration; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to one oral bisphosphonate; **or**
    - member is at very high risk for fracture indicated by at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - history of multiple fractures; **or**

- history of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids); **or**
- T-score less than −3.0; **or**
- high risk for falls; **or**
- history of injurious falls; **or**
- very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm; **or**

- contraindication to oral bisphosphonates.

Treatment/prevention of osteoporosis (alendronate solution, Binosto)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for requested formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age.

Treatment/prevention of osteoporosis (ibandronate injection, Prolia)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate; **or**
    - member is at very high risk for fracture indicated by at least one of the following:
      - history of fracture within the past 12 months; **or**
      - history of fractures while on osteoporosis therapy; **or**
      - history of multiple fractures; **or**
      - history of fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids); **or**
      - T-score less than −3.0; **or**
      - high risk for falls; **or**
      - history of injurious falls; **or**
      - very high fracture probability by FRAX (fracture risk assessment tool) or other validated fracture risk algorithm; **or**
    - contraindication to oral bisphosphonates.

Treatment/prevention of osteoporosis (risedronate, risedronate delayed-release)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to an adequate trial or adverse reaction to an oral bisphosphonate.

Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer or treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non metastatic prostate cancer (Prolia)

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to an adequate trial or adverse reaction to a bisphosphonate; **or**
  - contraindication to oral and injectable bisphosphonates.

MassHealth Evaluation Criteria

Table 50 - Narcolepsy and Miscellaneous Sleep Disorder Therapy Agents

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Narcolepsy and Sleep Disorder

I. Prior-Authorization Requirements

Narcolepsy and Miscellaneous Sleep Disorder Therapy Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
calcium oxybate / magnesium oxybate / potassium oxybate / sodium oxybate	Xywav	PA	
pitolisant	Wakix	PA	
sodium oxybate	Xyrem	PA	BP
solriamfetol	Sunosi	PA	
tasimelteon	Hetlioz	PA	BP, A90

Narcolepsy and Miscellaneous Sleep Disorder Therapy Agents – Modafinil Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
armodafinil	Nuvigil	PA - < 6 years and PA > 1 unit/day	#
modafinil 100 mg	Provigil	PA - < 6 years and PA > 1.5 units/day	#
modafinil 200 mg	Provigil	PA - < 6 years and PA > 2 units/day	#

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Clinical trials for solriamfetol did not evaluate its use in combination with other medications that could affect excessive sleepiness, including cerebral stimulants, modafinil agents, or sodium oxybate.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- cataplexy associated with narcolepsy - sodium oxybate, Wakix, Xywav

- excessive daytime sleepiness (EDS) associated with narcolepsy - sodium oxybate, Sunosi, Wakix, Xywav
- EDS associated with obstructive sleep apnea (OSA) - Sunosi
- idiopathic hypersomnia - sodium oxybate, Xywav
- non-24-hour sleep-wake disorder - tasimelteon
- Smith-Magenis syndrome (SMS) - tasimelteon

Non-FDA approved, for example:

- EDS associated with OSA - sodium oxybate, Wakix, Xywav

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

armodafinil and modafinil exceeding quantity limits

- Documentation of all of the following is required:
  - appropriate dosing; **and**
  - medical necessity for exceeding the quantity limits.

concomitant use of modafinil and armodafinil (a history of at least one paid MassHealth pharmacy claim for the other agents within the last 30 days)

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for concomitant use of modafinil and armodafinil.

sodium oxybate and Xywav

- Documentation of all of the following is required for a diagnosis of cataplexy associated with narcolepsy:
  - appropriate diagnosis; **and**
  - medical records documenting the results of the sleep study used to confirm narcolepsy (PSG or MSLT); **and**
  - prescriber is a neurologist or sleep specialist, or consult notes from a neurologist or sleep specialist are provided; **and**

- inadequate response or adverse reaction to one, or contraindication to all of the following: atomoxetine, SSRI, tricyclic antidepressant, venlafaxine; **and**
- requested dose is ≤ nine grams (18 mL)/day; **and**
- for Xywav, clinical rationale for use instead of sodium oxybate.

- Documentation of all of the following is required for a diagnosis of EDS associated with narcolepsy (without cataplexy):
  - appropriate diagnosis; **and**
  - medical records documenting the results of the sleep study used to confirm narcolepsy (PSG or MSLT); **and**
  - prescriber is a neurologist or sleep specialist, or consult notes from a neurologist or sleep specialist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to all cerebral stimulant agents; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: armodafinil, modafinil; **and**
  - requested dose is ≤ nine grams (18 mL)/day; **and**
  - for Xywav, clinical rationale for use instead of sodium oxybate.
- Documentation of all of the following is required for a diagnosis of idiopathic hypersomnia:
  - appropriate diagnosis; **and**
  - medical records documenting the results of the PSG ruling out other causes; **and**
  - medical records documenting the results of the MSLT; **and**
  - prescriber is a neurologist or sleep specialist, or consult notes from a neurologist or sleep specialist are provided; **and**
  - member does not have hypersomnia due to another medical, behavioral, or psychiatric disorder; **and**
  - member is not currently utilizing a drug that can cause EDS; **and**
  - inadequate response or adverse reaction to one or contraindication to all cerebral stimulant agents; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: armodafinil, modafinil; **and**
  - requested dose is ≤ nine grams (18 mL)/day; **and**
  - for Xywav, clinical rationale for use instead of sodium oxybate.
- Documentation of all of the following is required for a diagnosis of EDS associated with OSA:
  - appropriate diagnosis; **and**
  - medical records of the sleep study used to diagnose OSA (PSG); **and**
  - medical records documenting the member is utilizing CPAP/BiPAP, an oral appliance, or has undergone successful surgical treatment for OSA; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: armodafinil, modafinil; **and**
  - inadequate response, adverse reaction, or contraindication to Sunosi; **and**
  - requested dose is ≤ nine grams (18 mL)/day; **and**
  - for Xywav, clinical rationale for use instead of sodium oxybate.

Sunosi

- Documentation of all of the following is required for a diagnosis of EDS associated with narcolepsy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical records documenting the results of the sleep study used to confirm narcolepsy [polysomnogram (PSG) or Multiple Sleep Latency Test (MSLT)]; **and**
  - inadequate response or adverse reaction to one, or contraindication to all cerebral stimulant agents; **and**
  - inadequate response or adverse reaction to one, or contraindication to both of the following: armodafinil, modafinil; **and**
  - one of the following:
    - the requested medication will not be used in combination with stimulants or stimulant-like agents; **or**
    - clinical rationale for use of the requested agent in combination with other stimulants or stimulant-like agents; **and**
  - requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for a diagnosis of EDS associated with obstructive sleep apnea (OSA):
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**

- medical records of the sleep study used to diagnose OSA (PSG); **and**
- one of the following:
  - medical records documenting the member is utilizing CPAP/BiPAP, an oral appliance, or has undergone successful surgical treatment for OSA; **or**
  - contraindication to CPAP/BiPAP or an oral appliance; **and**
- inadequate response or adverse reaction to one, or contraindication to both of the following: armodafinil, modafinil; **and**
- one of the following:
  - the requested medication will not be used in combination with stimulants or stimulant-like agents; **or**
  - clinical rationale for use of the requested agent in combination with other stimulants or stimulant-like agents; **and**
- requested quantity is ≤ one unit/day.

tasimelteon capsule

- Documentation of all of the following is required for non-24 hour sleep wake disorder:
  - appropriate diagnosis; **and**
  - member is totally blind; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a sleep specialist, or consult notes from a sleep specialist are provided; **and**
  - inadequate response (defined as at least 28 days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for SMS:
  - appropriate diagnosis; **and**
  - prescriber is a sleep specialist or consult notes from a sleep specialist are provided; **and**
  - member is ≥ three years of age; **and**
  - inadequate response (defined by at least 28 days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - requested quantity is ≤ one unit/day.

tasimelteon suspension

- Documentation of all of the following is required for SMS:
  - appropriate diagnosis; **and**
  - prescriber is a sleep specialist or consult notes from a sleep specialist are provided; **and**
  - member is ≥ three years of age; **and**
  - inadequate response (defined by at least 28 days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - medical necessity for use instead of capsule formulation; **and**
  - requested quantity is ≤ five mL/day.

Wakix

- Documentation of all of the following is required for a diagnosis of cataplexy associated with narcolepsy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical records documenting the results of the sleep study used to confirm narcolepsy (PSG or MSLT); **and**
  - prescriber is a neurologist or sleep specialist, or consult notes from a neurologist or sleep specialist are provided; **and**
  - inadequate response or adverse reaction to one, or contraindication to all of the following: atomoxetine, SSRI, tricyclic antidepressant, venlafaxine; **and**
  - inadequate response or adverse reaction to one, or contraindication to all oxybate products; **and**
  - requested quantity is ≤ two units/day.
- Documentation of all of the following is required for a diagnosis of EDS associated with narcolepsy (without cataplexy):
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**

- medical records documenting the results of the sleep study used to confirm narcolepsy (PSG or MSLT); **and**
- prescriber is a neurologist or sleep specialist or consult notes from a neurologist or sleep specialist are provided; **and**
- inadequate response or adverse reaction to three, or contraindication to all of the following: armodafinil or modafinil, cerebral stimulant agent, sodium oxybate, Sunosi; **and**
- requested quantity is ≤ two units/day.

- Documentation of all of the following is required for a diagnosis of EDS associated with OSA:
  - appropriate diagnosis; **and**
  - medical records of the sleep study used to diagnose OSA (PSG); **and**
  - medical records documenting the member is utilizing CPAP/BiPAP, an oral appliance, or has undergone successful surgical treatment for OSA; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: armodafinil, modafinil; **and**
  - inadequate response, adverse reaction, or contraindication to Sunosi; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: sodium oxybate, Xywav; **and**
  - requested quantity is ≤ two units/day.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy ***(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, and viloxazine] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**

- treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
- prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation; **and**
- one of the following:
  - member has a seizure diagnosis only; **or**
  - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
  - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
  - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and**
  - one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

armodafinil and modafinil for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current alpha agonist(s) and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 51 - Antiglaucoma Agents - Ophthalmic

Drug Category: Ophthalmic

Medication Class/Individual Agents: Antiglaucoma Agents

I. Prior-Authorization Requirements

Antiglaucoma Agents: Ophthalmic – Alpha-Adrenergic Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
apraclonidine	Iopidine		# , M90
brimonidine 0.1%, 0.15% eye drops	Alphagan P		BP, M90
brimonidine 0.2% eye drops			M90

Antiglaucoma Agents: Ophthalmic – Carbonic Anhydrase Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
brinzolamide	Azopt		BP, M90
dorzolamide	Trusopt		# , M90

Antiglaucoma Agents: Ophthalmic – Beta-Adrenergic Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
betaxolol 0.25%	Betoptic S		
betaxolol 0.5%			M90
carteolol			M90
levobunolol			M90
timolol ophthalmic gel forming solution	Timoptic-XE	PA	M90
timolol ophthalmic unit dose solution	Timoptic Ocudose	PA	BP, M90
timolol-Betimol	Betimol	PA	
timolol-Istalol	Istalol		BP, M90
timolol-Timoptic	Timoptic		# , M90

Antiglaucoma Agents: Ophthalmic – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
brimonidine / timolol,	Combigan	PA	M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Patients diagnosed with ocular hypertension or suspected open-angle glaucoma should be offered medication based on the risk factors for developing primary open-angle glaucoma such as high intraocular pressure (IOP), type 2 diabetes mellitus, and older age.[1]
- Ophthalmic prostaglandin analogues are often considered first-line. If target IOP has not been achieved, switching to an alternative medication or adding additional medication (e.g., ophthalmic beta-blockers, alpha-2 adrenergic agonists, carbonic anhydrase inhibitors, parasympathomimetics) is recommended.[2]

[1] Gedde SJ, Lind JT, Wright MM, Chen PP, Muir KW, Vinod K, et al. Primary Open-Angle Glaucoma Suspect Preferred Practice Pattern Guidelines. Ophthalmology. 2020 Nov; 128(1):P151-192.

[2] Gedde SJ, Vinod K, Wright MM, Muir KW, Lind JT, Chen PP, et al. Primary Open-Angle Glaucoma Preferred Practice Pattern Guidelines. Ophthalmology. 2020 Nov;128(1):P71-P150.

Antiglaucoma Agents: Ophthalmic – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ophthalmic			
brinzolamide / brimonidine	Simbrinza		
dorzolamide / timolol	Cosopt		# , M90
dorzolamide / timolol, preservative free	Cosopt PF	PA	BP, M90
netarsudil / latanoprost	Rocklatan	PA	

Antiglaucoma Agents: Ophthalmic – Prostaglandins			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bimatoprost 0.01% ophthalmic solution	Lumigan		
bimatoprost 0.03% ophthalmic solution		PA	M90
bimatoprost implant	Durysta	PA	MB
latanoprost emulsion	Xelpros	PA	
latanoprost solution - Iyuzeh	Iyuzeh	PA	
latanoprost solution - Xalatan	Xalatan		# , M90
latanoprostene	Vyzulta	PA	
tafluprost	Zioptan	PA	BP, M90
travoprost 0.004% eye drop	Travatan Z		BP, M90

Antiglaucoma Agents: Ophthalmic – Miotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acetylcholine chloride	Miochol-E		MB
carbachol 0.01%	Miostat		MB
echothiophate iodide	Phospholine Iodide		
pilocarpine 1%, 2%, 4% ophthalmic solution	Isopto Carpine		# , M90

Antiglaucoma Agents: Ophthalmic – Rho Kinase Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
netarsudil	Rhopressa	PA	

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Ocular hypertension
- Open-angle glaucoma

Non-FDA-approved, for example:

- infantile hemangioma

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.

- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Betimol
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to an ophthalmic timolol product available without PA.

SmartPA: Claims for Betimol will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for an ophthalmic timolol product that is available without PA.†

bimatoprost 0.03% ophthalmic solution
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: latanoprost solution, travoprost 0.004% eye drop.

brimonidine/timolol, ophthalmic
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to dorzolamide/timolol.

dorzolamide/timolol preservative free and Xelpros
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - sensitivity to benzalkonium chloride or any other preservative used in ophthalmic preparations.

Durysta
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to Lumigan; **or**
    - medical necessity for the use of an implantable formulation as noted by one of the following:
      - limited dexterity; **or**
      - visual impairment; **or**
      - intellectual disability; **and**

Iyuzeh and tafluprost
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to Xelpros; **and**
  - one of the following:
    - inadequate response, adverse reaction or contraindication to latanoprost solution available without PA; **or**
    - sensitivity to benzalkonium chloride or any other preservative used in ophthalmic preparations.

SmartPA: Claims for Iyuzeh or tafluprost will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for latanoprost solution available without PA and Xelpros.†

Rhopressa
- Documentation of the following is required:

- appropriate diagnosis; **and**
- member is ≥ 18 years of age; **and**
- one of the following:
  - inadequate response to combination therapy with a prostaglandin analog and an ophthalmic beta-blocker; **or**
  - contraindication or adverse reaction to prostaglandin analogs and ophthalmic beta-blockers; **or**
  - both of the following:
    - contraindication to ophthalmic beta-blockers; **and**
    - inadequate response or adverse reaction to a prostaglandin analog in combination with one of the following: ophthalmic alpha-2 adrenergic agonist, parasympathomimetic, carbonic anhydrase inhibitor; **or**
  - both of the following:
    - contraindication to prostaglandin analogs; **and**
    - inadequate response or adverse reaction to an ophthalmic beta-blocker in combination with one of the following: ophthalmic alpha-2 adrenergic agonist, parasympathomimetic, carbonic anhydrase inhibitor.

Rocklatan
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response to combination therapy with a prostaglandin analog and an ophthalmic beta-blocker; **or**
    - both of the following:
      - contraindication to ophthalmic beta-blockers; **and**
      - inadequate response or adverse reaction to a prostaglandin analog in combination with one of the following: ophthalmic alpha-2 adrenergic agonist, parasympathomimetic, carbonic anhydrase inhibitor.

timolol ophthalmic gel forming solution
- Documentation of the following is required for diagnosis of ocular hypertesion or open-angle glaucoma:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to an ophthalmic timolol-containing product available without PA.
- Documentation of the following is required for diagnosis of infantile hemangioma:
  - appropriate diagnosis.

SmartPA: Claims for timolol ophthalmic gel forming solution will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for an ophthalmic timolol-containing product.†

timolol ophthalmic unit dose solution
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to an ophthalmic timolol product available without PA; **or**
    - sensitivity to benzalkonium chloride.

SmartPA: Claims for timolol ophthalmic unit dose solution will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for an ophthalmic timolol product that is available without a PA.†

Vyzulta
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 17 years of age; **and**
  - one of the following:

- inadequate response to combination therapy with latanoprost solution and an ophthalmic beta-blocker; **or**
- both of the following:
  - inadequate response to latanoprost solution; **and**
  - contraindication or adverse reaction to an ophthalmic beta-blocker.

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 52 - Multiple Sclerosis Agents

Drug Category: Central Nervous System (CNS)

Medication Class/Individual Agents: Multiple Sclerosis Agents

I. Prior-Authorization Requirements

Multiple Sclerosis Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alemtuzumab 12 mg	Lemtrada	PA	MB
cladribine tablet	Mavenclad	PA	
dalfampridine	Ampyra	PA - > 2 units/day	# , A90
dimethyl fumarate	Tecfidera	PA - > 2 units/day	# , A90
diroximel fumarate	Vumerity	PA	
fingolimod capsule	Gilenya	PA - > 1 unit/day	# , A90
fingolimod orally disintegrating tablet	Tascenso ODT	PA	
glatiramer	Copaxone		BP
monomethyl fumarate	Bafiertam	PA	
natalizumab	Tysabri		
ocrelizumab	Ocrevus	PA	
ofatumumab prefilled syringe	Kesimpta	PA	
ozanimod for multiple sclerosis	Zeposia	PA	
ponesimod	Ponvory	PA	
siponimod	Mayzent	PA	
teriflunomide	Aubagio	PA - > 1 unit/day	# , A90
ublituximab-xiiy	Briumvi	PA	

Multiple Sclerosis Agents – Interferons			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
interferon beta-1a-Avonex	Avonex		
interferon beta-1a-Rebif	Rebif		
interferon beta-1b-Betaseron	Betaseron		
interferon beta-1b-Extavia	Extavia	PA	
peginterferon beta-1a	Plegridy	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Siponimod

- Genetic testing of CYP2C9 variants is required prior to initiation.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Active secondary-progressive MS (SPMS)
- Clinically isolated syndrome (CIS)
- Relapsing-remitting MS (RRMS)
- Primary-progressive MS (Ocrevus)
- To improve walking in patients with MS (dalfampridine)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Bafiertam

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for Bafiertam instead of dimethyl fumarate and Vumerity; **and**
  - requested quantity is ≤ four units/day.

Briumvi
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - requested dose is 450 mg every 24 weeks.

dalfampridine and dimethyl fumarate > two units/day
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limits.

Extavia
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for Extavia instead of Betaseron (interferon beta-1b).

fingolimod capsule and teriflunomide > one unit/day
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding the quantity limits.

Kesimpta
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: Briumvi or Ocrevus, dimethyl fumarate or Vumerity, fingolimod capsule, glatiramer acetate therapy, interferon therapy, teriflunomide, Tysabri; **and**
  - requested dose is 20 mg at weeks 0, 1, 2, 4 and then every month.

Lemtrada
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - requested dose is 12 mg daily for five days in first year of therapy or 12 mg daily for three days in second year of therapy; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: Briumvi or Ocrevus, dimethyl fumarate or Vumerity, fingolimod capsule, glatiramer acetate therapy, interferon therapy, teriflunomide, Tysabri.

Mavenclad
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**

- inadequate response or adverse reaction to three or contraindication to all of the following: Briumvi or Ocrevus, dimethyl fumarate or Vumerity, fingolimod capsule or Mayzent, glatiramer acetate therapy, interferon therapy, teriflunomide, Tysabri; **and**
- requested dose is 3.5 mg/kg divided into two yearly treatment courses (1.75 mg/kg per course).

Mayzent

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - requested dose is appropriate based on CYP2C9 genotype; **and**
  - genetic testing for CYP2C9 genotype showing the member does not have a CYP2C9 *3/*3 genotype; **and**
  - medical necessity for Mayzent instead of fingolimod capsule; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Briumvi or Ocrevus, dimethyl fumarate or Vumerity, glatiramer acetate therapy, interferon therapy, teriflunomide.

Ocrevus

- Documentation of all of the following is required for a diagnosis of primary progressive MS:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - requested dose is 600 mg every six months.
- Documentation of all of the following is required for a diagnosis of CIS, RRMS, and active SPMS:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - inadequate response, adverse reaction, or contraindication to Briumvi; **and**
  - requested dose is 600 mg every six months.

Plegridy

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for Plegridy instead of Avonex or Rebif (interferon beta-1a); **and**
  - requested dose is ≤ two units/28 days; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Briumvi or Ocrevus, dimethyl fumarate or Vumerity, fingolimod capsule, glatiramer acetate therapy, Lemtrada, teriflunomide, Tysabri.

Ponvory and Zeposia

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for the requested agent instead of fingolimod capsule; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Briumvi or Ocrevus, dimethyl fumarate or Vumerity, glatiramer acetate therapy, interferon therapy, teriflunomide; **and**
  - requested quantity is ≤ one unit/day.

Tascenso ODT

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - member is ≥ 10 years of age; **and**

- one of the following:
  - for the 0.25 mg ODT, member weight is ≤ 40 kg; **or**
  - for the 0.5 mg ODT, member weight is > 40 kg; **and**
- medical necessity for Tascenso ODT instead of fingolimod capsule; **and**
- requested quantity is ≤ one unit/day.

Vumerity

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or consult notes from a neurology office are provided; **and**
  - medical necessity for Vumerity instead of dimethyl fumarate; **and**
  - requested quantity is ≤ four capsules/day.

MassHealth Evaluation Criteria
Table 53 - Otic Agents

Drug Category: Otic Agents

Medication Class/Individual Agents: Otic Agents

I. Prior-Authorization Requirements

Otic Agents – Combination Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acetic acid / hydrocortisone			A90
ciprofloxacin / dexamethasone otic suspension		PA	A90
ciprofloxacin / fluocinolone	Otovel	PA	A90
ciprofloxacin / hydrocortisone	Cipro HC		
colistin / neomycin / thonzonium / hydrocortisone	Cortisporin-TC		A90
neomycin / polymyxin B / hydrocortisone otic			A90

Otic Agents – Single-Entity Products			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acetic acid			A90
ciprofloxacin 0.2% otic solution		PA	A90
fluocinolone oil, otic drops	Dermotic		BP, A90
ofloxacin otic solution			A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

American Academy of Otolaryngology--Head and Neck Surgery Foundation. Clinical Practice Guideline: Acute Otitis Externa (AOE)[1]:

- Topical preparations are indicated for initial therapy of diffuse, uncomplicated AOE.
- If the infection extends outside of the ear canal or there are specific host factors (diabetes, immune deficiency, or inability to effectively deliver topical therapy despite aural toilet), systemic antimicrobial therapy should be administered.
- No significant differences in AOE clinical outcomes were found regarding the use of an antimicrobial versus an antiseptic, a quinolone antibiotic versus a nonquinolone antibiotic(s) or a steroid-antimicrobial agent versus an antimicrobial agent alone.
- If a patient has a known suspected perforation of the tympanic membrane, including a tympanostomy tube, a non-ototoxic topical preparation should be utilized (substances with ototoxic potential include aminoglycosides, alcohol, and ones with a low pH including most acidifying and antiseptic agents).

	Clinical Notes
	[1] *Rosenfeld RM, Schwartz SR, Cannon CR, et al. Clinical practice guideline: acute otitis externa [published correction appears in Otolaryngol Head Neck Surg. 2014 Mar;150(3):504] [published correction appears in Otolaryngol Head Neck Surg. 2014 Mar;150(3):504]. Otolaryngol Head Neck Surg. 2014;150(1 Suppl):S1-S24. doi:10.1177/0194599813517083.*

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acute otitis media (ciprofloxacin/dexamethasone otic suspension)
- Acute otitis media with tympanostomy tubes (Otovel)
- External Otitis (ciprofloxacin 0.2% otic solution, ciprofloxacin/dexamethasone otic suspension)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

ciprofloxacin 0.2% otic solution

- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- one of the following:
  - medical necessity for unit dosing; **or**
  - inadequate response or adverse reaction to two or contraindication to all of the following: Cipro HC, ciprofloxacin/dexamethasone, Cortisporin TC, neomycin/polymyxinB/hydrocortisone otic, ofloxacin otic solution

SmartPA: Claims for ciprofloxacin 0.2% otic solution will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for two of the following within the last 30 days: Cipro HC, ciprofloxacin/dexamethasone, Cortisporin TC, neomycin/polymyxinB/hydrocortisone otic, ofloxacin otic solution.†

ciprofloxacin/dexamethasone otic suspension

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 6 months of age; **and**
  - one of the following:
    - member has tympanostomy tubes; **or**
    - inadequate response, adverse reaction, or contraindication to Cipro HC.

SmartPA: Claims for ciprofloxacin/dexamethasone otic suspension will usually process at the pharmacy without a PA request if the member is ≥ 6 months of age and has a history of paid MassHealth pharmacy claims for Cipro HC within the last 30 days or if the member has tympanostomy tubes.

Otovel

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ six months of age; **and**
  - inadequate response, adverse reaction, or contraindication to ciprofloxacin/dexamethasone otic suspension.

SmartPA: Claims for Otovel will usually process at the pharmacy without a PA request if the member is ≥ six months of age and has a history of paid MassHealth pharmacy claims for ciprofloxacin/dexamethasone otic suspension within the past 30 days.†

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 54 - Pediculicides and Scabicides

Drug Category: Dermatological

Medication Class/Individual Agents: Pediculicide/Scabicide

I. Prior-Authorization Requirements

Pediculicides and Scabicides				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
crotamiton cream	Eurax			**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** **Centers for Disease Control and Prevention: Treatment of Head Lice (2016)**[1] • Pyrethrins and permethrin are first-line treatments; however, a second course of therapy may be needed to kill newly hatched lice. • Benzoyl alcohol is pediculicidal but not ovicidal. A second treatment is necessary after the first treatment to kill newly hatched lice. • Ivermectin lotion is not ovicidal, but prevents newly hatched lice from surviving. It should not be used for retreatment without talking to a health care provider. • Malathion is pediculicidal and partially ovicidal. Retreatment may be necessary if the first treatment is unsuccessful. • Spinosad is pediculicidal and ovicidal. Therefore, retreatment is often not needed. Repeat treatment should only be given if live lice are seen seven days after the first treatment. • Lindane is not recommended as a first-line treatment for head lice due to potential neurotoxic reactions. Its use should be restricted to patients who have failed treatment or cannot tolerate other medications. **Centers for Disease Control and Prevention: Treatment of Scabies (2016)**[2]
crotamiton lotion	Eurax	PA	BP	
lindane shampoo		PA	A90	
malathion	Ovide	PA	A90	
permethrin			*, A90	
permethrin cream			A90	
piperonyl butoxide / pyrethrins			*, A90	
spinosad	Natroba	PA	A90	

	Clinical Notes
	• Permethrin is the first-line treatment for scabies, killing scabies mites and eggs. It is FDA-approved for the treatment in patients at least two months of age. Two (or more) applications, each about a week apart, may be necessary to eliminate all mites. • Crotamiton is FDA-approved for the treatment of scabies in adults, but not for treatment in children. Frequent treatment failure has been reported with this agent. • Lindane is not recommended as a first-line therapy. Overuse, misuse or accidental ingestion can be toxic to the nervous system; its use should be restricted to patients who have failed treatment or cannot tolerate other medications. • Oral ivermectin is a safe and effective treatment for scabies. The safety of ivermectin in children weighing less than 15 kg and in pregnant women has not been established. 1.Centers for Disease Control and Prevention. Treatment of Head Lice [guideline on the internet]. 2016. [cited 2017 Feb 10]. Available at: https://www.cdc.gov/parasites/lice/head/treatment.html 2. Centers for Disease Control and Prevention. Treatment of Head Scabies [guideline on the internet]. 2016. [cited 2017 Feb 10]. Available at: http://www.cdc.gov/parasites/scabies/health_professionals/meds.html.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

* The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Head lice (ivermectin lotion OTC, lindane shampoo, malathion, spinosad)
- Scabies (crotamiton lotion)

Non-FDA-approved, for example:

- Pubic lice (lindane shampoo)

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

crotamiton lotion

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response to permethrin 5% within the last 30 days; **or**
  - adverse reaction or contraindication to permethrin 5%; **and**
  - inadequate response to oral ivermectin within the last 30 days; **or**
  - adverse reaction or contraindication to oral ivermectin; **and**
  - inadequate response within the last 30 days or adverse reaction to Eurax cream.

SmartPA: Claims for crotamiton lotion will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for permethrin 5%, oral ivermectin, and Eurax cream within the last 30 days.†

ivermectin lotion OTC and spinosad

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ six months of age; **and**
  - inadequate response or adverse reaction to a permethrin product or a piperonyl butoxide/pyrethrins product within the last 30 days; **or**
  - adverse reaction at any time or contraindication to both permethrin and piperonyl butoxide/pyrethrins products.

SmartPA: Claims for spinosad will usually process at the pharmacy without a PA request if the member is ≥ six months of age and has a history of a paid MassHealth pharmacy claim for a permethrin product or a piperonyl butoxide/pyrethrins product within the last 30 days.†

lindane shampoo

- Documentation of all of the following is required for a diagnosis of of head lice:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to a permethrin product or a piperonyl butoxide/pyrethrins product within the last 30 days; **or**
  - adverse reaction at any time or contraindication to both permethrin and piperonyl butoxide/pyrethrins products; **and**

- inadequate response within the last 30 days, adverse reaction, or contraindication to malathion.

- Documentation of all of the following is required for a diagnosis of pubic lice:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to a permethrin product or a piperonyl butoxide/pyrethrins product within the last 30 days; **or**
  - adverse reaction at any time or contraindication to both permethrin and piperonyl butoxide/pyrethrins products; **and**
  - inadequate response within the last 30 days, adverse reaction, or contraindication to a second lice treatment available without PA.

malathion
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - inadequate response or adverse reaction to a permethrin product or a piperonyl butoxide/pyrethrins product within the last 30 days; **or**
  - adverse reaction at any time or contraindication to both of the following: permethrin product, piperonyl butoxide/pyrethrins product.

SmartPA: Claims for malathion will usually process at the pharmacy without a PA request if the member is ≥ two years of age and has a history of a paid MassHealth pharmacy claim for a permethrin product or a piperonyl butoxide/pyrethrins product within the last 30 days.†

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 55 - Androgens

Drug Category: Androgen Therapy

Medication Class/Individual Agents: Androgens

I. Prior-Authorization Requirements

Androgens				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
methyltestosterone		PA		**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** The Endocrine Society: **Clinical Practice Guideline Testosterone Therapy in Men with Hypogonadism (2018)**[1] • The Endocrine Society recommends the use of testosterone replacement therapy (TRT) in men with low testosterone levels due to hypogonadism, drug therapy and human immunodeficiency virus (HIV) infection who are experiencing related complications. However, they recommend against the use of testosterone in older members with age-related decline in testosterone levels and lack of related symptoms.[1] • The International Society for the Study of the Aging Male as well as the European Association of Urology state the diagnosis of male hypogonadism should be based on signs and symptoms of androgen deficiency, together with consistently low serum testosterone levels.[2,3] • Choice of therapy should be a joint decision between the member and physician and should be made after consideration of member preferences, the pharmacokinetic profiles of the respective agents, treatment burden and cost. • Several organizations recommend discussing the cessation of TRT three to six months after initiation of treatment in individuals who experience normalization of
testosterone 1% gel packet	Androgel	PA		
testosterone 1% gel tube	Testim	PA	BP	
testosterone 1% gel tube, packet, pump	Vogelxo	PA		
testosterone 1.62% gel packet	Androgel	PA		
testosterone 1.62% gel pump	Androgel	PA		
testosterone 2% gel pump	Fortesta	PA		
testosterone 2% solution		PA		
testosterone cypionate	Depo-Testosterone	PA		
testosterone enanthate	Xyosted	PA		
testosterone enanthate		PA		
testosterone intramuscular pellet	Testopel	PA		
testosterone nasal gel	Natesto	PA		
testosterone patch	Androderm	PA		
testosterone undecanoate capsule	Jatenzo	PA		
testosterone undecanoate capsule	Tlando	PA		
testosterone undecanoate injection	Aveed	PA	MB	

	Clinical Notes
	total testosterone levels but fail to achieve symptom improvement.[4,5] [1] Bhasin S, Brito JP, Cunningham GR, Hayes FJ, Hodis HN, Matsumoto AM, et al. Testosterone therapy in men with hypogonadism: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2018 May 1;103(5):1715-44. [2] Lunenfeld B, Mskhalaya G, Zitzmann M, Arver S, Kalinchenko S, Tishova Y, Morgentaler A. Recommendations on the diagnosis, treatment and monitoring of hypogonadism in men. Aging Male. 2015; 18(1): 5 to 15. Doi: 10.3109/13685538.2015.1004049. [3] Dohle GR, Arver S, Bettochi C, Jones TH, Kliesch S, Punab M. European Association of Urology: Guidelines on male hypogonadism. Male hypogonadism. 2015 Mar. Available from: http://uroweb.org/wp-content/uploads/18-Male-Hypogonadism_LR1.pdf. [4] Mulhall JP, Trost LW, Brannigan RE, Kurtz EG, Redmon JB, Chiles KA, et al. American Urological Association (AUA). Evaluation and management of testosterone deficiency (2018). Available from: https://www.auanet.org/guidelines/testosterone-deficiency-guideline. [5] Qaseem A, Horwitch CA, vijan S, Etxeandia-Ikobaltzeta I, Kansagara D. Testosterone treatment in adult men with age-related low testosterone: A clinical guideline from the American College of Physicians. Annals of Internal Medicine. 2020 Jan 21;172(2): 126-134.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Delayed puberty

- Hypogonadotropic hypogonadism
- Metastatic mammary cancer (female sex assigned at birth)
- Primary hypogonadism

non-FDA-approved, for example:

- Delayed puberty
- Gender identity disorder
- Gender dysphoria
- Therapy after gender reassignment surgery

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Androderm, Natesto, Testopel, testosterone cypionate, testosterone enanthate, testosterone 1% gel packet and tube, testosterone 1.62% gel packet and pump, and testosterone 2% gel pump and solution

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - low testosterone level with dates drawn and reference ranges (< 300 ng/dL total serum testosterone); **and**
  - for testosterone 1% gel 2.5 gram packet (Androgel) and testosterone 1.62% gel 1.25 gram packet, one of the following:
    - requested quantity is ≤ one packet/day; **or**
    - clinical rationale for exceeding the quantity limit.

SmartPA: Claims for Androderm, Natesto, Testopel, testosterone cypionate, testosterone enanthate, testosterone 1% gel 5 gram packet, testosterone 1 % gel packet and tube, testosterone 1.62% gel 2.5 gram packet and pump, and testosterone 2% gel pump and solution will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for primary hypogonadism or hypogonadotropic hypogonadism and a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days.†

SmartPA: Claims for testosterone 1% gel 2.5 gram packet at a quantity of ≤1 unit/day and testosterone 1.62% gel 1.25 gram packet at a quantity of ≤1 unit/day will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for primary hypogonadism or hypogonadotropic hypogonadism and a history of paid MassHealth pharmacy claims of

the requested agent for at least 90 out of the last 120 days.†

Any testosterone product used for delayed puberty

- Documentation of all the following is required:
  - individual drug criteria must be met first where applicable; **and**
  - appropriate diagnosis; **and**
  - prescriber is a pediatric endocrinologist or consultation notes from a pediatric endocrinologist are provided; **and**
  - member is ≥ 14 years of age and < 17 years of age; **and**
  - one of the following:
    - Tanner staging of I or II for sexual maturation ratings; **or**
    - other physical signs of delayed puberty such as: arm span exceeding the member's height by > 5 cm, abnormal testicular growth (testicular volume < 4 mL), bone ages documented as less than the member's current age; **and**
  - low testosterone level with dates drawn and reference ranges (< 300 ng/dL total serum testosterone).

Any testosterone product used for gender identity disorder, gender dysphoria, therapy after gender reassignment surgery

- Documentation of all the following is required:
  - individual drug criteria must be met first where applicable, excluding testosterone levels prior to initiating therapy; **and**
  - diagnosis of one of the following:
    - gender identity disorder; **or**
    - gender dysphoria; **or**
    - transgenderism; **or**
    - therapy after gender reassignment surgery.

SmartPA: Claims for Androderm, Natesto, Testopel, testosterone cypionate, testosterone enanthate, testosterone 1% gel 5 gram packet, testosterone 1% gel packet and tube, testosterone 1.62% gel 2.5 gram packet and pump, and testosterone 2% gel pump and solution will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender identity disorder or personal history of sex reassignment.†
SmartPA: Claims for testosterone 1% gel 2.5 gram packet at a quantity of ≤1 unit/day and testosterone 1.62% gel 1.25 gram packet at a quantity of ≤1 unit/day will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for gender identity disorder or personal history of sex reassignment.†

Aveed

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - low testosterone level with dates drawn and reference ranges (< 300 ng/dL total serum testosterone); **and**
  - inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to both of the following: testosterone cypionate intramuscular injection, testosterone enanthate intramuscular injection.

Jatenzo and Tlando

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - low testosterone level with dates drawn and reference ranges (< 300 ng/dL total serum testosterone); **and**
  - inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to two or a contraindication to all non-injectable formulations of testosterone; **and**
  - for Jatenzo, one of the following:
    - requested quantity is ≤ two units/day; **or**
    - clinical rationale for exceeding the quantity limit.

methyltestosterone for members assigned female sex at birth

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - appropriate dosing; **and**
  - for methyltestosterone capsules, medical necessity for use of capsules instead of tablets.

methyltestosterone for members assigned male sex at birth

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - low testosterone level with dates drawn and reference ranges (< 300 ng/dL total serum testosterone); **and**
  - inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to Jatenzo or Tlando; **and**
  - inadequate response (defined as ≥ 90 days of therapy) or adverse reaction to two non-injectable formulations of testosterone, or a contraindication to all non-injectable formulations of testosterone; **and**
  - appropriate dosing; **and**
  - for methyltestosterone capsules, medical necessity for use of capsules instead of tablets.

testosterone enanthate for members assigned female sex at birth

- Documentation of the following is required:
  - diagnosis of metastatic mammary cancer.

Xyosted

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - low testosterone level with dates drawn and reference ranges (< 300 ng/dL total serum testosterone); **and**
  - one of the following:
    - inadequate response (defined as ≥ 90 days of therapy), adverse reaction, or contraindication to both of the following: testosterone cypionate intramuscular injection, testosterone enanthate intramuscular injection; **or**
    - both of the following:
      - member has needle phobia; **and**
      - inadequate response (defined as ≥ 90 days of therapy), or adverse reaction to two or contraindication to all non-injectable formulations of testosterone.

Please note: The MassHealth agency does not pay for any drug when used for the treatment of sexual dysfunction as described in 130 CMR 406.413(B): Drug Exclusions (see link below).
https://www.mass.gov/regulations/130-CMR-406000-pharmacy-services

†**Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 56 - Alzheimer's Agents

Drug Category: CNS Agents

Medication Class/Individual Agents: Alzheimer's Agents

I. Prior-Authorization Requirements

Alzheimer's Agents – Cholinesterase Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
donepezil 10 mg tablet	Aricept	PA - < 6 years and PA > 2 units/day	# , A90
donepezil 5 mg, 23 mg tablet	Aricept	PA - < 6 years and PA > 1 unit/day	# , A90
donepezil orally disintegrating tablet		PA - < 6 years and PA > 1 unit/day	A90
donepezil patch	Adlarity	PA	
galantamine extended-release capsule	Razadyne ER	PA - > 1 unit/day	# , A90
galantamine solution		PA	A90
galantamine tablet		PA - > 2 units/day	A90
rivastigmine capsule		PA - > 2 units/day	A90
rivastigmine patch	Exelon	PA - > 1 unit/day	BP, A90

Alzheimer's Agents – Anti-Amyloid Monoclonal Antibodies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aducanumab-avwa	Aduhelm	PA	
lecanemab-irmb	Leqembi	PA	

Alzheimer's Agents – NMDA Receptor Antagonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
memantine extended-release	Namenda XR	PA - < 6 years and PA > 1 unit/day	# , A90
memantine solution		PA	A90
memantine tablet	Namenda	PA - < 6 years and PA > 2 units/day	# , A90
memantine titration pack	Namenda	PA - < 6 years and PA > 49 units/28 days	A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

American Psychiatric Association (APA):[1,2]

- There is modest evidence to support the efficacy of cholinesterase inhibitors in mild-to-severe AD and memantine in moderate-to-severe AD.
- Cholinesterase inhibitors should be considered for patients with dementia with Lewy bodies (DLB).
- Cholinesterase inhibitors can be considered for patients with mild-to-moderate dementia associated with Parkinson's disease (PDD), although the data is weak.
- Memantine has not been shown to improve cognition in patients with DLB or PDD.
- The benefit of memantine for mild-to-moderate AD is unclear. Memantine may provide modest benefits and has few adverse effects; it may be considered for members with moderate-to-severe AD.

1. Rabins PV, Blacker D, Rovner BW, Rummans T, Schneider LS, Tariot PN, et al. American Psychiatric Association practice guideline for the treatment of patients with Alzheimer's disease and other dementias. Second edition. Am J Psychiatry. 2007 Dec;164(12 Suppl):5-56.

2. Rabins PV, Rovner BW, Rummans T, Schneider LS, Tariot PN. Guideline Watch (October 2014): Practice

Alzheimer's Agents – Combination Products				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
memantine / donepezil extended-release	Namzaric	PA		*Guideline for the Treatment of Patients With Alzheimer's Disease and Other Dementias. Focus (Am Psychiatr Publ). 2017 Jan;15(1):110-128. doi: 10.1176/appi.focus.15106. Epub 2017 Jan 11.*

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Alzheimer's Disease (AD)
- Dementia associated with Parkinson's Disease
- Mild cognitive impairment (MCI) or mild dementia due to AD

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Adlarity

- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- requested quantity is ≤ 4 units/28 days; **and**
- medical necessity for the requested formulation instead of donepezil tablets or ODT.

Aduhelm

- Documentation of all of the following is required:
  - diagnosis of mild cognitive impairment (MCI) or mild dementia associated with Alzheimer's Disease (AD); **and**
  - prescriber is a specialist in the treatment of dementia of AD; **and**
  - medical records documenting baseline (within the past three months) cognitive function based on one of the following objective assessments:
    - Mini Mental State Exam (MMSE) score ≥ 24; **or**
    - Montreal Cognitive Assessment (MoCA) score ≥ 15; **or**
    - Saint Louis University Mental Status Examination (SLUMS) score ≥ 16.1; **and**
  - medical records documenting confirmed evidence of clinically significant AD neuropathology based on one of the following:
    - Cerebral Spinal Fluid (CSF) biomarkers; **or**
    - Amyloid positron emission tomography (PET); **and**
  - member has had a brain magnetic resonance imaging (MRI) in the previous twelve months; **and**
  - appropriate dosing; **and**
  - member and/or authorized representative (e.g., power of attorney, invoked health care proxy) has been informed of the known and potential risks and lack of established clinical benefit associated with Aduhelm treatment; **and**
  - member does not have any of the following non-AD neurodegenerative disorders:
    - probable dementia with Lewy bodies by consensus criteria; **and**
    - suspected frontotemporal degeneration; **and**
    - dementia in down syndrome; **and**
  - member has not had any of the following in the past year:
    - stroke or transient ischemic attack; **and**
    - any unexplained loss of consciousness; **and**
  - member does not have coagulopathy or requirement for therapeutic anticoagulation and/or dual antiplatelet therapy (only aspirin ≤ 325 mg/day monotherapy is allowed); **and**
  - member does not have any of the following neurological or psychiatric conditions:
    - uncontrolled seizure disorder; **and**
    - uncontrolled mood disorder, anxiety disorder, or psychosis; **and**
  - member does not have significant cerebrovascular disease as established by brain MRI showing any of the following:
    - acute or sub-acute hemorrhage; **and**
    - prior macro-hemorrhage or prior subarachnoid hemorrhage (unless finding is not due to an underlying structural or vascular hemorrhage); **and**
    - ≥ four microhemorrhages; **and**
    - cortical infarct; **and**
    - > one lacunar infarct; **and**
    - superficial siderosis; **and**
    - history of diffuse white matter disease; **and**
  - member does not have any of the following cardiovascular conditions:
    - uncontrolled hypertension; **and**
    - coronary artery disease (including unstable angina and myocardial infarction); **and**
    - heart failure; **and**
    - arrhythmia; **and**
    - clinically significant carotid atherosclerosis and/or peripheral arterial disease; **and**
  - inadequate response, adverse reaction, or contraindication to Leqembi; **and**

- member does not have any uncontrolled clinically significant chronic medical conditions (e.g., liver disease, kidney disease, pulmonary disease, autoimmune disease requiring chronic immunosuppression, malignant neoplasm, active chronic infection [HIV, HCV], poorly controlled diabetes mellitus).

- For recertification, documentation of all of the following is required:
  - appropriate dosing; **and**
  - attestation that all MRI monitoring has been completed in accordance with the FDA-approved label; **and**
  - medical records documenting current (within the last three months) cognitive function based on one of the following objective assessments:
    - MMSE; **or**
    - MoCA: **or**
    - SLUMS; **and**
  - one of the following (Amyloid-related imaging abnormalities-hemosiderin [ARIA-H], microhemorrhages):
    - member has had no new incident microhemorrhage; **or**
    - member has had one to four new incident microhemorrhage(s) and microhemorrhages are asymptomatic (no clinical symptoms); **or**
    - member has had five to nine new incident microhemorrhages and microhemorrhages are asymptomatic (no clinical symptoms) and the microhemorrhages have been stabilized; **or**
    - member has had one to nine new incident microhemorrhages and microhemorrhages resulted in mild, moderate or severe clinical symptoms and the microhemorrhages have been stabilized; **and**
  - one of the following (ARIA-H, superficial siderosis):
    - member has had no new incident areas of superficial siderosis; **or**
    - member has had one new incident area of superficial siderosis and superficial siderosis is asymptomatic (no clinical symptoms); **or**
    - member has had two new incident areas of superficial siderosis and superficial siderosis is asymptomatic (no clinical symptoms) and the superficial siderosis has been stabilized; **or**
    - member has had one to two new incident areas of superficial siderosis and superficial siderosis resulted in mild, moderate or severe clinical symptoms and the superficial siderosis has been stabilized; **and**
  - one of the following (Amyloid-related imaging abnormalities-edema [ARIA-E]):
    - member has had no new ARIA-E; **or**
    - member has mild ARIA-E on MRI and ARIA-E is asymptomatic (no clinical symptoms); **or**
    - member has had moderate or severe ARIA-E on MRI and ARIA-E is asymptomatic (no clinical symptoms) and the ARIA-E is stable; **or**
    - member has had mild, moderate or severe ARIA-E on MRI and ARIA-E resulted in mild, moderate or severe clinical symptoms and the ARIA-E is stable; **and**
  - one of the following:
    - member does not have any of the following:
      - initiation of anticoagulation; **and**
      - development of active immune-mediated/autoimmune conditions (e.g., Crohn's disease, systemic lupus erythematosus, aplastic anemia, myasthenia gravis, meningitis/encephalitis); **and**
      - initiation of immunomodulatory medications (e.g., cancer immunotherapies, rituximab, azathioprine); **and**
      - development of other neurologic conditions (e.g., intracerebral bleeds, traumatic brain injury, stroke); **or**
    - clinical rationale for continued use of Aduhelm in a member with at least one of the above noted conditions.

galantamine solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ 6 mL/day; **and**
  - one of the following:

- inadequate response or adverse reaction to galantamine tablets or galantamine extended-release capsules; **or**
- medical necessity for the solution formulation instead of solid oral formulation.

Leqembi

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist in the treatment of dementia or AD; **and**
  - medical records documenting confirmed evidence of clinical significant AD neuropathology based on one of the following
    - amyloid PET; **or**
    - cerebral spinal fluid (CSF) biomarkers; **and**
  - member has had a brain magnetic resonance imaging (MRI) within the last twelve months; **and**
  - appropriate dosing; **and**
  - medical records documenting baseline (within the last three months) cognitive function based on one of the following objective assessments;
    - MMSE score ≥ 22; **or**
    - MoCA score ≥ 15; **or**
    - SLUMS score ≥ 16.1.
- For recertification, documentation of all of the following is required:
  - appropriate dosing; **and**
  - attestation that all MRI monitoring has been completed in accordance with the FDA-approved label; **and**
  - medical records documenting current (within the last three months) cognitive function based on one of the following objective assessments:
    - MMSE; **or**
    - MoCA; **or**
    - SLUMS.

memantine solution

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ 10 mL/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to memantine tablets or memantine extended-release capsules; **or**
    - medical necessity for the solution formulation instead of solid oral formulation.

Namzaric

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one unit/day; **and**
  - medical necessity for the use of the combination product instead of the commercially available separate agents.

All agents at quantities requested above FDA approved limits

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting titration to doses exceeding FDA-recommendations.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional

polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy (*pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha2 agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, and viloxazine] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period*) for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**
      - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
      - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**

- member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and**
- one of the following:
  - cross-titration/taper of mood stabilizer therapy; **or**
  - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

donepezil and memantine for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist [e.g., psychiatrist, child adolescent psychiatrist (including psychiatric nurse practitioners), neurologist, pediatric neurologist, developmental and behavioral pediatrics] or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 57 - Oncology Agents

Drug Category: Oncology Agents

Medication Class/Individual Agents: Antineoplastics

I. Prior-Authorization Requirements

Antimicrotubulars

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
cabazitaxel	Jevtana	PA	MB	IV	**Jevtana** • Documentation of the following is required: • diagnosis of metastatic castration-resistant prostate cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with prednisone; **and** • inadequate response or adverse reaction to one docetaxel-containing regimen.
ixabepilone	Ixempra		MB	IV	
paclitaxel injectable suspension	Abraxane		MB	IV	
paclitaxel injection				IV	

Interferon

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
interferon gamma-1b	Actimmune			SC	**Besremi** • Documentation of the following is required: • diagnosis of polycythemia vera; **and** • prescriber is a hematologist; **and** • appropriate dosing; **and** • one of the following: • polycythemia vera is low risk; **or** • polycythemia vera is high risk and inadequate response, adverse reaction, or contraindication to hydroxyurea.
ropeginterferon alfa-2b-njft	Besremi	PA		SC	

Mitotic Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
brentuximab	Adcetris	PA	MB	IV	**Adcetris for relapsed or refractory Hodgkin Lymphoma in adult members** • Documentation of the following is required: • appropriate diagnosis; **and**
docetaxel	Docefrez		MB	IV	
docetaxel	Docivyx		MB	IV	
docetaxel			MB	IV	
eribulin	Halaven	PA	MB	IV	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

polatuzumab vedotin-piiq	Polivy	PA	MB	IV	• member is ≥ 18 years of age; **and**
					• prescriber is an oncologist or hematologist; **and**
					• appropriate dosing; **and**
					• one of the following:
					  • member is at high risk of relapse as post-autologous hematopoietic stem cell transplantation (auto-HSCT); **or**
					  • inadequate response to auto-HSCT; **or**
					  • member is not a candidate for auto-HSCT and inadequate response or adverse reaction to two prior multi-agent chemotherapy regimens; **or**
					  • clinical rationale as to why the other available treatment regimens cannot be used.
					Adcetris for treatment-naïve Hodgkin Lymphoma in adult members
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • member is ≥ 18 years of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with doxorubicin, vinblastine, and dacarbazine.
					Adcetris for treatment-naïve Hodgkin Lymphoma in pediatric members
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • member is ≥ two and < 18 years of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with all of the following: cyclophosphamide, doxorubicin, etoposide, prednisone, vincristine.
					Adcetris for primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF)
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing.
					Adcetris for previously untreated CD-30 expressing PTCL, including systemic anaplastic large cell lymphoma (sALCL) used in combination with chemotherapy
					• Documentation of the following is required:

	Clinical Notes
	• appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with cyclophosphamide, doxorubicin, and prednisone. **Adcetris for sALCL after failure of at least one prior multiagent chemotherapy regimen, used as monotherapy** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • inadequate response or adverse reaction to one prior chemotherapy regimen or agent; **or** • clinical rationale as to why the other available treatment regimens cannot be used. **Halaven for metastatic or recurrent breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to two prior chemotherapy regimens that included an anthracycline and a taxane; **and** • inadequate response, adverse reaction, or contraindication to vinorelbine (may have been part of prior chemotherapy regimens). **Halaven for unresectable or metastatic liposarcoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to an anthracycline-containing regimen. **Polivy** • Documentation of the following is required: • diagnosis of diffuse large B-cell lymphoma (DLBCL); **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to at least one or contraindication to all systemic therapies.

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
arsenic trioxide	Trisenox		#	IV	
daunorubicin			MB	IV	
doxorubicin	Adriamycin		MB	IV	
doxorubicin liposomal injection	Doxil		MB	IV	
epirubicin	Ellence		#	IV	
idarubicin	Idamycin PFS		MB	IV	
streptozocin	Zanosar		MB	IV	
teniposide				IV	
valrubicin	Valstar		MB	Intravesically	

Miscellaneous

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

aldesleukin	Proleukin	PA		PO	**Adstiladrin**
					• Documentation of the following is required:
					  • diagnosis of non-muscle-invasive bladder cancer (NMIBC); **and**
					  • disease is high-risk with carcinoma in situ (CIS); **and**
					  • prescriber is an oncologist or urologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response, adverse reaction, or contraindication to BCG.
					Akeega
					• Documentation of the following is required:
					  • diagnosis of mCRPC; **and**
					  • member has deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) cancer; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with prednisone; **and**
					  • requested quantity is ≤ two units/day.
					Fusilev, Khapzory, and levoleucovorin injection
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • member is ≥ six years of age; **and**
					  • medical records documenting member is not a candidate for leucovorin therapy due to hypersensitivity to a component of leucovorin; **and**
					  • for Khapzory, clinical rationale for use instead of Fusilev (levoleucovorin powder for injection).

belzutifan	Welireg	PA		PO	
eflornithine	Iwilfin	PA		PO	
enasidenib	Idhifa	PA		PO	
iobenguane I 131	Azedra		MB	IV	
ivosidenib	Tibsovo	PA		PO	
leucovorin			A90	IV / PO	
levoleucovorin injection		PA		IV	
levoleucovorin powder for injection	Fusilev	PA		IV	
levoleucovorin powder for injection	Khapzory	PA		IV	
mitotane	Lysodren			PO	
nadofaragene firadenovec-vncg	Adstiladrin	PA	MB	Intravesicular	
niraparib/abiraterone	Akeega	PA		PO	
olutasidenib	Rezlidhia	PA		PO	
omacetaxine mepesuccinate	Synribo	PA		SC	
selinexor	Xpovio	PA		PO	
sipuleucel-T	Provenge	PA	MB	IV	
talimogene laherparepvec	Imlygic	PA	MB	Intralesional	
tazemetostat	Tazverik	PA		PO	
tebentafusp-tebn	Kimmtrak	PA	MB	IV	
thyrotropin alfa	Thyrogen			IM	
vemurafenib	Zelboraf	PA		PO	
venetoclax	Venclexta	PA		PO	

	Clinical Notes

	Idhifa
	• Documentation of the following is required:
	  • diagnosis of IDH2-mutated AML; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ one unit/day; **and**
	  • one of the following:
	  • member is not a candidate for intensive remission induction therapy; **or**
	  • relapsed or refractory IDH2-mutated AML.
	Imlygic
	• Documentation of the following is required:
	  • diagnosis of unresectable melanoma; **and**
	  • prescriber is an oncologist; **and**
	  • requested quantity is ≤ four mL/treatment; **and**
	  • unresectable cutaneous, subcutaneous, or nodal lesions; **and**
	  • melanoma is recurrent after initial surgery.
	Iwilfin
	• Documentation of the following is required:
	  • diagnosis of high-risk neuroblastoma; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member has a partial response to prior multiagent, multimodality therapy which includes anti-GD2 immunotherapy (e.g., Unituxin); **and**
	  • requested quantity is ≤ eight units/day.
	Kimmtrak
	• Documentation of the following is required:
	  • diagnosis of unresectable or metastatic uveal melanoma; **and**
	  • member is positive for HLA-A*02:01 genotype
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is refractory to radiation therapy or radiation therapy is not appropriate.
	Proleukin
	• Documentation of the following is required:
	  • diagnosis of chronic graft versus host disease (GVHD); **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • disease is refractory to steroid treatment; **and**
	  • for members ≥ 18 years of age, inadequate response or

	Clinical Notes
	adverse reaction to one or contraindication to both of the following: cyclosporine, tacrolimus. Please note, requests for all other indications, drug may be subject to additional non-rebate restrictions. Please see MassHealth Pharmacy Operational document for additional information. **Provenge** • Documentation of the following is required: • diagnosis of metastatic castration-resistant prostate cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • ECOG score 0-1 (good performance status); **and** • estimated life expectancy > six months; **and** • no hepatic metastases; **and** • no/minimal symptoms; **and** • requested quantity is ≤ three doses (one completed cycle). **Rezlidhia** • Documentation of the following is required: • diagnosis of relapsed or refractory IDH1 mutated AML; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • requested quantity is ≤ two units/day. **Synribo** • Documentation of the following is required: • diagnosis of chronic myelogenous leukemia (CML); **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to two or contraindication to all of the following: Bosulif (bosutinib), Iclusig (ponatinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib). **Tazverik for FL** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • requested quantity is ≤ eight units/day; **and** • member is ≥ 18 years of age; **and** • one of the following:

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	• both of the following:
	  • member has FL with an EZH2 mutation (as detected by an FDA-approved test); **and**
	  • prior therapy for the treatment of FL with at least two systemic therapies; **or**
	• both of the following:
	  • member has relapsed or refractory FL; **and**
	  • member has no satisfactory alternative treatment options.
	Tazverik for metastatic or locally advanced epithelioid sarcoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ eight units/day; **and**
	  • member is ≥ 16 years of age.
	Tibsovo for IDH1-mutated AML
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ two units/day; **and**
	  • one of the following:
	  • member is not a candidate for chemotherapy; **or**
	  • relapsed or refractory IDH1-mutated AML.
	Tibsovo for IDH1-mutated cholangiocarcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ two units/day; **and**
	  • prior treatment of IDH1-mutated cholangiocarcinoma with at least one of the following systemic therapies:
	  • cisplatin, gemcitabine, and pembrolizumab; **or**
	  • cisplatin, durvalumab, and gemcitabine; **or**
	  • single agent and combination chemotherapies involving 5-fluorouracil, capecitabine, cisplatin, gemcitabine, oxaliplatin, or paclitaxel; **or**
	  • entrectinib or larotrectinib (for NTRK gene fusion positive); **or**
	  • nivolumab and ipilimumab (for TMB-H tumors); **or**
	  • pembrolizumab (for MSI-H/dMMR tumors); **or**
	  • pralsetinib or selpercatinib (for RET gene fusion-

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	positive).
	Tibsovo for relapsed or refractory IDH1 mutated myelodysplastic syndrome (MDS)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ two units/day.
	Venclexta for AML
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • member is not a candidate for intensive induction therapy; **or**
	  • member has poor-risk AML; **or**
	  • clinical rationale for use of requested agent instead of intensive induction chemotherapy; **and**
	  • requested agent will be used in combination with one of the following: azacitidine, decitabine, low-dose cytarabine.
	Venclexta for CLL or SLL
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • member has not received treatment for CLL or SLL and requested agent will be used in combination with Gazyva (obinutuzumab); **or**
	  • prior therapy with at least one systemic therapy.
	Venclexta for multiple myeloma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • member has t(11;14) mutation; **and**
	  • prior therapy with at least one prior chemotherapy regimen.
	Welireg for advanced renal cell carcinoma
	• Documentation of the following is required:

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	• appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested quantity is ≤ three units/day; **and** • inadequate response, adverse reaction, or contraindication to both of the following: a programmed death receptor-1 (PD-1) inhibitor or programmed death-ligand 1 (PD-L1) inhibitor, and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI). **Welireg for von Hippel-Lindau (VHL) disease** • Documentation of the following is required: • diagnosis of VHL disease as confirmed by germline VHL alteration; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested quantity is ≤ three units/day; **and** • member has renal cell carcinoma, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumors; **and** • member is not a candidate for or does not require immediate surgery. **Xpovio** • Documentation of the following is required for monotherapy: • diagnosis of multiple myeloma; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • member has received at least four prior chemotherapy regimens or contraindication to the use of recommended chemotherapy regimens; **and** • inadequate response or adverse reaction to two or contraindication to all of the following proteasome inhibitors: bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade (bortezomib); **and** • inadequate response or adverse reaction to two or contraindication to all of the following immunomodulatory agents: Pomalyst (pomalidomide), Revlimid (lenalidomide), Thalomid (thalidomide); **and** • inadequate response or adverse reaction to one or contraindication to all of the following anti-CD38 monoclonal antibodies: Darzalex (daratumumab), Darzalex Faspro (daratumumab-hyaluronidase-fihj), Sarclisa (isatuximab-irfc); **and**

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	• requested medication will be used in combination with dexamethasone.
	• Documentation of the following is required for combination therapy:
	  • diagnosis of multiple myeloma; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one prior chemotherapy regimen for the requested indication; **and**
	  • requested medication will be used in combination with Velcade (bortezomib) or bortezomib and dexamethasone.
	• Documentation of the following is required for diagnosis of diffuse large B-cell lymphoma (DLBCL):
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • member has received at least two prior chemotherapy regimens or contraindication to the use of recommended chemotherapy regimens.
	Zelboraf for Erdheim-Chester Disease
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • requested quantity is ≤ eight units/day; **and**
	  • positive BRAF V600 mutation.
	Zelboraf for low-grade or high-grade gliomas
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • positive BRAF V600E mutation; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with Cotellic (cobimetinib) ≤ 60 mg/day.
	Zelboraf for unresectable or metastatic melanoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • requested quantity is ≤ eight units/day; **and**
	  • positive BRAF V600E mutation.

mTOR Kinase Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg	Afinitor	PA	BP, A90	PO	**everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg and everolimus tablets for oral suspension for treatment-resistant epilepsy associated with tuberous sclerosis complex (TSC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is a neurologist or consult notes from a neurologist are provided; **and** • inadequate response to combination therapy with at least two anticonvulsants or contraindication to all other anticonvulsants; **and** • requested agent will be used as adjunctive therapy with at least one anticonvulsant agent; **and** • requested quantity is ≤ one unit/day. **everolimus tablets for oral suspension for subependymal giant cell astrocytoma (SEGA) with TSC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested quantity is ≤ one unit/day. **everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg for advanced hormone receptor-positive, HER2-negative breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested regimen includes exemestane, fulvestrant, or tamoxifen; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: anastrozole, letrozole, tamoxifen, toremifene, exemestane; **and** • requested quantity is ≤ one unit/day. **everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg for advanced renal cell carcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • tumor is clear cell histology and requested agent will be used as monotherapy or in combination with Lenvima; **or** • tumor is non-clear cell histology and inadequate
everolimus tablets for oral suspension	Afinitor Disperz	PA	BP, A90	PO	
sirolimus gel	Hyftor	PA		Topical	
sirolimus injection	Fyarro	PA		IV	
temsirolimus	Torisel		#	IV	

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	response or adverse reaction to one or contraindication to both of the following: Cabometyx, sunitinib; **and** • requested quantity is ≤ one unit/day. **everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg for renal angiomyolipoma with TSC, advanced PNET, advanced neuroendocrine tumors (NET) of gastrointestinal or lung origin, and SEGA with TSC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is a specialist (e.g., oncologist or nephrologist) or consult notes from a specialist are provided; **and** • appropriate dosing; **and** • requested quantity is ≤ one unit/day. **Fyarro** • Documentation of the following is required: • diagnosis of locally advanced or metastatic malignant perivascular epithelioid cell tumor (PEComa); **and** • appropriate dosing. **Hyftor** • Documentation of the following is required: • diagnosis of facial angiofibroma; **and** • member is ≥ six years of age; **and** • prescriber is a neurologist or dermatologist or consult notes from a neurologist or dermatologist are provided; **and** • one of the following: • for members < 12 years of age, requested quantity is ≤ 20 grams/30 days (2 tubes/30 days); **or** • for members ≥ 12 years of age, requested quantity is ≤ 30 grams/30 days (3 tubes/30 days).

Tyrosine Kinase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
alectinib	Alecensa	PA		PO	**Alecensa for metastatic non-small cell lung cancer (NSCLC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer is anaplastic lymphoma kinase (ALK)-
asciminib	Scemblix	PA		PO	
avapritinib	Ayvakit	PA		PO	
axitinib	Inlyta	PA		PO	
bosutinib	Bosulif	PA		PO	
brigatinib	Alunbrig	PA		PO	
cabozantinib capsule	Cometriq	PA		PO	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
cabozantinib tablet	Cabometyx	PA		PO	positive; **and** • requested quantity is ≤ eight units/day. **Alecensa for non-small cell lung cancer (NSCLC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer is anaplastic lymphoma kinase (ALK)-positive (tumors ≥ 4 cm or node positive); **and** • requested agent will be used as adjuvant treatment; **and** • requested quantity is ≤ eight units/day. **Alunbrig** • Documentation of the following is required: • diagnosis of metastatic NSCLC; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer is ALK-positive; **and** • one of the following: • for 30 mg tablets, requested quantity is ≤ two units/day; **or** • for 90 mg or 180 mg tablets, or the 90 mg-180 mg tablet pack, requested quantity is ≤ one unit/day. **Augtyro** • Documentation of the following is required: • diagnosis of locally advanced or metastatic NSCLC; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer is ROS1-positive; **and** • one of the following: • member has a resistance mutation G2032R; **or** • inadequate response or adverse reaction to one or contraindication to both of the following: Rozlytrek (entrectinib), Xalkori (crizotinib); **and** • requested quantity is ≤ eight units/day. **Ayvakit for unresectable or metastatic GIST** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has disease harboring a PDGFRA exon 18 mutation (including PDGFRA D842V mutations); **and** • requested quantity is ≤ one unit/day. **Ayvakit for advanced systemic mastocytosis (AdvSM),**
ceritinib	Zykadia	PA		PO	
crizotinib	Xalkori	PA		PO	
dasatinib	Sprycel		BP	PO	
erlotinib	Tarceva	PA	A90	PO	
gefitinib	Iressa	PA	A90	PO	
gilteritinib	Xospata	PA		PO	
imatinib	Gleevec		# , A90	PO	
lapatinib	Tykerb		BP, A90	PO	
lenvatinib	Lenvima	PA		PO	
midostaurin	Rydapt	PA		PO	
nilotinib	Tasigna		BP	PO	
pazopanib	Votrient	PA	BP, A90	PO	
pexidartinib	Turalio	PA		PO	
ponatinib	Iclusig	PA		PO	
quizartinib	Vanflyta	PA		PO	
repotrectinib	Augtyro	PA		PO	
sorafenib	Nexavar	PA	BP, A90	PO	
sunitinib	Sutent	PA	BP, A90	PO	
tivozanib	Fotivda	PA		PO	
tucatinib	Tukysa	PA		PO	
vandetanib	Caprelsa	PA		PO	

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	systemic mastocytosis (SM) with associated hematological neoplasm, mast cell leukemia
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ one unit/day; **and**
	  • one of the following:
	  • D816V c-Kit mutation positive (as determined by an FDA-approved test); **or**
	  • both of the following:
	  • member has aggressive SM without the D816V c-Kit mutation (as determined by an FDA-approved test) or with c-Kit mutation status unknown; **and**
	  • inadequate response, adverse reaction, or contraindication to imatinib.
	Ayvakit for indolent systemic mastocytosis (ISM)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is a specialist (e.g., hematologist, oncologist, allergist/immunologist) or consult notes from a specialist are provided; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ one unit/day; **and**
	  • inadequate response, adverse reaction, or contraindication to both of the following: $histamine_1$ antihistamine, $histamine_2$ antihistamine; **and**
	  • for symptoms involving the cardiovascular or pulmonary system, an inadequate response, adverse reaction or contraindication to Xolair; **and**
	  • for symptoms involving the skin or gastrointestinal system, an inadequate response, adverse reaction or contraindication to a leukotriene inhibitor (montelukast, zafirlukast, zileuton).
	Bosulif
	• Documentation of the following is required:
	  • diagnosis of CML; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • member has chronic phase Philadelphia chromosome-positive (Ph+) CML; **or**
	  • inadequate response or adverse reaction to one prior therapy for CML or contraindication to all other

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	therapies for CML.
	Cabometyx for advanced renal cell carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • both of the following:
	  • member has clear cell histology; **and**
	  • requested agent will be used in combination with Opdivo; **or**
	  • all of the following:
	  • member has clear cell histology; **and**
	  • member has received a previous treatment in the metastatic setting; **and**
	  • requested agent will be used as monotherapy; **or**
	  • member has non-clear cell histology; **and**
	  • requested quantity is ≤ one unit/day.
	Cabometyx for locally recurrent, advanced, and/or metastatic differentiated thyroid carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one of the following, or contraindication to both of the following: Lenvima (lenvatinib), sorafenib; **and**
	  • requested quantity is ≤ one unit/day; **and**
	  • one of the following:
	  • member is refractory to radioactive iodine; **or**
	  • radioactive iodine treatment is not appropriate.
	Cabometyx for unresectable HCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to sorafenib; **and**
	  • requested quantity is ≤ one unit/day.
	Caprelsa
	• Documentation of the following is required:
	  • diagnosis of symptomatic or progressive medullary thyroid cancer; **and**
	  • one of the following:

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	• for 100 mg tablets, requested quantity is ≤ two units/day; **or** • for 300 mg tablets, requested quantity is ≤ one unit/day; **or** • medical necessity for exceeding quantity limit of two units/day for 100 mg tablets or one unit/day for 300 mg tablets. **Cometriq** • Documentation of the following is required: • diagnosis of symptomatic or progressive medullary thyroid cancer; **and** • one of the following: • requested dose is ≤ 140 mg/day; **or** • medical necessity for exceeding the 140 mg/day dose. **erlotinib for advanced or metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations; **and** • requested quantity is ≤ one unit/day. **erlotinib for advanced or metastatic pancreatic cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member will be using the requested agent in combination with gemcitabine; **and** • requested quantity is ≤ one unit/day. **Fotivda** • Documentation of the following is required: • diagnosis of advanced renal cell carcinoma; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • tumor is clear cell histology; **and** • inadequate response or adverse reaction to two or contraindication to all systemic therapies; **and** • requested quantity is ≤ one unit/day. **gefitinib** • Documentation of the following is required: • diagnosis of metastatic NSCLC; **and**

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	• prescriber is an oncologist; **and**
	• appropriate dosing; **and**
	• member has EGFR mutations; **and**
	• requested quantity is ≤ one unit/day.
	Iclusig for Ph+ ALL
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • inadequate response or adverse reaction to one or contraindication to all of the following: imatinib, Sprycel (dasatinib), Tasigna (nilotinib); **or**
	  • confirmed T315I mutation.
	Iclusig for CML
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • inadequate response or adverse reaction to two or contraindication to all of the following: Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib); **or**
	  • confirmed T315I mutation.
	Inlyta
	• Documentation of the following is required:
	  • diagnosis of advanced renal cell carcinoma; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • both of the following:
	  • tumor is clear cell histology; **and**
	  • requested agent will be used in combination with Bavencio (avelumab) or Keytruda (pembrolizumab); **or**
	  • both of the following:
	  • requested agent will be used as monotherapy; **and**
	  • member has failed one prior line of systemic therapy.
	Lenvima for advanced renal cell carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**

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	• appropriate dosing; **and**
	• one of the following:
	  • all of the following:
	  • tumor is clear cell histology; **and**
	  • requested agent will be used in combination with everolimus; **and**
	  • member has failed one first-line therapy for advanced renal cell carcinoma; **or**
	  • both of the following:
	  • tumor is clear cell histology; **and**
	  • requested agent will be used in combination with Keytruda (pembrolizumab); **or**
	  • tumor is non-clear cell histology and inadequate response or adverse reaction to one or contraindication to both of the following: Cabometyx, sunitinib.
	Lenvima for differentiated thyroid cancer (DTC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing.
	Lenvima for endometrial carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one prior line of systemic therapy or contraindication to systemic therapy; **and**
	  • requested agent will be used in combination with Keytruda (pembrolizumab).
	Lenvima for unresectable hepatocellular carcinoma (HCC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing.
	pazopanib for advanced renal cell carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ four units/day.
	pazopanib for soft tissue sarcoma
	• Documentation of the following is required:

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	• appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to prior chemotherapy; **and** • requested quantity is ≤ four units/day. **pazopanib for GIST** • Documentation of the following is required: • appropriate diagnosis; **and** • inadequate response, adverse reaction, or contraindication to all of the following: imatinib, Qinlock (ripretinib), sunitinib, Stivarga (regorafenib); **and** • requested quantity is ≤ four units/day. **Rydapt for FLT3-mutated acute myeloid leukemia (AML)** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • for induction therapy, requested agent will be used in combination with cytarabine and daunorubicin; **or** • for consolidation therapy, requested agent will be used in combination with cytarabine; **or** • for maintenance therapy, requested agent will be used as monotherapy. **Rydapt for aggressive systemic mastocytosis (SM), SM with associated hematological neoplasm, and mast cell leukemia** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • both of the following: • member has aggressive SM without the D816V c-Kit mutation (as determined by an FDA-approved test) or with c-Kit mutation status unknown; **and** • inadequate response, adverse reaction, or contraindication to imatinib; **or** • D816V c-Kit mutation positive (as determined by an FDA-approved test). **Scemblix**

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	• Documentation of the following is required:
	  • diagnosis of CML; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • confirmed T315I mutation; **or**
	  • inadequate response or adverse reaction to two or contraindication to all of the following: Bosulif (bosutinib), Iclusig (ponatinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib).
	sorafenib for advanced renal cell carcinoma, DTC, or unresectable HCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ four units/day.
	sorafenib for FLT3-ITD mutated AML
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • member has relapsed/refractory disease; **and**
	  • requested agent will be used in combination with a hypomethylating agent (5-azacytidine or decitabine); **and**
	  • requested quantity is ≤ four units/day.
	sunitinib for advanced renal cell carcinoma and advanced pancreatic neuroendocrine tumors (PNET)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ one unit/day.
	sunitinib for GIST
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to imatinib; **and**
	  • requested quantity is ≤ one unit/day.
	sunitinib for renal cell carcinoma (adjuvant setting)
	• Documentation of the following is required:

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	• appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • tumor is clear cell histology; **and** • requested quantity is ≤ one unit/day. **Tukysa for advanced unresectable or metastatic HER2-positive breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with trastuzumab and capecitabine; **and** • inadequate response or adverse reaction to one anti-HER2-based regimen; **and** • requested quantity is ≤ four units/day. **Tukysa for RAS wild-type (WT), HER2-positive unresectable or metastatic colorectal cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with trastuzumab; **and** • inadequate response or adverse reaction to at least one or contraindication to all of the following regimens: CAPEOX, FOLFOX, FOLFIRI, FOLFOXIRI, FOLFIRINOX, irinotecan-based therapy, oxaliplatin-based therapy; **and** • requested quantity is ≤ four units/day. **Turalio** • Documentation of the following is required: • diagnosis of tenosynovial giant cell tumor; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or consult notes from an oncologist are provided; **and** • appropriate dosing; **and** • member is not a candidate for surgery. **Vanflyta for FLT3-ITD mutated AML** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and**

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	• requested quantity is ≤ two units/day; **and**
	• one of the following:
	  • for relapsed or refractory disease, requested agent will be used as monotherapy; **or**
	  • for induction therapy, clinical rationale for use of requested agent instead of Rydapt and requested agent will be used in combination with cytarabine and daunorubicin or idarubicin; **or**
	  • for consolidation therapy, clinical rationale for use of requested agent instead of Rydapt and requested agent will be used in combination with cytarabine; **or**
	  • for maintenance therapy, requested agent will be used as monotherapy and one of the following:
	  • member received the requested agent as part of induction and/or consolidation therapy; **or**
	  • clinical rationale for use of the requested agent instead of both Rydapt and sorafenib.
	Xalkori for systemic anaplastic large cell lymphoma (ALCL)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer is ALK-positive; **and**
	  • one of the following:
	  • member has relapsed or refractory disease to one prior agent or regimen; **or**
	  • clinical rationale as to why the other available treatment regimens cannot be used; **and**
	  • for Xalkori (crizotinib) oral pellets, medical necessity for the use of the oral pellet formulation instead of the capsule as noted by one of the following:
	  • member is < 13 years of age; **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • requested dose cannot be obtained from capsule formulation.
	Xalkori for unresectable, recurrent, or refractory inflammatory myofibroblastic tumors (IMT)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • member is ≥ one year of age; **and**

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	• appropriate dosing; **and**
	• cancer is ALK-positive; **and**
	• for Xalkori (crizotinib) oral pellets, medical necessity for the use of the oral pellet formulation instead of the capsule as noted by one of the following:
	  • member is < 13 years of age; **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • requested dose cannot be obtained from capsule formulation.
	Xalkori for ALK-positive or ROS1 positive metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer is ALK-positive or ROS1 positive; **and**
	  • for Xalkori (crizotinib) oral pellets, medical necessity for the use of the oral pellet formulation instead of the capsule as noted by one of the following:
	  • member is < 13 years of age; **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • requested dose cannot be obtained from capsule formulation.
	Xalkori for MET positive amplification metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer is MET positive amplification; **and**
	  • for Xalkori (crizotinib) oral pellets, medical necessity for the use of the oral pellet formulation instead of the capsule as noted by one of the following:
	  • member is < 13 years of age; **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • requested dose cannot be obtained from capsule formulation.
	Xospata
	• Documentation of the following is required:
	  • diagnosis of relapsed or refractory FLT3-mutated AML; **and**
	  • member is ≥ 18 years of age; **and**

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	• prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • requested quantity is ≤ three units/day. **Zykadia for ALK-positive metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer is ALK-positive; **and** • requested quantity is ≤ three units/day. **Zykadia for ROS1-rearrangement metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • cancer is ROS1-rearrangement; **and** • requested quantity is ≤ three units/day.

Antimetabolites

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
allopurinol sodium	Aloprim		#	IV	**Infugem** • Documentation of the following is required: • diagnosis of breast cancer, non-small cell lung cancer, ovarian cancer or pancreatic cancer; **and** • prescriber is an oncologist or hematologist; **and** • member is ≥ 18 years of age; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to a gemcitabine product available without PA. **nelarabine** • Documentation of the following is required: • diagnosis of T-cell acute lymphoblastic leukemia (T-ALL) or T-cell lymphoblastic lymphoma (T-LBL); **and** • prescriber is an oncologist; **and** • appropriate dosing. **Pemfexy** • Documentation of the following is required: • diagnosis of malignant pleural mesothelioma or NSCLC; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or
capecitabine	Xeloda		# , A90	PO	
cladribine injection			MB	IV	
clofarabine	Clolar		MB	IV	
cytarabine			MB	IV	
floxuridine			MB	Intra-arterial	
fludarabine				IV	
fluorouracil injection			MB	IV	
gemcitabine premixed infusion	Infugem	PA	MB	IV	
gemcitabine vial			MB	IV	
hydroxyurea capsule	Hydrea		# , A90	PO	
mercaptopurine oral suspension	Purixan	PA		PO	
mercaptopurine tablet			A90	PO	
methotrexate injection				IM / IV / Intra-arterial	
methotrexate tablet			A90	PO	
nelarabine	Arranon	PA	MB	IV	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
pemetrexed			MB	IV	contraindication to a pemetrexed product available without PA. **Purixan** • Documentation of the following is required: • diagnosis of acute lymphoblastic leukemia (ALL); **and** • one of the following: • member is < 13 years of age; **or** • medical necessity for the use of an oral suspension formulation (e.g. swallowing disorder). **SmartPA:** Claims for Purixan (mercaptopurine oral suspension) will usually process at the pharmacy without a PA request if the member has a MassHealth history of medical claims for ALL and the member is < 13 years of age. †
pemetrexed disodium	Alimta		MB	IV	
pemetrexed-Pemfexy	Pemfexy	PA	MB	IV	
pentostatin	Nipent		MB	IV	
pralatrexate	Folotyn		MB	IV	

Kinase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
abemaciclib	Verzenio	PA		PO	**Aliqopa** • Documentation of the following is required: • diagnosis of FL; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • prior therapy with at least two systemic therapies. **Balversa** • Documentation of the following is required: • diagnosis of FGFR3-mutated locally advanced or metastatic urothelial carcinoma; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to at least one prior systemic therapy for requested indication, or contraindication to the use of all systemic therapy; **and** • inadequate response or adverse reaction to one prior PD-1 or PD-L1 inhibitor therapy or contraindication to the use of all PD-1 or PD-L1 inhibitors. **Braftovi for mCRC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • requested quantity is ≤ four units/day; **and** • positive BRAF V600E mutation; **and**
afatinib	Gilotrif	PA		PO	
alpelisib-Piqray	Piqray	PA		PO	
belumosudil	Rezurock	PA		PO	
binimetinib	Mektovi	PA		PO	
capivasertib	Truqap	PA		PO	
capmatinib	Tabrecta	PA		PO	
cobimetinib	Cotellic	PA		PO	
copanlisib	Aliqopa	PA	MB	IV	
dabrafenib	Tafinlar	PA		PO	
dacomitinib	Vizimpro	PA		PO	
duvelisib	Copiktra	PA		PO	
encorafenib	Braftovi	PA		PO	
erdafitinib	Balversa	PA		PO	
fedratinib	Inrebic	PA		PO	
fruquintinib	Fruzaqla	PA		PO	
futibatinib	Lytgobi	PA		PO	
idelalisib	Zydelig	PA		PO	
lorlatinib	Lorbrena	PA		PO	
mobocertinib	Exkivity	PA		PO	
momelotinib	Ojjaara	PA		PO	
neratinib	Nerlynx	PA		PO	
osimertinib	Tagrisso	PA		PO	
pacritinib	Vonjo	PA		PO	
palbociclib	Ibrance PD	PA		PO	
pemigatinib	Pemazyre	PA		PO	
pralsetinib	Gavreto	PA		PO	
regorafenib	Stivarga	PA		PO	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
ribociclib	Kisqali	PA		PO	• requested agent will be used in combination with Erbitux (cetuximab) or Vectibix (panitumumab); **and** • inadequate response or adverse reaction to one or a contraindication to all of the following regimens: CAPEOX, FOLFOX, irinotecan-based therapy, oxaliplatin-based therapy. **Braftovi for unresectable or metastatic melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • requested quantity is ≤ six units/day; **and** • positive BRAF V600E or V600K mutation; **and** • requested agent will be used in combination with Mektovi (binimetinib). **Braftovi for metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • requested quantity is ≤ six units/day; **and** • positive BRAF V600E mutation; **and** • requested agent will be used in combination with Mektovi (binimetinib). **Copiktra for CLL or SLL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • prior therapy with at least two systemic therapies. **Cosela** • Documentation of the following is required: • diagnosis of extensive-stage small cell lung cancer (ES-SCLC); **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member is ≥ 18 years of age; **and** • requested agent will be used in combination with a platinum/etoposide-containing or topotecan-containing regimen. **Cotellic for low-grade or high-grade gliomas** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • positive BRAF V600E mutation; **and**
ripretinib	Qinlock	PA		PO	
ruxolitinib tablet	Jakafi	PA		PO	
selpercatinib	Retevmo	PA		PO	
selumetinib	Koselugo	PA		PO	
tepotinib	Tepmetko	PA		PO	
trametinib	Mekinist	PA		PO	
trilaciclib	Cosela	PA	MB	IV	

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	• appropriate dosing; **and** • requested agent will be used in combination with Zelboraf (vemurafenib) ≤ 960 mg every 12 hours. **Cotellic for unresectable or metastatic melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • requested quantity is ≤ three units/day; **and** • positive BRAF V600E or V600K mutation; **and** • requested agent will be used in combination with Zelboraf (vemurafenib). **Cotellic for histiocytic neoplasms** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • member is ≥ 18 years of age; **and** • requested quantity is ≤ three units/day. **Exkivity for advanced or metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has EGFR exon 20 insertion mutation; **and** • inadequate response or adverse reaction to at least one platinum-based chemotherapy regimen or contraindication to the use of platinum-based chemotherapy; **and** • requested quantity is ≤ four units/day. **Fruzaqla for mCRC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all of the following regimens: CAPEOX, FOLFOX, FOLFIRI, FOLFOXIRI, irinotecan-based therapy, oxaliplatin-based therapy; **and** • inadequate response or adverse reaction to one or contraindication to both of the following: Lonsurf (trifluridine/tipiracil), Stivarga (regorafenib); **and** • if BRAF/KRAS/NRAS wild-type cancer is present,

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	inadequate response or adverse reaction to one or contraindication to both of the following: Erbitux (cetuximab), Vectibix (panitumumab); **and** • one of the following: • for 1 mg capsule, requested quantity is ≤ four units/day; **or** • for 5 mg capsule, requested quantity is ≤ one unit/day. **Gavreto and Retevmo for advanced or metastatic medullary thyroid cancer or thyroid cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member is ≥ 12 years of age; **and** • cancer is RET-fusion positive; **and** • requested quantity is ≤ four units/day; **and** • one of the following: • member has thyroid cancer and one of the following: member refractory to radioactive iodine, or radioactive iodine treatment is not appropriate; **or** • member has medullary thyroid cancer. **Gavreto and Retevmo for advanced or metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member is ≥ 18 years of age; **and** • cancer is RET-fusion positive; **and** • requested quantity is ≤ four units/day. **Gilotrif** • Documentation of the following is required: • diagnosis of metastatic NSCLC; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • member has epidermal growth factor receptor (EGFR) mutations; **or** • inadequate response or adverse reaction to one or contraindication to all platinum-based chemotherapy; **and** • requested quantity is ≤ one unit/day. **Ibrance for HER2-negative, HR-positive breast cancer** • Documentation of the following is required:

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	• appropriate diagnosis; **and**
	• prescriber is an oncologist; **and**
	• appropriate dosing; **and**
	• one of the following:
	  • the requested agent will be used in combination with an aromatase inhibitor; **or**
	  • the requested agent will be used in combination with fulvestrant; **and**
	• requested quantity is ≤ one unit/day.
	Inrebic
	• Documentation of the following is required:
	  • diagnosis of one of the following:
	  • intermediate or high-risk primary myelofibrosis (PMF); **or**
	  • post-polycythemia vera myelofibrosis (post-PV MF); **or**
	  • post-essential thrombocythemia myelofibrosis (post-ET MF); **and**
	  • member is ≥ 18 years of age; **and**
	  • inadequate response, adverse reaction, or contraindication to Jakafi (ruxolitinib tablet); **and**
	  • requested quantity is ≤ four units/day.
	Jakafi for acute graft versus host disease (aGVHD) or chronic graft versus host disease (cGVHD)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 12 years of age; **and**
	  • inadequate response, adverse reaction, or contraindication to systemic glucocorticoids; **and**
	  • requested quantity is ≤ two units/day.
	Jakafi for polycythemia vera (PV)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: Besremi (ropeginterferon alfa-2b-njft), hydroxyurea, Pegasys (peginterferon alfa-2a); **and**
	  • requested quantity is ≤ two units/day.
	Jakafi for intermediate or high-risk or symptomatic low-risk PMF, post-PV MF, or post-ET MF
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • requested quantity is ≤ two units/day.

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	Kisqali
	• Documentation of the following is required:
	  • diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • requested agent will be used in combination with an aromatase inhibitor; **or**
	  • requested agent will be used in combination with fulvestrant.
	Koselugo for plexiform neurofibromas (PN) with neurofibromatosis type 1 (NF1)
	• Documentation of the following is required for members ≥ two years of age and < 18 years of age at the start of therapy:
	  • appropriate diagnosis; **and**
	  • prescriber is a neurologist or oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ two years of age and < 18 years of age at the start of therapy; **and**
	  • member has at least one measurable PN and complete resection of PN is not feasible without substanstial risk or morbidity.
	• Documentation of the following is required for members ≥ 18 years of age:
	  • appropriate diagnosis; **and**
	  • prescriber is a neurologist or oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • member has at least one measurable PN and complete resection of PN is not feasible without substanstial risk or morbidity.
	Lorbrena
	• Documentation of the following is required:
	  • diagnosis of metastatic NSCLC; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer is ALK-positive; **and**
	  • inadequate response, adverse reaction, or contraindication to Alecensa; **and**
	  • requested quantity is ≤ one unit/day.
	Lytgobi and Pemazyre for unresectable locally advanced or metastatic cholangiocarcinoma

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	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • tumor has FGFR2 fusion or other rearrangement; **and**
	  • member is ≥ 18 years of age; **and**
	  • member has received at least one prior treatment; **and**
	  • for Lytgobi, one of the following:
	  • for a 20 mg daily dose, requested quantity is ≤ five units per day; **or**
	  • for a 16 mg daily dose, requested quantity is ≤ four units per day; **or**
	  • for a 12 mg daily dose, requested quantity is ≤ three units per day.
	Mekinist for locally advanced or metastatic anaplastic thyroid cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • one of the following:
	  • for 0.5 mg tablets, requested quantity is ≤ three units/day; **or**
	  • for 2 mg tablets, requested quantity is ≤ one unit/day; **and**
	  • positive BRAF V600E mutation; **and**
	  • requested agent will be used in combination with Tafinlar (dabrafenib); **and**
	  • member has no satisfactory locoregional treatment options.
	Mekinist for low-grade glioma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • positive BRAF V600E mutation; **and**
	  • requested agent will be used in combination with Tafinlar (dabrafenib); **and**
	  • one of the following:
	  • for 0.5 mg tablets, requested quantity is ≤ three units/day; **or**
	  • for 2 mg tablets, requested quantity is ≤ one unit/day; **or**
	  • for solution, requested quantity is ≤ 40 mL/day.
	Mekinist for adjuvant treatment of melanoma
	• Documentation of the following is required:

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	• appropriate diagnosis; **and**
	• prescriber is an oncologist; **and**
	• one of the following:
	  • for 0.5 mg tablets, requested quantity is ≤ three units/day; **or**
	  • for 2 mg tablets, requested quantity is ≤ one unit/day; **and**
	• positive BRAF V600E or V600K mutation; **and**
	• requested agent will be used in combination with Tafinlar (dabrafenib); **and**
	• involvement of lymph nodes following complete resection.
	Mekinist for unresectable or metastatic melanoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • one of the following:
	  • for 0.5 mg tablets, requested quantity is ≤ three units/day; **or**
	  • for 2 mg tablets, requested quantity is ≤ one unit/day; **and**
	  • positive BRAF V600E or V600K mutation; **and**
	  • one of the following:
	  • requested agent will be used in combination with Tafinlar (dabrafenib); **or**
	  • all of the following:
	  • requested agent will be used as a single agent; **and**
	  • no history of prior therapy with a BRAF inhibitor (i.e., Tafinlar [dabrafenib] or Zelboraf [vemurafenib]); **and**
	  • clinical rationale for bypassing use of a BRAF inhibitor (i.e., Tafinlar [dabrafenib] or Zelboraf [vemurafenib]).
	Mekinist for metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • one of the following:
	  • for 0.5 mg tablets, requested quantity is ≤ three units/day; **or**
	  • for 2 mg tablets, requested quantity is ≤ one unit/day; **and**
	  • positive BRAF V600E mutation; **and**
	  • requested agent will be used in combination with

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	Tafinlar (dabrafenib).
	Mekinist for low-grade serous carcinoma of the ovary, fallopian tube, or primary peritoneum
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • medical records documenting an inadequate response, adverse reaction, or contraindication to one platinum-containing regimen and one hormonal therapy; **and**
	  • one of the following:
	  • for 0.5 mg tablets, requested quantity is ≤ three units/day; **or**
	  • for 2 mg tablets, requested quantity is ≤ one unit/day.
	Mekinist for unresectable or metastatic solid tumors
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • member is ≥ one year of age; **and**
	  • one of the following:
	  • for 0.5 mg tablets, requested quantity is ≤ three units/day; **or**
	  • for 2 mg tablets, requested quantity is ≤ one unit/day; **or**
	  • for solution, requested quantity is ≤ 40 mL/day; **and**
	  • positive BRAF V600E mutation; **and**
	  • requested agent will be used in combination with Tafinlar (dabrafenib).
	Mektovi for unresectable or metastatic melanoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • requested quantity is ≤ six units/day; **and**
	  • positive BRAF V600E or V600K mutation; **and**
	  • requested agent will be used in combination with Braftovi (encorafenib).
	Mektovi for metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • requested quantity is ≤ six units/day; **and**
	  • positive BRAF V600E mutation; **and**
	  • requested agent will be used in combination with Braftovi (encorafenib).

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	Mektovi for low-grade serous carcinoma of the ovary, fallopian tube, or primary peritoneum
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • requested quantity is ≤ six units/day; **and**
	  • medical records documenting an inadequate response, adverse reaction, or contraindication to one platinum-containing regimen and one hormonal therapy.
	Nerlynx for adjuvant therapy for early stage breast cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member received trastuzumab therapy within the last two years; **and**
	  • requested quantity is ≤ six units/day.
	Nerlynx for treatment of advanced or metastatic breast cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to two anti-HER2-based regimens; **and**
	  • requested agent will be used in combination with capecitabine; **and**
	  • requested quantity is ≤ six units/day.
	Ojjaara
	• Documentation of the following is required:
	  • diagnosis of one of the following:
	  • intermediate or high-risk or symptomatic low-risk PMF; **or**
	  • intermediate or high-risk or symptomatic low-risk post-PV MF; **or**
	  • intermediate or high-risk or symptomatic low-risk post-ET MF; **and**
	  • member is ≥ 18 years of age; **and**
	  • one of the following:
	  • current hemoglobin is ≤ 10 g/dL; **or**
	  • inadequate response, adverse reaction, or contraindication to Jakafi (ruxolitinib); **and**
	  • requested quantity is ≤ one unit/day.

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	Pemazyre for myeloid/lymphoid neoplasms (MLNs) with FGFR1 rearrangement
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age.
	Piqray
	• Documentation of the following is required:
	  • diagnosis of HR-positive, HER2-negative, PIK3CA-mutated breast cancer; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • disease has progressed following treatment with endocrine-based therapy; **and**
	  • requested agent will be used in combination with fulvestrant.
	Qinlock
	• Documentation of the following is required:
	  • diagnosis of gastrointestinal stromal tumor (GIST); **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to at least three prior kinase inhibitor therapies, one of which is imatinib; **and**
	  • requested quantity is ≤ three units/day.
	Retevmo for locally advanced or metastatic solid tumor
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • cancer is RET fusion-positive; **and**
	  • requested quantity is ≤ four units/day; **and**
	  • one of the following:
	  • inadequate response or adverse reaction to at least one prior systemic therapy, or contraindication to the use of all systemic therapy; **or**
	  • member has no satisfactory alternative treatment options.
	Rezurock
	• Documentation of the following is required:
	  • diagnosis of cGVHD; **and**

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	• member is ≥ 12 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to systemic glucocorticoids; **and** • prior therapy for the treatment of cGVHD with at least one prior line of non-steroid systemic therapy; **and** • requested quantity is ≤ one unit/day. **Stivarga for GIST** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to both of the following: imatinib and sunitinib. **Stivarga for HCC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has Child-Pugh Class A; **and** • inadequate response, adverse reaction, or contraindication to sorafenib. **Stivarga for mCRC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all of the following regimens: CAPEOX, FOLFIRI, FOLFOX, FOLFOXIRI, irinotecan-based therapy, oxaliplatin-based therapy; **and** • if BRAF/KRAS/NRAS wild-type cancer is present, inadequate response or adverse reaction to one or a contraindication to both of the following: Erbitux (cetuximab), Vectibix (panitumumab). **Stivarga for osteosarcoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or

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	contraindication to both of the following regimens: cisplatin and doxorubicin, high-dose methotrexate, cisplatin, and doxorubicin. **Tabrecta for MET exon 14 skipping metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has mutation that leads to MET exon 14 skipping; **and** • requested quantity is ≤ four units/day. **Tabrecta for MET positive amplification metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer is MET positive amplification; **and** • requested quantity is ≤ four units/day. **Tafinlar for locally advanced or metastatic anaplastic thyroid cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **and** • positive BRAF V600E mutation; **and** • requested agent will be used in combination with Mekinist (trametinib); **and** • member has no satisfactory locoregional treatment options. **Tafinlar for low-grade glioma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • one of the following: • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **or** • for 10 mg tablet for oral solution, requested quantity is ≤ 30 units/day; **and** • positive BRAF V600E mutation; **and** • requested agent will be used in combination with Mekinist (trametinib). **Tafinlar for adjuvant treatment of melanoma** • Documentation of the following is required:

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	• appropriate diagnosis; **and** • prescriber is an oncologist; **and** • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **and** • positive BRAF V600E or V600K mutation; **and** • requested agent will be used in combination with Mekinist (trametinib); **and** • involvement of lymph nodes following complete resection. **Tafinlar for unresectable or metastatic melanoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **and** • for positive BRAF V600K, requested agent will be used in combination with Mekinist (trametinib); **and** • for positive BRAF V600E, one of the following: • requested agent will be used in combination with Mekinist (trametinib); **or** • requested agent will be used as monotherapy. **Tafinlar for metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **and** • positive BRAF V600E mutation; **and** • requested agent will be used in combination with Mekinist (trametinib). **Tafinlar for unresectable or metastatic solid tumors** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • member is ≥ one year of age; **and** • one of the following: • for 50 mg and 75 mg capsule, requested quantity is ≤ four units/day; **or** • for 10 mg tablet for oral solution, requested quantity is ≤ 30 units/day; **and** • positive BRAF V600E mutation; **and** • requested agent will be used in combination with Mekinist (trametinib). **Tagrisso for advanced or metastatic NSCLC**

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	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ one unit/day; **and**
	  • one of the following:
	  • cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation; **or**
	  • both of the following:
	  • cancer displays the EGFR mutation and the T790M resistance mutation; **and**
	  • inadequate response or adverse reaction to one of the following or contraindication to all of the following: erlotinib, gefitinib, Gilotrif (afatinib), Vizimpro (dacomitinib).
	Tagrisso for adjuvant treatment for stage IB to IIIA NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested quantity is ≤ one unit/day; **and**
	  • cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation; **and**
	  • requested agent will be used as adjuvant therapy following tumor resection.
	Tagrisso for first-line treatment of locally advanced or metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation; **and**
	  • requested agent will be given in combination with pemetrexed and platinum-based chemotherapy.
	Tepmetko for MET exon 14 skipping metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer harbors MET exon 14 skipping alterations; **and**
	  • requested quantity is ≤ two units/day.
	Tepmetko for MET positive amplification metastatic NSCLC

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	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer is MET positive amplification; **and**
	  • requested quantity is ≤ two units/day.
	Truqap for HR-positive, HER2-negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-mutations
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • disease has progressed following treatment with endocrine-based therapy; **and**
	  • if member has a PIK3CA mutation, inadequate response, adverse reaction, or contraindication to Piqray (alpelisib); **and**
	  • requested agent will be used in combination with fulvestrant; **and**
	  • requested quantity is ≤ four units/day.
	Verzenio for HR-positive, HER2-negative early breast cancer (EBC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • the requested agent will be used in combination with an aromatase inhibitor; **or**
	  • the requested agent will be used in combination with tamoxifen; **and**
	  • requested quantity is ≤ two units/day.
	Verzenio for HR-positive, HER2-negative advanced or metastatic breast cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • the requested agent will be used in combination with an aromatase inhibitor; **or**
	  • the requested agent will be used in combination with

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	fulvestrant; **or** • the requested agent will be used as monotherapy when disease has progressed after both hormonal therapy and chemotherapy; **and** • requested quantity is ≤ two units/day. **Vizimpro** • Documentation of the following is required: • diagnosis of metastatic NSCLC; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has EGFR mutations; **and** • requested quantity is ≤ one unit/day. **Vonjo** • Documentation of the following is required: • diagnosis of one of the following: • intermediate or high-risk or symptomatic low-risk PMF; **or** • intermediate or high-risk or symptomatic low-risk post-PV MF; **or** • intermediate or high-risk or symptomatic low-risk post-ET MF; **and** • member is ≥ 18 years of age; **and** • one of the following: • current platelet count is ≤ 50 x 10^9/L; **or** • current hemoglobin is ≤ 10 g/dL; **or** • inadequate response, adverse reaction, or contraindication to Jakafi (ruxolitinib); **and** • requested quantity is ≤ four units/day. **Zydelig** • Documentation of the following is required: • diagnosis of CLL; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • relapsed or refractory CLL; **or** • prior therapy with at least one systemic therapy.

Alkylating Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
bendamustine	Belrapzo		MB	IV	**Gleostine for Brain Tumor** • Documentation of the following is required: • appropriate diagnosis; **and**
bendamustine	Bendeka		MB	IV	
bendamustine	Treanda		MB	IV	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
bendamustine	Vivimusta		MB	IV	• prescriber is an oncologist; **and** • appropriate dosing; **and** • member has received surgical and/or radiotherapeutic procedures, as appropriate. **Hepzato for uveal melanoma with unresectable hepatic metastases** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age • prescriber is an oncologist or consult notes from oncologist are provided; **and** • appropriate dosing; **and** • member has liver metastases that affect < 50% of the liver; and • one of the following: • member does not have any extra hepatic disease; or • extra hepatic disease is limited to the bone, lymph nodes, subcutaneous tissue, or lung and is amenable to resection or radiation; and • requested duration is ≤ six doses. **Leukeran for Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • prior therapy with at least two systemic therapies. **Leukeran for Follicular Lymphoma (FL) or Marginal Zone Lymphoma (MZL)** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to rituximab monotherapy. **Zepzelca** • Documentation of the following is required: • diagnosis of metastatic small cell lung cancer (SCLC); **and** • prescriber is an oncologist; **and** • appropriate dosing; **and**
busulfan injection	Busulfex		MB	IV	
busulfan tablet	Myleran			PO	
carboplatin			MB	IV	
carmustine	Bicnu		MB	IV/ Implantation	
chlorambucil	Leukeran	PA		PO	
cisplatin			MB	IV	
cyclophosphamide capsule, tablet			A90	PO	
cyclophosphamide injection			MB	IV	
dacarbazine			MB	IV	
estramustine	Emcyt			PO	
ifosfamide	Ifex		MB	IV	
lomustine	Gleostine	PA		PO	
lurbinectedin	Zepzelca	PA	MB	IV	
mechlorethamine gel	Valchlor			Topical	
melphalan hepatic delivery system	Hepzato	PA	MB	IV	
melphalan hydrochloride injection	Alkeran		MB	IV	
melphalan injection	Evomela		MB	IV	
melphalan tablet	Alkeran		# , A90	PO	
oxaliplatin			MB	IV	
procarbazine	Matulane			PO	
temozolomide	Temodar		# , A90	IV / PO	

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	• inadequate response, adverse reaction, or contraindication to platinum-based chemotherapy.

Anti-VEGF

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
bevacizumab	Avastin	PA	MB	IV	**Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for cervical cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with one of the following: • paclitaxel and carboplatin;**or** • paclitaxel and cisplatin; **or** • paclitaxel and topotecan. **Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for recurrent glioblastoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing. **Avastin for hepatocellular carcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with Tecentriq (atezolizumab). **Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for metastatic colorectal cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with fluoropyrimidine-, capecitabine-, oxaliplatin-, or irinotecan-containing therapy. **Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for metastatic renal cell carcinoma**
bevacizumab-adcd	Vegzelma	PA	MB	IV	
bevacizumab-awwb	Mvasi	PA	MB	IV	
bevacizumab-bvzr	Zirabev	PA	MB	IV	
bevacizumab-maly	Alymsys	PA	MB	IV	
ramucirumab	Cyramza	PA	MB	IV	
ziv-aflibercept	Zaltrap	PA	MB	IV	

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	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • if predominant clear cell histology, requested agent will be used in combination with interferon alfa.
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for non-squamous non-small cell lung cancer (NSCLC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with both of the following: carboplatin, paclitaxel.
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for non-squamous NSCLC with EGFR Mutation Positive
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • requested agent will be used in combination with erlotinib.
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for adenocarcinoma, large cell, NSCLC not otherwise specified (NOS) with PD-L1 Expression Positive
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • requested agent will be used in combination with all of the following: carboplatin, paclitaxel, atezolizumab.
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for initial therapy of advanced or metastatic adenocarcinoma, large cell, NSCLC NOS (performance status [PS] 0-2)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • member has a contraindication to to PD-1 or PD-L1 inhibitors; **and**
	  • requested agent will be used in combination with one of the following:
	  • carboplatin and pemetrexed; **or**
	  • cisplatin and pemetrexed.
	Alymsys, Avastin, Mvasi, and Zirabev for maintenance

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	therapy of advanced or metastatic adenocarcinoma, large cell, NSCLC NOS (PS 0-2)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • one of the following:
	  • requested agent will be used as monotherapy; **or**
	  • requested agent will be used in combination with one of the following: atezolizumab or pemetrexed.
	Alymsys, Avastin, Mvasi, Vegzelma, and Zirabev for ovarian, fallopian, or primary peritoneal cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing.
	Avastin for wet age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, or myopic choroidal neovascularization
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • requested dosing is 1.25 mg intravitreally every four or eight weeks or as needed.
	Cyramza for gastric or gastro-esophageal junction (GEJ) adenocarcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or contraindication to both of the following: a fluoropyrimidine-containing chemotherapy regimen, a platinum-containing chemotherapy regimen.
	Cyramza for HCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member has alpha fetoprotein (AFP) ≥ 400 ng/mL; **and**
	  • inadequate response, adverse reaction, or contraindication to sorafenib.
	Cyramza for metastatic colorectal cancer

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	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with one of the following: FOLFIRI or irinotecan; **and**
	  • inadequate response or adverse reaction to one or contraindication to both of the following: 5-fluorouracil/leucovorin, a capecitabine-based regimen.
	Cyramza for NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • both of the following:
	  • requested agent will be used in combination with docetaxel; **and**
	  • inadequate response, adverse reaction, or contraindication to a platinum-containing chemotherapy regimen; **or**
	  • all of the following:
	  • requested agent will be used in combination with erlotinib; **and**
	  • cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: Gilotrif (afatinib), gefitinib, Tagrisso (osimertinib), Vizimpro (dacomitinib).
	Zaltrap
	• Documentation of the following is required:
	  • diagnosis of metastatic colorectal cancer; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with either irinotecan or FOLFIRI; **and**
	  • inadequate response or adverse reaction to one of the following regimens or a contraindication to all of the following regimens: a fluoropyrimidine (capecitabine or fluorouracil), CAPEOX, FOLFOX, oxaliplatin-based therapy; **and**
	  • inadequate response, adverse reaction, or contraindication to a bevacizumab product.

Aromatase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
anastrozole	Arimidex		# , A90	PO	
exemestane	Aromasin		# , A90	PO	
letrozole	Femara		# , A90	PO	

Monoclonal Antibodies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

alemtuzumab 30 mg	Campath			IV	Arzerra for relapsed or refractory CLL
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • member is ≥ 18 years of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response, adverse reaction, or contraindication to both of the following: alemtuzumab, fludarabine.
					Arzerra for untreated CLL
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • member is ≥ 18 years of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • contraindication to fludarabine; **and**
					  • one of the following:
					  • requested agent will be used in combination with chlorambucil; **or**
					  • clinical rationale as to why the agent will not be used with chlorambucil.
					Blincyto
					• Documentation of the following is required:
					  • diagnosis of ALL; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • one of the following:
					  • member with complete remission following initial treatment; **or**
					  • both of the following:
					  • Philadelphia chromosome-positive; **and**
					  • inadequate response or adverse reaction to one tyrosine kinase inhibitor for the treatment of ALL; **or**
					  • all of the following:
					  • Philadelphia chromosome-negative; **and**

blinatumomab	Blincyto	PA	MB	IV	
cetuximab	Erbitux		MB	IV	
daratumumab	Darzalex	PA	MB	IV	
daratumumab / hyaluronidase-fihj	Darzalex Faspro	PA	MB	SC	
elotuzumab	Empliciti	PA	MB	IV	
isatuximab-irfc	Sarclisa	PA	MB	IV	
loncastuximab tesirine-lpyl	Zynlonta	PA		IV	
margetuximab-cmkb	Margenza	PA	MB	IV	
mogamulizumab-kpkc	Poteligeo	PA	MB	IV	
naxitamab-gqgk	Danyelza	PA	MB	IV	
necitumumab	Portrazza	PA	MB	IV	
obinutuzumab	Gazyva	PA	MB	IV	
ofatumumab vial	Arzerra	PA	MB	IV	
panitumumab	Vectibix		MB	IV	
pertuzumab	Perjeta	PA	MB	IV	
rituximab	Rituxan	PA	MB	IV	
rituximab / hyaluronidase human	Rituxan Hycela	PA	MB	SC	
rituximab-abbs	Truxima	PA	MB	IV	
rituximab-arrx	Riabni	PA	MB	IV	
rituximab-pvvr	Ruxience	PA	MB	IV	
tafasitamab-cxix	Monjuvi	PA		IV	
trastuzumab	Herceptin	PA	MB	IV	
trastuzumab / hyaluronidase-oysk	Herceptin Hylecta	PA	MB	SC	
trastuzumab-anns	Kanjinti	PA	MB	IV	
trastuzumab-dkst	Ogivri	PA	MB	IV	
trastuzumab-dttb	Ontruzant	PA	MB	IV	
trastuzumab-pkrb	Herzuma	PA	MB	IV	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
trastuzumab-qyyp	Trazimera	PA	MB	IV	• B-cell precursor ALL; **and** • prior therapy for the treatment of ALL with one systemic therapy. **Danyelza** • Documentation of the following is required: • diagnosis of high-risk neuroblastoma of bone or bone marrow; **and** • member is ≥ one year of age; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member had had partial response, minor response, or stable disease to prior treatment; **and** • requested agent will be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) agent. **Darzalex and Darzalex Faspro for multiple myeloma** • Documenation of the following is required for monotherapy: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all of the following proteasome inhibitors: bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade (bortezomib); **and** • inadequate response or adverse reaction to one or contraindication to all of the following immunomodulatory agents; Pomalyst (pomalidomide), Revlimid (lenalidomide), Thalomid (thalidomide); **and** • one of the following: • inadequate response or adverse reaction to one proteasome inhibitor and one immunomodulatory agent noted above; **or** • history of a total of three trials with chemotherapy regimens for the requested indication. • Documentation of the following is required for combination therapy: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • both of the following: • member is newly diagnosed and eligible for transplant; **and**

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	• requested agent will be used in combination with Velcade (bortezomib) or bortezomib and thalidomide and dexamethasone; **or** • both of the following; • inadequate response or adverse reaction to at least one prior line of systemic therapy; **and** • requested agent will be used in combination with dexamethasone and at least one other agent for treatment of multiple myeloma (excluding anti-CD38 agents); **or** • all of the following: • member is newly diagnosed and ineligible for transplant; **and** • one of the following: • requested agent will be used in combination with Revlimid (lenalidomide) and dexamethasone; **or** • requested agent will be used in combination with Velcade (bortezomib) or bortezomib and melphalan and prednisone; **or** • clinical rationale for the use of the requested combination instead of Velcade (bortezomib) or bortezomib and Revlimid (lenalidomide) and dexamethasone. **Darzalex Faspro for light chain amyloidosis** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • concurrent therapy with Velcade (bortezomib) or bortezomib and cyclophosphamide and dexamethasone. **Empliciti** • Documentation of the following is required: • diagnosis of multiple myeloma; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • both of the following: • inadequate response or adverse reaction to at least one prior chemotherapy regimen for the requested indication; **and** • requested agent will be used in combination with Revlimid (lenalidomide) and dexamethasone; **or**

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	• all of the following:
	  • inadequate response or adverse reaction to at least two prior chemotherapy regimens for the requested indication; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following proteasome inhibitors: bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade (bortezomib); **and**
	  • inadequate response, adverse reaction, or contraindication to Revlimid (lenalidomide); **and**
	  • requested medication will be used in combination with Pomalyst (pomalidomide) and dexamethasone.
	Gazyva for CLL or SLL
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • member has CLL or SLL without del(17p)/TP53 mutation; **or**
	  • member has CLL or SLL with del(17p)/TP53 mutation AND is treatment naive.
	Gazyva for FL
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • relapsed or refractory FL after treatment with a rituximab-containing regimen; **or**
	  • concurrent therapy with first-line chemotherapy agent.
	Herceptin, Herceptin Hylecta, Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera for HER2-overexpressing breast cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing.
	Herceptin, Herzuma, Kanjinti, Ogivri, Ontruzant, and

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	Trazimera for RAS wild-type (WT), HER2-positive unresectable or metastatic colorectal cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to at least one or contraindication to all of the following regimens: CAPEOX, FOLFOX, FOLFIRI, FOLFOXIRI, FOLFIRINOX, irinotecan-based therapy, oxaliplatin-based therapy; **and**
	  • requested agent will be used in combination with Tukysa.
	Herceptin, Herzuma, Kanjinti, Ogivri, Ontruzant, and Trazimera for HER2-overexpessing metastatic gastric or gastroesophageal adenocarcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with chemotherapy.
	Margenza
	• Documentation of the following is required:
	  • diagnosis of metastatic HER-2 positive breast cancer; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with chemotherapy (capecitabine, eribulin, gemcitabine, or vinorelbine); **and**
	  • inadequate response or adverse reaction to two anti-HER-2 based regimens.
	Monjuvi for diffuse large B cell lymphoma (DLBCL)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or contraindication to all systemic therapies.
	Perjeta
	• Documentation of the following is required:

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	• diagnosis of HER-2 positive breast cancer; **and**
	• prescriber is an oncologist; **and**
	• appropriate dosing; **and**
	• one of the following:
	  • for recurrent or stage IV disease, requested agent will be used in combination with Herceptin (trastuzumab) and docetaxel or paclitaxel; **or**
	  • for adjuvant or neoadjuvant chemotherapy, requested agent will be used in combination with trastuzumab and chemotherapy.
	Portrazza
	• Documentation of the following is required:
	  • diagnosis of advanced or metastatic NSCLC; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer of squamous cell histology; **and**
	  • requested agent will be used in combination with gemcitabine and cisplatin; **and**
	  • medical necessity for use of the requested agent instead of all other clinically appropriate alternatives.
	Poteligeo for mycosis fungoides
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • Stage IA disease and member is refractory to skin-directed therapy; **or**
	  • Stage IB to III disease.
	Poteligeo for Sézary syndrome
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing.
	Riabni, Rituxan, Ruxience, and Truxima
	• Documentation of the following is required for autoimmune encephalitis:
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: intravenous glucocorticoids, intravenous immune globulin, plasma exchange; **and**
	  • inadequate response, adverse reaction, or contraindication to cyclophosphamide.

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	• Documentation of the following is required for autoimmune epilepsy:
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: intravenous glucocorticoids, intravenous immune globulin, plasma exchange; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, cyclophosphamide, mycophenolate.
	• Documentation of the following is required for autoimmune hemolytic anemia (AIHA) or IgG-related disease:
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to all corticosteroids.
	• Documentation of the following is required for CLL:
	  • appropriate diagnosis; **and**
	  • appropriate dosing.
	• Documentation of the following is required for moderate-to-severe cryoglobulinemia syndrome:
	  • appropriate diagnosis; **and**
	  • requested agent will be used in combination with systemic glucocorticoids.
	• Documentation of the following is required for graft versus host disease (GVHD):
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and**
	  • inadequate response or adverse reaction to two or contraindication to all of the following: abatacept, alemtuzumab, belumosudil, cyclosporine, etanercept, everolimus, hydroxychloroquine, ibrutinib, imatinib, methotrexate, mycophenolate mofetil, ruxolitinib, sirolimus, tacrolimus, temsirolimus.
	• Documentation of the following is required for granulomatosis with polyangitis (GPA) or microscopic polyangitis (MPA):
	  • For induction (initial) therapy, documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to cyclophosphamide; **and**
	  • one of the following:

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	• requested agent will be used in combination with a glucocorticoid; **or** • adverse reaction or contraindication to glucocorticoids. • Documentation of the following is required for idiopathic membranous nephropathy (IMN): • appropriate diagnosis; **and** • inadequate response or adverse reaction to one or contraindication to both of the following: chlorambucil, cyclophosphamide; **and** • inadequate response or adverse reaction to one or contraindication to both of the following: cyclosporine, tacrolimus. • Documentation of the following is required for idiopathic thrombocytopenia purpura (ITP): • appropriate diagnosis; **and** • inadequate response or adverse reaction to one or contraindication to all corticosteroids. • Documentation of the following is required for lupus nephritis (LN): • appropriate diagnosis; **and** • inadequate response, adverse reaction, or contraindication to both of the following: cyclophosphamide, mycophenolate. • Documentation of the following is required for minimal change disease: • appropriate diagnosis; **and** • inadequate response, adverse reaction, or contraindication to both of the following: cyclophosphamide, cyclosporine. • Documentation of the following is required for multiple sclerosis: • appropriate diagnosis; **and** • prescriber is a neurologist or consult notes from a neurologist are provided. • Documentation of the following is required for generalized myasthenia gravis (MG): • appropriate diagnosis; **and** • inadequate response, adverse reaction, or contraindication to pyridostigmine; **and** • inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and** • one of the following: • member has muscle-specific tyrosine kinase (MuSK)-positive MG; **or**

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	• inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, cyclophosphamide, cyclosporine, eculizumab, efgartigimod, intravenous immune globulin, mycophenolate, ravulizumab, tacrolimus. • Documentation of the following is required for neuromyelitis optica spectrum disorder (NMOSD) maintenance therapy: • appropriate diagnosis; **and** • inadequate response or adverse reaction to one or contraindication to both of the following: azathioprine, mycophenolate. • Documentation of the following is required for Non-Hodgkin's Lymphoma (NHL): • appropriate diagnosis; **and** • appropriate dosing. • Documentation of the following is required for pemphigus foliaceus (PF): • appropriate diagnosis; **and** • one of the following: • requested agent will be used in combination with systemic glucocorticoids; **or** • inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids; **and** • appropriate dosing. • Documentation of the following is required for Polymyositis (PM) or Dermatomyositis (DM): • appropriate diagnosis; **and** • inadequate response or adverse reaction to one or contraindication to all corticosteroids; **and** • inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclophosphamide, cyclosporine, methotrexate. • Documentation of the following is required for Post-Transplantation Lymphoproliferative Disease (PTLD) or Waldenström’s macroglobulinemia: • appropriate diagnosis. • Documentation of the following is required for rheumatoid arthritis (RA): • appropriate diagnosis; **and** • appropriate dosing; **and** • inadequate response, adverse reaction to one or contraindication to all of the following: Cimzia, Enbrel, Humira, infliximab, Simponi Aria, Simponi; **and**

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	• one of the following:
	  • requested agent will be used in combination with methotrexate; **or**
	  • adverse reaction or contraindication to methotrexate.
	• Documentation of the following is required for Systemic Lupus Erythematosus (SLE):
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclophosphamide, cyclosporine, leflunomide, methotrexate, mycophenolate.
	• Documentation of the following is required for Thrombotic Thrombocytopenia Purpura (TTP):
	  • appropriate diagnosis; **and**
	  • one of the following:
	  • member underwent plasma exchange; **or**
	  • clinical rationale as to why plasma exchange was not performed; **and**
	  • inadequate response or adverse reaction to one or contraindication to all corticosteroids.
	Rituxan for pediatric members with mature B-cell NHL or mature B-cell acute leukemia (B-AL)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • appropriate dosing; **and**
	  • member is ≥ six months and < 18 years of age.
	Rituxan for Pemphigus Vulgaris (PV)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • requested agent will be used in combination with systemic glucocorticoids; **or**
	  • inadequate response or adverse reaction to one or contraindication to all systemic corticosteroids.
	Rituxan Hycela for CLL, diffuse large B-cell lymphoma, or FL
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • appropriate dosing.
	Sarclisa
	• Documentation of the following is required:
	  • diagnosis of multiple myeloma; **and**
	  • prescriber is an oncologist or hematologist; **and**

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	• appropriate dosing; **and**
	• one of the following:
	  • both of the following:
	  • inadequate response or adverse reaction to one chemotherapy regimen for the requested indication; **and**
	  • requested agent will be used in combination with Kyprolis (carfilzomib) and dexamethasone; **or**
	  • all of the following:
	  • inadequate response, adverse reaction, or contraindication to Revlimid (lenalidomide); **and**
	  • history of a total of at least two trials with appropriate regimens for the requested indication; **and**
	  • requested agent will be used in combination with Pomalyst (pomalidomide) and dexamethasone; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following proteasome inhibitors**:** bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade (bortezomib).
	Zynlonta
	• Documentation of the following is required:
	  • diagnosis of relapsed or refractory large B cell lymphoma; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • prior therapy with at least two or contraindication to all recommended chemotherapy regimens.

Asparaginase

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

asparaginase erwinia chrysanthemi	Erwinase	PA	MB	IV	**Asparlas**
					• Documentation of the following is required:
					  • diagnosis of ALL; **and**
					  • member is ≥ one month and < 22 years of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response, adverse reaction, or contraindication to Oncaspar (pegaspargase); **or**
					  • clinical rationale for use instead of Oncaspar

asparaginase erwinia chrysanthemi-rywn	Rylaze	PA	MB	IM	
calaspargase pegol-mknl	Asparlas	PA	MB	IV	
pegaspargase	Oncaspar		MB	IM or IV	

	Clinical Notes

	(pegaspargase).
	• For recertification requests that exceed a total treatment duration of 36 weeks, documentation of clinical evidence supporting such an extended duration is required.
	
	Erwinase, Rylaze
	• Documentation of the following is required:
	  • diagnosis of ALL; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • hypersensitivity to *E. coli*-derived asparaginase.
	• For recertification requests that exceed a total treatment duration of 36 weeks, documentation of clinical evidence supporting such an extended duration is required.

PD-1/PD-L1 Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

atezolizumab	Tecentriq	PA	MB	IV	**Bavencio, Keytruda, and Zynyz for metastatic Merkel cell carcinoma**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • for Bavencio and Zynyz, an inadequate response, adverse reaction, or contraindication to Keytruda.
					Bavencio for first-line treatment of RCC
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • tumor is clear cell histology; **and**
					  • requested agent will be used in combination with Inlyta (axitinib).
					Bavencio for locally advanced or metastatic urothelial carcinoma (UC)
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • one of the following:
					  • inadequate response or adverse reaction to one or contraindication to all platinum-containing

avelumab	Bavencio	PA	MB	IV	
cemiplimab-rwlc	Libtayo	PA	MB	IV	
dostarlimab-gxly	Jemperli	PA	MB	IV	
durvalumab	Imfinzi	PA	MB	IV	
nivolumab	Opdivo	PA	MB	IV	
pembrolizumab	Keytruda	PA	MB	IV	
retifanlimab-dlwr	Zynyz	PA	MB	IV	
toripalimab-tpzi	Loqtorzi	PA	MB	IV	

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	regimens; **or** • disease has not progressed following treatment with four-to-six cycles of first-line platinum-containing regimen. **Imfinzi for extensive-stage (ES) SCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has extensive stage disease; **and** • requested agent will be used in combination with etoposide and either carboplatin or cisplatin. **Imfinzi and Keytruda for locally advanced or metastatic biliary tract cancer (BTC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with cisplatin and gemcitabine. **Imfinzi for metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with Imjudo (tremelimumab-actl) and platinum-based regimen; **and** • member does not have EGFR or ALK genomic tumor aberrations. **Imfinzi for unresectable hepatocellular carcinoma (HCC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with Imjudo (tremelimumab-actl). **Imfinzi for stage III NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • disease has not progressed following combination therapy with platinum-based chemotherapy and

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	radiation therapy.
	Jemperli for dMMR recurrent or advanced solid tumors
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • cancer is dMMR; **and**
	  • inadequate response or adverse reaction to one or contraindication to all other treatments for dMMR.
	Jemperli for recurrent or advanced dMMR or MSI-H endometrial cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • one of the following:
	  • cancer is MSI-H and requested agent will be used in combination with carboplatin and paclitaxel every three weeks for six doses followed by monotherapy of Jemperli every six weeks; **or**
	  • cancer is dMMR and one of the following:
	  • requested agent will be used as monotherapy and an inadequate response or adverse reaction to one or contraindication to all lines of platinum-based regimens; **or**
	  • requested agent will be used in combination with carboplatin and paclitaxel every three weeks for six doses followed by monotherapy of Jemperli every six weeks.
	Keytruda for non-muscle invasive bladder cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or urologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to BCG; **and**
	  • disease is high-risk with carcinoma in situ.
	Keytruda for high-risk early stage TNBC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**

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	• requested agent will be used in combination with chemotherapy and then continued as a single agent following surgery. **Keytruda for cervical cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • both of the following: • requested agent will be used in combination with chemotherapy, with or without bevacizumab; **and** • tumor expresses PD-L1 (CPS ≥ 1); **or** • both of the following: • requested agent will be used in combination with chemoradiotherapy; **and** • member has FIGO 2014 Stage III-IVA cervical cancer; **or** • all of the following: • disease progression following one systemic chemotherapy regimen; **and** • requested agent will be used as monotherapy; **and** • tumor expresses PD-L1 (CPS ≥ 1). **Keytruda for MSI-H/dMMR solid tumors or mCRC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing. **Keytruda for advanced endometrial carcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one prior line of systemic therapy or contraindication to all systemic therapies; **and** • member is not a candidate for surgery or radiation; **and** • one of the following: • for advanced endometrial carcinoma that is not MSI-H or dMMR, requested agent will be used in combination with Lenvima (lenvatinib); **or** • for advanced endometrial carcinoma that is MSI-H or dMMR, requested agent will be used as monotherapy.

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	Keytruda for advanced, recurrent or metastatic esophageal or EGJ cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • if previously untreated, requested agent will be used in combination with a fluoropyrimidine- and platinum-containing regimen; **or**
	  • requested agent will be used as monotherapy and member had at least one prior line of systemic therapy for squamous cell tumor with PD-L1 (CPS ≥ 10).
	Keytruda for recurrent locally advanced unresectable or metastatic HER2-positive gastric or GEJ adenocarcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with trastuzumab, fluoropyrimidine-, and platinum-containing regimen.
	Keytruda for locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with a fluoropyrimidine- and platinum-containing regimen.
	Keytruda for HCC secondary to hepatitis B
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one, or contraindication to both of the following: sorafenib, Lenvima (lenvatinib).
	Keytruda and Opdivo for Hodgkin Lymphoma in adult members
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**

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	• prescriber is an oncologist or hematologist; **and**
	• appropriate dosing; **and**
	• member is ≥ 18 years of age; **and**
	• one of the following:
	  • member has progressed after autologous hematopoietic stem cell transplant with or without brentuximab; **or**
	  • member is ineligible for transplant or inadequate response to two lines of prior chemotherapy; **or**
	  • member has received allogeneic transplant.
	Keytruda and Opdivo for Hodgkin Lymphoma in pediatric members
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • member is < 18 years of age; **and**
	  • inadequate response or adverse reaction to two or more lines of prior chemotherapy.
	Keytruda for recurrent or metastatic head and neck squamous cell carcinoma (HNSCC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens; **or**
	  • cancer is non-nasopharyngeal and one of the following:
	  • requested agent is used in combination with a platinum agent (cisplatin, carboplatin) and fluorouracil; **or**
	  • tumor is PD-L1 positive (CPS ≥ 1).
	Keytruda and Opdivo for stage IIB, IIC, or III melanoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used as adjuvant treatment following complete resection.
	Keytruda and Opdivo for unresectable or metastatic melanoma

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	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing.
	Keytruda for resectable NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in the neoadjuvant setting in combination with one of the following:
	  • carboplatin and paclitaxel; **or**
	  • cisplatin and gemcitabine; **or**
	  • cisplatin and paclitaxel; **or**
	  • cisplatin and pemetrexed; **and**
	  • requested agent will be continued as monotherapy as adjuvant treatment after surgery.
	Keytruda for stage IB (T2a ≥4 cm), II, or IIIA NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used as adjuvant treatment following resection and platinum-based regimen.
	Keytruda for stage III NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • PD-L1 expression [tumor proportion score (TPS) ≥ 1%]; **and**
	  • requested agent will be used in combination with carboplatin and one of the following: paclitaxel, pemetrexed.
	Keytruda for unresectable or metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • for nonsquamous NSCLC in the first-line setting, requested agent will be used in combination with pemetrexed and one of the following: carboplatin, cisplatin; **or**

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	• for squamous NSCLC in the first-line setting, requested agent will be used in combination with carboplatin and one of the following: paclitaxel, albumin-bound paclitaxel ; **or**
	• PD-L1 expression and one of the following:
	  • both of the following:
	  • inadequate response or adverse reaction to one or containdication to all platinum-containing regimens; **and**
	  • requested agent will be used as monotherapy; **or**
	  • both of the following:
	  • member does not have EGFR or ALK genomic tumor aberrations; **and**
	  • requested agent will be used as monotherapy in the first-line setting.
	Keytruda for primary mediastinal B-cell lymphoma (PMBCL)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to two or contraindication to all systemic chemotherapies.
	Keytruda for advanced RCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • tumor is clear cell histology and one of the following:
	  • requested agent will be used in combination with Inlyta (axitinib); **or**
	  • requested agent will be used in combination with Lenvima (lenvatinib); **or**
	  • requested agent will be used as adjuvant treatment following nephrectomy; **or**
	  • tumor is non-clear cell histology and inadequate response or adverse reaction to one of the following, or contraindication to both of the following: Cabometyx (cabozantinib), sunitinib.
	Keytruda for metastatic squamous cell carcinoma of the esophagus (ESCC)

	Clinical Notes

	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • tumor expresses PD-L1 (CPS ≥ 10); **and**
	  • inadequate response or adverse reaction to one or contraindication to all other lines of systemic therapy.
	Keytruda and Libtayo for metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is ≥ 18 years of age; **and**
	  • member is not a candidate for surgery and/or radiation therapy.
	Keytruda for tumor mutational burden-high (TMB-H) cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • tumor has ≥ 10 mutations/megabase.
	Keytruda for unresectable locally advanced or metastatic triple-negative breast cancer (TNBC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member is PD-L1 positive (CPS ≥ 10); **and**
	  • requested agent will be used in combination with one of the following: paclitaxel protein-bound, paclitaxel, or gemcitabine plus carboplatin.
	Keytruda for locally advanced or metastatic UC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • requested agent will be used as monotherapy and an inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens; **or**

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	• requested agent will be used in combination with Padcev (enfortumab vedotin-ejfv). **Libtayo for basal cell carcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all hedgehog pathway inhibitors. **Libtayo for NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • member has locally advanced cancer and is not a candidate for surgical resection or definitive chemoradiation; **or** • member has metastatic disease; **and** • member does not have EGFR, ALK, or ROS1 tumor aberrations; **and** • one of the following: • requested agent will be used in combination with platinum-based regimen; **or** • requested agent will be used as monotherapy in the first-line setting and the tumor has PD-L1 expession ≥ 50%. **Loqtorzi** • Documentation of the following is required: • diagnosis of nasopharyngeal carcinoma (NPC); **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member is ≥ 18 years of age; **and** • one of the following: • cancer is metastatic or recurrent, locally advanced NPC, and requested agent will be used as first-line treatment in combination with cisplatin and gemcitabine; **or** • all of the following: • cancer is recurrent unresectable or metastatic NPC; **and** • disease progression during or following a platinum-containing chemotherapy regimen; **and** • requested agent will be used as monotherapy.

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	Opdivo for RCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • tumor is clear cell histology and requested agent will be used in combination with Yervoy (ipilimumab); **or**
	  • tumor is clear cell histology and requested agent will be used in combination with Cabometyx (cabozantinib); **or**
	  • tumor is clear cell histology and member has received prior anti-angiogenic therapy and requested agent will be used as monotherapy; **or**
	  • tumor is non-clear cell histology and inadequate response or adverse reaction to one of the following, or contraindication to both of the following: Cabometyx (cabozantinib), sunitinib.
	Opdivo for completely resected esophageal or gastroesophageal junction (GEJ) cancer
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member has residual pathologic disease; **and**
	  • member has received neoadjuvant chemoradiotherapy (CRT).
	Opdivo for advanced or metastatic gastric cancer, GEJ cancer or esophageal adenocarcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • cancer is HER-2 negative; **and**
	  • requested agent is to be used in combination with a fluoropyrimidine- and platinum-containing regimen.
	Opdivo for HCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with Yervoy (ipilimumab); **and**

	Clinical Notes
	• inadequate response, adverse reaction, or contraindication to sorafenib. **Opdivo for recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens. **Opdivo for MPM** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with Yervoy (ipilimumab). **Opdivo for MSI-H/dMMR mCRC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: fluoropyrimidine-containing regimen, irinotecan-containing regimen, oxaliplatin-containing regimen. **Opdivo for resectable NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in the neoadjuvant setting in combination with one of the following: • carboplatin and paclitaxel; **or** • cisplatin and gemcitabine; **or** • cisplatin and paclitaxel; **or** • cisplatin and pemetrexed. **Opdivo for unresectable or metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • inadequate response or adverse reaction to one or

	Clinical Notes
	contraindication to all platinum-containing regimens; **or** • requested agent will be used in combination with ipilimumab and either: pemetrexed and carboplatin, pemetrexed and cisplatin, or paclitaxel and carboplatin; **or** • tumor has PD-L1 expression ≥ 1% and the requested agent is used in combination with ipilimumab. **Opdivo for unresectable advanced, recurrent, or metastatic squamous cell carcinoma of the esophagus (ESCC)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • member has received prior fluoropyrimidine-based and platinum-based regimen; **or** • requested agent will be used in combination with a fluoropyrimidine- and platinum-based regimen in the first-line setting; **or** • requested agent will be used in combination with Yervoy (ipilimumab) in the first-line setting. **Opdivo for UC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • member with locally advanced or metastatic UC who has disease progression during or following one a platinum-containing regimen; **or** • requested agent will be used as adjuvant treatment for members at high risk of recurrence following radical resection of UC; **or** • requested agent will be used in unresectable or metastatic UC as first-line treatment in combination with cisplatin and gemcitabine. **Tecentriq for extensive-stage (ES) SCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has extensive stage disease; **and** • requested agent will be used in combination with

	Clinical Notes

	carboplatin and etoposide.
	Tecentriq for hepatocellular carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with bevacizumab; **and**
	  • member has Child-Pugh Class A.
	Tecentriq for stage II to IIIA NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • tumor has PD-L1 expression ≥ 1%; **and**
	  • requested agent will be used as adjuvant treatment following complete resection and platinum-based regimen.
	Tecentriq for unresectable or metastatic alveolar soft part sarcoma (ASPS)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing.
	Tecentriq for unresectable or metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • inadequate response or adverse reaction to one or contraindication to all platinum-containing regimens; **or**
	  • first-line setting for nonsquamous NSCLC and requested agent will be used in combination with all of the following: Avastin (bevacizumab), carboplatin, paclitaxel; **or**
	  • tumor has PD-L1 expression ≥ 50%; **or**
	  • first-line setting for nonsquamous NSCLC and requested agent will be used in combination with both of the following: albumin-bound paclitaxel and carboplatin.
	Tecentriq for unresectable or metastatic melanoma
	• Documentation of the following is required:

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	• appropriate diagnosis; **and**
	• prescriber is an oncologist; **and**
	• appropriate dosing; **and**
	• positive BRAF V600E or V600K mutation; **and**
	• documentation that the requested agent will be used in combination with Cotellic (cobimetinib) and Zelboraf (vemurafenib); **and**
	• inadequate response or adverse reaction to one of the following or contraindication to all of the following:
	  • Tafinlar (dabrafenib) + Mekinist (trametinib); **or**
	  • Cotellic (cobimetinib) + Zelboraf (vemurafenib); **or**
	  • Braftovi (encorafenib) + Mektovi (binimetinib).

Histone Deacetylase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

belinostat	Beleodaq	PA	MB	IV	**Beleodaq for peripheral T-cell lymphoma (PTCL)**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response or adverse reaction to one or contraindication to all second-line treatment options.
					Istodax (romidepsin lyophilized) and romidepsin non-lyophilized for cutaneous T-cell lymphoma (CTCL)
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist, hematologist, or dermatologist; **and**
					  • appropriate dosing.
					Istodax (romidepsin lyophilized) and romidepsin non-lyophilized for PTCL
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response or adverse reaction to one or contraindication to all second-line treatment options.

romidepsin lyophilized	Istodax	PA	MB	IV	
romidepsin non-lyophilized		PA	MB	IV	
vorinostat	Zolinza			PO	

Antibody-Drug Conjugates

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

ado-trastuzumab	Kadcyla	PA	MB	IV	**Besponsa**
					• Documentation of the following is required:
					  • diagnosis of ALL; **and**
					  • member is ≥ one year of age; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • one of the following:
					  • both of the following:
					  • Philadelphia chromosome-positive; **and**
					  • inadequate response or adverse reaction to one tyrosine kinase inhibitor for the treatment of ALL; **or**
					  • all of the following:
					  • Philadelphia chromosome-negative; **and**
					  • B-cell precursor ALL; **and**
					  • prior therapy for the treatment of ALL with one systemic therapy.
					Blenrep
					• Documentation of the following is required:
					  • diagnosis of multiple myeloma; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • member has received at least four prior chemotherapy regimens or contraindication to the use of recommended chemotherapy regimens; **and**
					  • inadequate response or adverse reaction to one or contraindication to all of the following proteasome inhibitors: bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade (bortezomib); **and**
					  • inadequate response or adverse reaction to one or contraindication to all of the following immunomodulatory agents: Pomalyst (pomalidomide), Revlimid (lenalidomide), Thalomid (thalidomide); **and**
					  • inadequate response or adverse reaction to one or contraindication to all of the following anti-CD38 monoclonal antibodies: Darzalex (daratumumab), Darzalex Faspro (daratumumab-hyaluronidase-fihj), Sarclisa (isatuximab-irfc).
					Elahere
					• Documentation of the following is required:
					  • diagnosis of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer; **and**
					  • prescriber is an oncologist; **and**

belantamab mafodotin-blmf	Blenrep	PA		IV	
fam-trastuzumab deruxtecan-nxki	Enhertu	PA	MB	IV	
gemtuzumab ozogamicin	Mylotarg	PA	MB	IV	
inotuzumab ozogamicin	Besponsa	PA	MB	IV	
mirvetuximab soravtansine-gynx	Elahere	PA	MB	IV	
tisotumab vedotin-tftv	Tivdak	PA	MB	IV	

	Clinical Notes
	• appropriate dosing; **and** • member is folate receptor-alpha positive; **and** • inadequate response or adverse reaction to at least one systemic therapy, or contraindication to all systemic therapies for the requested indication. **Enhertu for locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one trastuzumab-based regimen. **Enhertu for unresectable or metastatic HER2-positive breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one anti-HER2-based regimen. **Enhertu for unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one prior chemotherapy regimen. **Enhertu for unresectable or metastatic NSCLC with activating HER2 (ERBB2) mutations** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one prior systemic therapy. **Kadcyla** • Documentation of the following is required: • diagnosis of HER2-positive breast cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following:

	Clinical Notes
	• member has recurrent or metastatic breast cancer and an inadequate response or adverse reaction to trastuzumab and a taxane separately or in combination; **or** • member has early breast cancer and residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment. **Mylotarg for newly-diagnosed CD33-positive AML in adults and pediatric members one month of age and older** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ one month of age; **and** • prescriber is an oncologist or hematologist, or consult notes from an oncologist or hematologist are provided; **and** • appropriate dosing; **and** • one of the following: • requested agent will be used in combination with cytarabine and daunorubicin or fludarabine; **or** • member is ≥ 60 years of age; **or** • clinical rationale why combination therapy with cytarabine and daunorubicin or fludarabine is not appropriate. **Mylotarg for relapsed or refractory CD33-positive AML in adults and pediatric members two years of age and older** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ two years of age; **and** • prescriber is an oncologist or hematologist, or consult notes from an oncologist or hematologist are provided; **and** • appropriate dosing; **and** • one of the following: • relapsed or refractory AML; **or** • prior therapy for the treatment of AML with one systemic therapy. **Tivdak for recurrent or metastatic cervical cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member is ≥ 18 years of age; **and** • inadequate response, adverse reaction, or contraindication to one line of platinum-based

	Clinical Notes
	chemotherapy; **and** • if PD-L1, TMB-H, or MSI-H/dMMR positive, inadequate response, adverse reaction, or contraindication to Keytruda (pembrolizumab).

Bruton's Tyrosine Kinase Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
acalabrutinib	Calquence	PA		PO	**Brukinsa and Calquence for CLL or SLL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing. **Brukinsa and Calquence for MCL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • prior therapy with at least one systemic therapy. **Brukinsa for MZL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • prior therapy with at least one anti-CD20 monoclonal antibody-based regimen. **Brukinsa for Waldenstrom's macroglobulinemia (WM)** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing. **Calquence for MZL** • Documentation of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • prior therapy with at least one systemic therapy. **Imbruvica for cGVHD**
ibrutinib	Imbruvica	PA		PO	
pirtobrutinib	Jaypirca	PA		PO	
zanubrutinib	Brukinsa	PA		PO	

	Clinical Notes

	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ one year of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or contraindication to all systemic glucocorticoids.
	Imbruvica for CLL, SLL, and WM
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing.
	Imbruvica for central nervous system (CNS) lymphoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to a methotrexate-based regimen for the treatment of CNS lymphoma.
	Jaypirca
	• Documentation of the following is required:
	  • diagnosis of MCL; **and**
	  • member is ≥ 18 years of age; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • prior therapy for the treatment of MCL with at least two lines of systemic therapy, one of which is a Bruton's Tyrosine Kinase Inhibitor; **and**
	  • requested quantity is ≤ 2 units/day.

Topoisomerase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

etoposide capsule			A90	PO	**Etopophos**
					• Documentation of the following is required:
					  • diagnosis of small cell lung cancer or testicular cancer; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • member is ≥ 18 years of age; **and**
					  • appropriate dosing; **and**
					  • inadequate response, adverse reaction, or

etoposide injection			MB	IV	
etoposide phosphate	Etopophos	PA	MB	IV	
irinotecan	Camptosar		MB	IV	
irinotecan liposome	Onivyde	PA	MB	IV	
sacituzumab	Trodelvy	PA	MB	IV	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
govitecan-hziy					contraindication to an etoposide product available without PA. **Onivyde** • Documentation of the following is required: • diagnosis of metastatic adenocarcinoma of the pancreas; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • member is ≥ 18 years of age; **and** • one of the following: • requested agent will be used in combination with fluorouracil, leucovorin, and oxaliplatin; **or** • both of the following: • requested agent will be used in combination with fluorouracil and leucovorin; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: a fluoropyrimidine-based chemotherapy regimen, a gemcitabine-based chemotherapy regimen. **Trodelvy for HR-positive, HER2-negative unresectable locally advanced or metastatic breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all endocrine-based therapies; **and** • inadequate response or adverse reaction to at least two prior non-endocrine-based systemic therapies in the metastatic setting; **and** • if HER2 IHC 1+ or 2+/ISH negative (HER2-low) breast cancer, inadequate response, adverse reaction, or contraindication to Enhertu. **Trodelvy for unresectable locally advanced or metastatic triple negative breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to at least two prior systemic therapies, at least one for metastatic disease. **Trodelvy for locally advanced or metastatic urothelial**
topotecan capsule	Hycamtin			PO	
topotecan injection	Hycamtin		MB	IV	

	Clinical Notes
	cancer • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to both of the following: a platinum-containing regimen, a PD-1 or PD-L1 inhibitor.

Antiandrogens

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
abiraterone 125 mg	Yonsa	PA		PO	abiraterone 250 mg, 500 mg • Documentation of the following is required: • diagnosis of metastatic high-risk castration-sensitive prostate cancer or metastatic castration-resistant prostate cancer (mCRPC); **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with prednisone; **and** • for the 500 mg tablet, medical necessity for use instead of the 250 mg tablet; **and** • one of the following: • requested agent will be used in combination with a gonadotropin-releasing hormone (GnRH) analog; **or** • member had a bilateral orchiectomy. Erleada for metastatic castration-sensitive prostate cancer (mCSPC) • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to abiraterone; **and** • one of the following: • requested agent will be used in combination with a GnRH analog; **or** • member had a bilateral orchiectomy. Erleada for non-metastatic castration-resistant prostate cancer (NM-CRPC) • Documentation of the following is required: • appropriate diagnosis; **and**
abiraterone 250 mg, 500 mg	Zytiga	PA	A90	PO	
apalutamide	Erleada	PA		PO	
bicalutamide	Casodex		# , A90	PO	
darolutamide	Nubeqa	PA		PO	
enzalutamide	Xtandi	PA		PO	
nilutamide			A90	PO	

	Clinical Notes

	• prescriber is an oncologist or urologist; **and**
	• appropriate dosing; **and**
	• inadequate response, adverse reaction, or contraindication to Xtandi (enzalutamide); **and**
	• one of the following:
	  • requested agent will be used in combination with a GnRH analog; **or**
	  • member had a bilateral orchiectomy.
	Nubeqa for NM-CRPC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or urologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to Xtandi (enzalutamide); **and**
	  • one of the following:
	  • requested agent will be used in combination with a GnRH analog; **or**
	  • member had a bilateral orchiectomy.
	Nubeqa for metastatic hormone-sensitive prostate cancer (mHSPC) or mCSPC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or urologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with docetaxel; **and**
	  • one of the following:
	  • requested agent will be used in combination with a GnRH analog; **or**
	  • member had a bilateral orchiectomy.
	Nubeqa for M1 mCRPC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • if no prior docetaxel or no novel hormone therapy, inadequate response, adverse reaction, or contraindication to all of the following: abiraterone, docetaxel, and enzalutamide; **or**
	  • if prior docetaxel but no prior novel hormone therapy, inadequate response, adverse reaction, or contraindication to both of the following: abiraterone and enzalutamide; **or**

	Clinical Notes
	• if prior novel hormone therapy but no prior docetaxel, inadequate response, adverse reaction, or contraindication to docetaxel; **or** • if prior docetaxel and prior novel hormone therapy, inadequate response, adverse reaction, or contraindication to cabazitaxel. **Xtandi for mCSPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to abiraterone; **and** • one of the following: • requested agent will be used in combination with a GnRH analog; **or** • member had a bilateral orchiectomy. **Xtandi for mCRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • requested agent will be used in combination with a GnRH analog; **or** • member had a bilateral orchiectomy; **and** • one of the following: • requested agent will be used as monotherapy; **or** • requested agent will be used in combination with Talzenna (talazoparib). **Xtandi for NM-CRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or urologist; **and** • appropriate dosing; **and** • one of the following: • requested agent will be used in combination with a GnRH analog; **or** • member had a bilateral orchiectomy. **Xtandi for NM-CSPC with high risk biochemical recurrence (BCR)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or urologist; **and**

					Clinical Notes
					• appropriate dosing. **Yonsa** • Documentation of the following is required: • diagnosis of mCRPC; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with methylprednisolone; **and** • one of the following: • requested agent will be used in combination with a GnRH analog; **or** • member had a bilateral orchiectomy.

Antibiotics

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
bleomycin			MB	IV / IM / SC	**Jelmyto** • Documentation of the following is required: • diagnosis of low-grade upper-tract urothelial cancer; **and** • prescriber is an oncologist or urologist; **and** • appropriate dosing. • For recertification, documentation that the member achieved a complete response three months after initiation is required.
dactinomycin	Cosmegen		MB	IV	
mitomycin injection			MB	IV	
mitomycin pyelocalyceal solution	Jelmyto	PA	MB	Intravesically	

DNA Methylation Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
azacitidine tablet	Onureg	PA		PO	**Onureg** • Documentation of the following is required: • diagnosis of AML; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • achievement of first complete remission (CR) following intensive induction chemotherapy; **or** • complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy; **and** • member is not able to complete intensive curative therapy; **and** • requested quantity is ≤ 14 units/28 days.
azacitidine vial	Vidaza		MB	IV / SC	
decitabine	Dacogen		MB	IV	
decitabine / cedazuridine	Inqovi			PO	

Hedgehog Pathway Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

glasdegib	Daurismo	PA		PO	**Daurismo for acute myeloid leukemia (AML)**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with low dose cytarabine; **and**
					  • one of the following:
					  • member is ≥ 75 years of age; **or**
					  • member is ≥ 60 years of age and one of the following:
					  • member is not a candidate for intensive induction chemotherapy; **or**
					  • member has significant comorbidities that preclude the use of intensive induction chemotherapy.
					Erivedge for metastatic or locally advanced basal cell carcinoma (BCC)
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • requested quantity is ≤ one unit/day; **and**
					  • member is ≥ 18 years of age; **and**
					  • one of the following:
					  • member has persistent or recurring basal cell carcinoma following surgery and/or radiation therapy; **or**
					  • member is not a candidate for surgery or radiation therapy.
					Odomzo for locally advanced basal cell carcinoma (BCC)
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist or hematologist; **and**
					  • requested quantity is ≤ one unit/day; **and**
					  • member is ≥ 18 years of age; **and**
					  • one of the following:
					  • member has persistent or recurring basal cell carcinoma following surgery and/or radiation therapy; **or**
					  • member is not a candidate for surgery or radiation

sonidegib	Odomzo	PA		PO	
vismodegib	Erivedge	PA		PO	

	Clinical Notes
	therapy.

CD123-Directed Cytotoxins

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
tagraxofusp-erzs	Elzonris	PA	MB	IV	Elzonris • Documentation of the following is required: • diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN); and • prescriber is an oncologist or hematologist; and • appropriate dosing; and • first infusion will take place in an inpatient setting, and subsequent infusions may take place in an outpatient setting with appropriate monitoring.

Selective Estrogen Receptor Modulator (SERM)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
toremifene	Fareston		# , A90	PO	

Estrogen Receptor Antagonists

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
elacestrant	Orserdu	PA		PO	fulvestrant • Documentation of the following is required: • diagnosis of HR-positive advanced or metastatic breast cancer; and • prescriber is an oncologist; and • appropriate dosing; and • one of the following: • member is HER2-positive and one of the following: • requested agent will be use as monotherapy; or • requested agent will be used in combination with trastuzumab; or • member is HER2-negative and one of the following: • requested agent will be used as monotherapy; or • requested agent will be used in combination with a CDK inhibitor (abemaciclib, palbociclib, or ribociclib); or • requested agent will be used in combination with anastrozole or letrozole. Orserdu • Documentation of the following is required:
fulvestrant	Faslodex	PA	MB	IM	

	Clinical Notes

	• diagnosis of ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer; **and**
	• prescriber is an oncologist; **and**
	• appropriate dosing; **and**
	• inadequate response or adverse reaction to one line of endocrine therapy containing a CDK4/6 inhibitor; **and**
	• one of the following:
	  • for Orserdu 86 mg tablets, requested quantity is ≤ three units/day; **or**
	  • for Orserdu 345 mg tablets, requested quantity is ≤ one unit/day.

CTLA-4 Blocking Monoclonal Antibodies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

ipilimumab	Yervoy	PA	MB	IV	**Imjudo for metastatic NSCLC**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with Imfinzi (durvalumab) and platinum-based regimen; **and**
					  • member does not have EGFR or ALK genomic tumor aberrations; **and**
					  • requested quantity is ≤ five doses.
					Imjudo for unresectable hepatocellular carcinoma
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with Imfinzi (durvalumab); **and**
					  • requested quantity is one dose.
					Yervoy for hepatocellular carcinoma
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • requested agent will be used in combination with Opdivo (nivolumab); **and**
					  • inadequate response, adverse reaction, or contraindication to sorafenib.
					Yervoy for malignant pleural mesothelioma (MPM)

tremelimumab-actl	Imjudo	PA	MB	IV	

	Clinical Notes

	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with Opdivo (nivolumab).
	Yervoy for metastatic NSCLC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • PD-L1 expression ≥ 1% and requested agent will be used in combination with Opdivo (nivolumab); **or**
	  • requested agent will be used in combination with Opdivo (nivolumab) and two cycles of platinum doublet chemotherapy.
	Yervoy for microsatellitle instability-high (MSI-H)/mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC)
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: fluoropyrimidine-based therapy, irinotecan-based therapy, oxaliplatin-based therapy.
	Yervoy for renal cell carcinoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • member has clear cell histology; **and**
	  • requested agent will be used in combination with Opdivo (nivolumab).
	Yervoy for unresectable advanced or metastatic ESCC
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • requested agent will be used in combination with Opdivo (nivolumab) in the first-line setting.

	Clinical Notes

	Yervoy for unresectable or metastatic melanoma
	• Documentation of the following is required:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • inadequate response or adverse reaction to one or contraindication to both of the following: Keytruda (pembrolizumab), Opdivo (nivolumab); **or**
	  • for treatment of unresectable or metastatic melanoma, requested agent will be used in combination with Opdivo (nivolumab) or Keytruda (pembrolizumab).

Antineoplastic Combination

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

daunorubicin / cytarabine	Vyxeos	PA	MB	IV	**Kisqali-Femara Co-Pack**
					• Documentation of the following is required:
					  • diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing.
					Lonsurf for metastatic colorectal cancer
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response or adverse reaction to at least one or contraindication to all of the following regimens: CAPEOX, FOLFOX, FOLFIRI, FOLFOXIRI, irinotecan-based therapy, oxaliplatin-based therapy; **and**
					  • if BRAF/KRAS/NRAS wild-type cancer is present, inadequate response or adverse reaction to one or contraindication to both of the following: Erbitux (cetuximab), Vectibix (panitumumab).
					Lonsurf for metastatic gastric or GEJ adenocarcinoma
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • inadequate response or adverse reaction to two prior lines of chemotherapy containing one of the following

pertuzumab / trastuzumab / hyaluronidase-zzxf	Phesgo	PA	MB	SC	
ribociclib / letrozole	Kisqali-Femara Co-Pack	PA		PO	
trifluridine / tipiracil	Lonsurf	PA		PO	

	Clinical Notes
	or contraindication to all appropriate chemotherapy and HER2/neu-targeted therapy: fluoropyrimidine-based therapy, platinum-based therapy, either a taxane - or irinotecan-based therapy, and if appropriate, HER2/neu-targeted therapy. **Phesgo** • Documentation of the following is required: • diagnosis of HER2-positive breast cancer; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • for early breast cancer, requested agent will be used in combination with chemotherapy; **or** • for metastatic breast cancer, requested agent will be used in combination with docetaxel. **Vyxeos** • Documentation of the following is required: • diagnosis of newly diagnosed therapy-related AML or AML with myelodysplasia-related changes (AML-MRC); **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • member is ≥ one year of age; **and** • inadequate response, adverse reaction, or contraindication to use of separate daunorubicin and cytarabine chemotherapy agents.

KRAS Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
adagrasib	Krazati	PA		PO	**Krazati and Lumakras for advanced or mCRC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has KRAS G12C mutation; **and** • inadequate response or adverse reaction to one or contraindication to all platinum-based chemotherapy; **and** • one of the following: • for Krazati, requested quantity is ≤ six units/day; **or** • for Lumakras 120 mg tablet, requested quantity is ≤ eight units/day; **or** • for Lumakras 320 mg tablet, requested quantity is ≤
sotorasib	Lumakras	PA		PO	

	Clinical Notes
	three units/day. **Krazati and Lumakras for metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has KRAS G12C mutation; **and** • inadequate response or adverse reaction to one or contraindication to all first-line systemic therapies; **and** • one of the following: • for Krazati, requested quantity is ≤ six units/day; **or** • for Lumakras 120 mg tablet, requested quantity is ≤ eight units/day; **or** • for Lumakras 320 mg tablet, requested quantity is ≤ three units/day.

Proteasome Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
bortezomib	Velcade		MB	IV / SC	**Kyprolis** • Documentation of the following is required for monotherapy: • diagnosis of multiple myeloma; **and** • appropriate dosing; **and** • prescriber is an oncologist or hematologist; **and** • inadequate response or adverse reaction to at least one prior chemotherapy regimen for the requested indication. • Documentation of the following is required for combination therapy: • diagnosis of multiple myeloma; **and** • appropriate dosing; **and** • prescriber is an oncologist or hematologist; **and** • inadequate response or adverse reaction to at least one prior chemotherapy regimen for the requested indication; **and** • requested agent will be used in combination with dexamethasone with or without additional agents for the treatment of multiple myeloma (excluding proteasome inhibitors). **Ninlaro** • Documentation of the following is required: • diagnosis of multiple myeloma; **and**
bortezomib			MB	IV	
carfilzomib	Kyprolis	PA	MB	IV	
ixazomib	Ninlaro	PA		PO	

	Clinical Notes
	• appropriate dosing; **and** • prescriber is an oncologist or hematologist; **and** • inadequate response or adverse reaction to at least one prior chemotherapy regimen for the requested indication; **and** • requested agent will be used in combination with dexamethasone with or without additional agents for the treatment of multiple myeloma (excluding proteasome inhibitors); **and** • requested quantity is ≤ three capsules/28 days.

Poly-Adenosine Diphosphate Ribose Polymerase (PARP) Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
niraparib	Zejula	PA		PO	**Lynparza for BRCA-mutated breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has deleterious or suspected deleterious gBRCAm; **and** • member has completed neoadjuvant or adjuvant chemotherapy; **and** • requested quantity is ≤ four units/day. **Lynparza for BRCA-mutated mCRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has a deleterious or suspected deleterious germline or somatic mutation in BRCA1 or BRCA2; **and** • requested agent will be used in combination with both of the following: • abiraterone; **and** • prednisone or prednisolone; **and** • requested quantity is ≤ four units/day. **Lynparza for homologous recombination repair (HRR) gene -mutated mCRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has deleterious or suspected deleterious
olaparib	Lynparza	PA		PO	
rucaparib	Rubraca	PA		PO	
talazoparib	Talzenna	PA		PO	

	Clinical Notes
	germline or somatic HRR gene mutation; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: Xtandi (enzalutamide), Yonsa (abiraterone), Zytiga (abiraterone); **and** • requested quantity is ≤ four units/day. **Lynparza for advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer** • For first-line maintenance therapy as monotherapy, documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has deleterious or suspected deleterious gBRCAm or sBRCAm cancer; **and** • member has achieved a partial or complete response to first-line platinum-based chemotherapy; **and** • requested quantity is ≤ four units/day. • For first-line maintenance therapy as combination therapy, documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • one of the following: • cancer has a deleterious germline or somatic mutation in BRCA1 or BRCA2; **or** • cancer is homologous recombination deficiency (HRD) positive status; **and** • member has achieved a partial or complete response to first-line platinum-based chemotherapy; **and** • requested agent will be used in combination with bevacizumab; **and** • requested quantity is ≤ four units/day. • For recurrent disease, documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member achieved a partial or complete response to platinum-based chemotherapy; **and** • requested quantity is ≤ four units/day. **Lynparza for metastatic pancreatic adenocarcinoma (first-line maintenance therapy)** • Documentation of the following is required:

	Clinical Notes
	• appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has deleterious or suspected deleterious gBRCAm; **and** • member has disease which has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen; **and** • requested quantity is ≤ four units/day. **Rubraca for BRCA-mutated mCRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has deleterious gBRCAm or sBRCAm; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: Xtandi (enzalutamide), Yonsa (abiraterone), Zytiga (abiraterone); **and** • inadequate response, adverse reaction, or contraindication to taxane-based chemotherapy; **and** • requested quantity is ≤ four units/day. **Rubraca for advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (maintenance therapy)** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has deleterious gBRCAm or sBRCAm cancer; **and** • member has achieved a partial or complete response to platinum-based chemotherapy; **and** • requested quantity is ≤ four units/day. **Talzenna for locally advanced or metastatic breast cancer** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer has deleterious or suspected deleterious gBRCAm; **and** • one of the following: • for the 0.5 mg, 0.75 mg, or 1 mg capsule, requested quantity is ≤ one unit/day; **or**

	Clinical Notes
	• for the 0.25 mg capsule, requested quantity is ≤ three units/day. **Talzenna for HRR gene-mutated mCRPC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • requested agent will be used in combination with enzalutamide; **and** • requested quantity is ≤ one unit/day. **Zejula for advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer** • For first-line maintenance therapy, documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has achieved a partial or complete response to platinum-based chemotherapy; **and** • requested quantity is ≤ one unit/day. • For maintenance therapy, documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • member has deleterious or suspected deleterious gBRCAm cancer; **and** • member has achieved a partial or complete response to platinum-based chemotherapy; **and** • requested quantity is ≤ one unit/day.

Gamma Secretase Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
nirogacestat	Ogsiveo	PA		PO	**Ogsiveo** • Documentation of the following is required: • diagnosis of one of the following: • desmoid tumor; **or** • aggressive fibromatosis; **and** • member is ≥ 18 years of age; **and** • prescriber is an oncologist or sarcoma specialist; **and** • appropriate dosing; **and** • tumor progression; **and** • inadequate response, adverse reaction, or

	Clinical Notes
	contraindication to sorafenib; **and** • requested quantity is ≤ two units/day.

LAG-3/PD-1 Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
nivolumab / relatlimab-rmbw	Opdualag	PA	MB	IV	Opdualag • Documentation of the following is required: • diagnosis of unresectable or metastatic melanoma; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: • Opdivo (nivolumab) in combination with Yervoy (ipilimumab); **or** • Opdivo (nivolumab); **or** • Keytruda (pembrolizumab); **and** • one of the following: • member is negative for the BRAF V600E or V600K mutation; **or** • member is positive for the BRAF V600E or V600K mutation and inadequate response or adverse reaction to one or contraindication to all of the following: • Braftovi (encorafenib) and Mektovi (binimetinib); **or** • Tafinlar (dabrafenib) and Mekinist (trametinib); **or** • Zelboraf (vemurafenib) and Cotellic (cobimetinib).

Nectin-4 Directed Antibody

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
enfortumab vedotin-ejfv	Padcev	PA	MB	IV	Padcev • Documentation of the following is required: • diagnosis of locally advanced or metastatic urothelial cancer; **and** • prescriber is an oncologist or consult notes from an oncologist are provided; **and** • appropriate dosing; **and** • one of the following: • all of the following:

	Clinical Notes
	• inadequate response or adverse reaction to a platinum-based chemotherapy; **and** • inadequate response or adverse reaction to a PD-1 inhibitor or PD-L1 inhibitor therapy; **and** • requested agent will be used as monotherapy; **or** • all of the following: • contraindication to all cisplatin-containing chemotherapy; **and** • member has received at least one prior line of therapy for requested indication; **and** • requested agent will be used as monotherapy; **or** • both of the following: • contraindication to all cisplatin-containing chemotherapy; **and** • requested agent will be used in combination with Keytruda.

Immunomodulator/Immunosuppressant

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
lenalidomide	Revlimid	PA	BP, A90	PO	**Pomalyst for multiple myeloma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to both of the following: lenalidomide, Thalomid (thalidomide); **and** • inadequate response or adverse reaction to one or contraindication to all of the following proteasome inhibitors: bortezomib, Kyprolis (carfilzomib), Ninlaro (ixazomib), Velcade (bortezomib). **Pomalyst for Kaposi sarcoma** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist or hematologist; **and** • appropriate dosing; **and** • one of the following: • member has acquired immunodeficiency syndrome (AIDS) and has failed highly active antiretroviral therapy; **or** • member is human immunodeficiency virus (HIV)-negative; **and** • inadequate response, adverse reaction, or
pomalidomide	Pomalyst	PA		PO	
thalidomide	Thalomid		BP	PO	

	Clinical Notes

	contraindication to both of the following: pegylated liposomal doxorubicin, paclitaxel.
	lenalidomide
	• Documentation of the following is required for FL, MZL, myelodysplastic syndrome, or mantle cell lymphoma (MCL):
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • for the 2.5 mg, 5 mg, or 10 mg strength, requested quantity is ≤ one unit/day; **or**
	  • for the 15 mg, 20 mg, or 25 mg strength, requested quantity is ≤ 21 capsules for a 28 day supply; **and**
	  • for previously untreated MZL, clinical rationale for use instead of one of the following:
	  • bendamustine + rituximab; **or**
	  • rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (RCHOP); **or**
	  • rituximab, cyclophosphamide, vincristine, and prednisone (RCVP); **or**
	  • rituximab; **and**
	  • for treatment of FL or MZL, the requested agent will be used in combination with rituximab.
	• Documentation of the following is required for multiple myeloma:
	  • appropriate diagnosis; **and**
	  • prescriber is an oncologist or hematologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • for the 2.5 mg, 5 mg, or 10 mg strength, requested quantity is ≤ one unit/day; **or**
	  • for the 15 mg strength, one of the following:
	  • requested quantity is ≤ 21 capsules/28 day supply; **or**
	  • requested quantity is ≤ one unit/day and inadequate response to 10 mg daily; **or**
	  • for the 20 mg or 25 mg strength, requested quantity is ≤ 21 capsules/28 day supply.
	SmartPA: Claims within quantity limits for lenalidomide will usually process at the pharmacy without a PA request if the member has a MassHealth history of medical claims for multiple myeloma. †

Tropomyosin Receptor Kinase (TRK) Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
entrectinib	Rozlytrek	PA		PO	**Rozlytrek for solid tumors with neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • for Rozlytrek oral pellet, medical necessity for the use of the oral pellet formulation instead of the oral capsule compounded into a suspension; **and** • one of the following: • tumor is metastatic; **or** • member is not a candidate for surgical resection; **and** • one of the following: • for the 50 mg oral pellet, requested quantity is ≤ 12 units/day; **or** • for the 100 mg capsule, requested quantity is ≤ one unit/day; **or** • for the 200 mg capsule, requested quantity is ≤ three units/day; **and** • one of the following: • requested agent is first-line for the requested indication; **or** • member has no satisfactory alternative treatment options; **or** • disease has progressed following at least one first-line treatment for the requested indication (e.g., chemotherapy, radiation, surgical intervention). **Rozlytrek for ROS1-positive metastatic NSCLC** • Documentation of the following is required: • appropriate diagnosis; **and** • prescriber is an oncologist; **and** • appropriate dosing; **and** • cancer is ROS1 positive; **and** • for Rozlytrek oral pellet, medical necessity for the use of the oral pellet formulation instead of the oral capsule compounded into a suspension; **and** • one of the following: • for the 50 mg oral pellet, requested quantity is ≤ 12 units/day; **or** • for the 100 mg capsule, requested quantity is ≤ one unit/day; **or** • for the 200 mg capsule, requested quantity is ≤ three units/day.
larotrectinib	Vitrakvi	PA		PO	

	Clinical Notes

	Vitrakvi
	• Documentation of the following is required:
	  • diagnosis of solid tumors with NTRK gene fusion without a known acquired resistance mutation; **and**
	  • prescriber is an oncologist; **and**
	  • appropriate dosing; **and**
	  • one of the following:
	  • tumor is metastatic; **or**
	  • member is not a candidate for surgical resection; **and**
	  • one of the following:
	  • requested agent is first-line for the requested indication; **or**
	  • member has no satisfactory alternative treatment options; **or**
	  • disease has progressed following at least one first-line treatment for the requested indication (e.g., chemotherapy, radiation, surgical intervention); **and**
	  • one of the following:
	  • for the 100 mg capsule, requested quantity is ≤ two units/day; **or**
	  • for the 25 mg capsule, requested quantity is ≤ six units/day; **or**
	  • for the oral solution, requested quantity is ≤ ten mL/day; **and**
	  • if the request is for oral solution formulation, medical necessity for the use of an oral solution formulation (e.g., swallowing disorder) must be provided.
	MassHealth Drug Utilization Review will be reaching out to prescribers after Vitrakvi PA approval to verify clinical effectiveness.

Multiple Receptor Antibodies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes

amivantamab-vmjw	Rybrevant	PA	MB	IV	**Rybrevant for advanced or metastatic non-small cell lung cancer**
					• Documentation of the following is required:
					  • appropriate diagnosis; **and**
					  • prescriber is an oncologist; **and**
					  • appropriate dosing; **and**
					  • cancer has EGFR exon 20 insertion mutation; **and**
					  • one of the following:
					  • requested agent will be used as monotherapy and

	Clinical Notes
	disease progression during or following one platinum-containing regimen; **or** • requested agent will be used in combination with carboplatin and pemetrexed.

Antiestrogen

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
tamoxifen solution	Soltamox			PO	
tamoxifen tablet			M90	PO	

Retinoids

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
bexarotene	Targretin		BP, A90	PO / Topical	
tretinoin capsule			A90	PO	

Anthracenediones

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
mitoxantrone			MB	IV	

Vinca Alkaloid

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Route of Administration	Clinical Notes
vinblastine			MB	IV	
vincristine			MB	IV	
vinorelbine				IV	

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

M90 Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Cancer

Non-**FDA-approved, for example:**

- Cancer

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Please see clinical criteria for agents requiring PA in the table above under the Clinical Notes section.

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 58 - Anticoagulants and Antiplatelet Agents

Drug Category: Blood and Circulation

Medication Class/Individual Agents: Anticoagulants and Antiplatelet Agents

I. Prior-Authorization Requirements

Platelet Aggregation Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
anagrelide	Agrylin		# , A90
aspirin / extended-release dipyridamole			M90
cilostazol			A90
clopidogrel	Plavix		# , A90
dipyridamole			M90
prasugrel	Effient		# , A90
ticagrelor	Brilinta		
vorapaxar	Zontivity	PA	

Intravenous/Subcutaneous Anticoagulants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dalteparin	Fragmin		
enoxaparin	Lovenox		#
fondaparinux	Arixtra		#
heparin			
heparin lock flush			

Oral Anticoagulants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
apixaban	Eliquis		
dabigatran capsule	Pradaxa		BP, M90
dabigatran oral pellet	Pradaxa	PA	
edoxaban	Savaysa	PA	
rivaroxaban 10 mg, 15 mg, 20 mg tablet, starter pack	Xarelto		
rivaroxaban 2.5 mg tablet	Xarelto	PA - > 2 units/day	
rivaroxaban suspension	Xarelto	PA - ≥ 18 years	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Antiplatelet Agents:

- Antiplatelet agents play a major role in the management of cardiovascular (CV), cerebrovascular, and peripheral vascular diseases. The recommendation for use of these agents as monotherapy or combination therapy depends on the specific clinical indication and the member's risk for thromboembolic events and/or bleeding events.
- Vorapaxar is the first in a new class of antiplatelet agents called protease-activated receptor-1 (PAR-1) antagonists. This drug is FDA approved for the reduction of thrombotic cardiovascular events in members with a history of myocardial infarction or with peripheral arterial disease. Vorapaxar has been studied only as an addition to aspirin and/or clopidogrel. There is no experience with the use of vorapaxar administered as monotherapy.

Anticoagulant Agents:

- There are several oral and injectable anticoagulants commercially available for the management of a variety of medical conditions. The oral anticoagulants include apixaban, dabigatran, edoxaban, rivaroxaban, and warfarin.

Oral Anticoagulants			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
warfarin			A90

Salicylates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aspirin 325 mg, 500 mg, 650 mg			*, A90
aspirin 81 mg			*, M90
aspirin suppository			*
aspirin with buffers			*, A90

Clinical Notes

- Warfarin is a vitamin K antagonist that works by interfering with the synthesis of vitamin K dependent clotting factors (II, VII, IX, and X) as well as the anticoagulant proteins C and S. It is dosed once daily. Due to its narrow therapeutic window and various food and drug interactions, it requires frequent monitoring of international normalized ratios (INR) to monitor for safety and efficacy. Warfarin does not require dosage adjustments in members with renal impairment.
- The direct oral anticoagulants (DOACs) target a single enzyme involved in the coagulation cascade. Dabigatran is a prodrug that is converted to dabigatran, a potent, competitive inhibitor of thrombin. Apixaban, edoxaban and rivaroxaban all selectively inhibit factor Xa, thereby preventing the generation of thrombin and ultimately preventing platelet activation and the formation of fibrin clots. These agents require dose adjustments in members with renal impairment. When used for non-valvular atrial fibrillation, apixaban may be used in severe renal impairment, including members on hemodialysis.
- Edoxaban and rivaroxaban are both approved for once-daily dosing (with the exception of the first 21 days for treatment of a deep vein thrombosis [DVT] or pulmonary embolism [PE] with rivaroxaban) whereas dabigatran and apixaban are both administered twice daily. In addition, these DOACs are not associated with the same food and drug interactions as with warfarin treatment. Available antidotes are currently FDA-approved for apixaban, dabigatran, rivaroxaban, and warfarin.

#	This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Myocardial infarction (Zontivity)

- Nonvalvular atrial fibrillation (Savaysa)
- Peripheral artery disease (PAD) (Zontivity)
- Reduction of risk of major CV events in chronic coronary artery disease (CAD)/PAD (Xarelto 2.5 mg)
- Treatment of DVT and/or PE (Savaysa)
- Treatment or reduction of risk of recurrent DVT and/or PE in pediatric members (Pradaxa oral pellet)

non FDA-approved, for example:

- Nonvalvular atrial fibrillation (Xarelto suspension)
- Reduction of risk of major thrombotic vascular events in CAD/PAD (Xarelto suspension)
- Treatment or reduction of risk of recurrent DVT and/or PE (Xarelto suspension)

Note: The above lists may not include all FDA-approved and non FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Pradaxa oral pellet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ three months of age and < 12 years of age; **and**
  - member has received or will receive ≥ five days of injectable or intravenous anticoagulation prior to starting the requested agent; **and**
  - inadequate response, adverse drug reaction, or contraindication to one of the following: Xarelto oral suspension, Xarelto tablets **and**
  - appropriate dosing; **and**
  - if the member is ≥ eight years of age, one of the following:
    - inadequate response, adverse drug reaction, or contraindication to dabigatran capsule; **or**
    - medical necessity for the requested formulation instead of the capsule formulation available without PA.

Savaysa

- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- appropriate dosing; **and**
- inadequate response, adverse drug reaction, or contraindication to all of the following: Eliquis, dabigatran capsule, and Xarelto.

Xarelto 2.5 mg tablet over quantity limits

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for exceeding FDA recommended dosing.

Xarelto suspension for members ≥ 18 years of age

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the suspension formulation as noted by one of the following:
    - member utilizes tube feeding (NG or gastric tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **and**
  - appropriate dosing.

Zontivity

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested quantity is ≤ one tablet/day; **and**
  - member does not have a history of stroke, transient ischemic attack, or intracranial hemorrhage; **and**
  - requested agent will be used in combination with one of the following: aspirin, clopidogrel.

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 59 - Anesthetics - Topical

Drug Category: Dermatological Agents

Medication Class/Individual Agents: Local Anesthetics

I. Prior-Authorization Requirements

Topical Anesthetics – Ophthalmic Topical Anesthetics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
chloroprocaine ophthalmic gel	Iheezo	PA	
fluorescein / benoxinate			A90
lidocaine ophthalmic gel	Akten		
proparacaine			A90
tetracaine			A90

Topical Anesthetics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
capsaicin high dose patch	Qutenza	PA	MB
chloroprocaine injection	Clorotekal		MB
chloroprocaine vial	Nesacaine		MB
lidocaine / prilocaine			A90
lidocaine 1.8% patch	Ztlido	PA	
lidocaine 4% patch		PA - > 4 patches/day	A90
lidocaine 5% patch	Lidoderm	PA - > 3 patches/day	# , A90
lidocaine ointment			A90
lidocaine topical jelly, solution			
lidocaine viscous solution			

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Lidocaine/prilocaine is indicated as a topical anesthetic on normal intact skin for local analgesia and on genital mucous membranes for superficial minor surgery and pre -treatment for infiltration anesthesia.
- Lidocaine/prilocaine may have improved dermal analgesia compared to other topical lidocaine products due to its eutectic mixture formulation. However, this agent is indicated only as short term anesthesia and should not be used chronically.

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA

status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Dermatological procedure requiring local analgesia (lidocaine/prilocaine)
- Neurologic pain condition (lidocaine 4% patch)
- Ocular surface anesthesia (Iheezo)
- Pain associated with diabetic peripheral neuropathy (Qutenza)
- Pain associated with post-herpetic neuralgia (lidocaine 5% patch, Qutenza, Ztlido)
- Surface anesthesia and temporary pain relief (lidocaine ointment)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Iheezo

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an ophthalmologist or consult notes from an ophthalmologist are provided; **and**
  - inadequate response or adverse reaction to one, or contraindication to all of the following: Akten, fluorescein/benoxinate, proparacaine, tetracaine.

lidocaine 4% patch > four patches/day

- Documentation of all the following is required:
  - appropriate diagnosis; **and**

- medical necessity for the use of > four patches/day.

lidocaine 5% patch > three patches/day

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the use of > three patches/day.

lidocaine 5 % ointment, lidocaine/prilocaine

- Available without PA. However, requests for members with a diagnosis code for premature ejaculation will deny at the pharmacy as PA required.
- Please note: The MassHealth agency does not pay for any drug when used for the treatment of sexual dysfunction as described in 130 CMR 406.413(B) "Limitations on Coverage of Drugs – Drug Exclusions" (see link below).

https://www.mass.gov/regulations/130-CMR-406000-pharmacy-services

Qutenza for diabetic peripheral neuropathy

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: topical capsaicin agent, lidocaine patch; **and**
  - one of the following:
    - medical necessity for transdermal formulation as noted by one of the following:
      - member utilizes tube feeding (G-tube/J-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - member is < 13 years of age; **or**
    - inadequate response, adverse reaction, or contraindication to all of the following classes of oral agents:
      - tricyclic antidepressant; **and**
      - anticonvulsant (gabapentin at a dose of at least 1,200 mg/day for two weeks, or pregabalin); **and**
      - venlafaxine or duloxetine.

Qutenza for post-herpetic neuralgia

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: topical capsaicin agent, lidocaine patch; **and**
  - one of the following:
    - medical necessity for transdermal formulation as noted by one of the following:
      - member utilizes tube feeding (G-tube/J-tube); **or**
      - member has a swallowing disorder or condition affecting ability to swallow; **or**
      - member is < 13 years of age; **or**
    - inadequate response, adverse reaction, or contraindication to both of the following classes of oral agents:
      - tricyclic antidepressant; **and**
      - anticonvulsant (gabapentin at a dose of at least 1,200 mg/day for two weeks, or pregabalin).

Ztlido

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to both of the following: 4% lidocaine patch, 5% lidocaine patch; **and**
  - one of the following:
    - requested quantity is ≤ three patches/day; **or**

- medical necessity for > three patches/day.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 60 - Hereditary Angioedema Agents

Drug Category: Complement Inhibitors

Medication Class/Individual Agents: Hereditary Angioedema Agents

I. Prior-Authorization Requirements

Hereditary Angioedema Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
berotralstat	Orladeyo	PA	
c1 esterase inhibitor, human-Berinert	Berinert	PA	
c1 esterase inhibitor, human-Cinryze	Cinryze	PA	
c1 esterase inhibitor, human-Haegarda	Haegarda	PA	
c1 esterase inhibitor, recombinant-Ruconest	Ruconest	PA	
ecallantide	Kalbitor	PA	MB
icatibant	Firazyr	PA	
lanadelumab-flyo	Takhzyro	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Berotralstat, Cinryze (c1 esterase inhibitor, human), Haegarda (c1 esterase inhibitor, human), and lanadelumab-flyo are approved for the routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema (HAE). Cinryze (c1 esterase inhibitor, human) and Haegarda (c1 esterase inhibitor, human) are also approved in children six years of age and older.
  - Prophylaxis may be administered short-term in anticipation of a procedure or period of stress, or long-term for the reduction of attack rates. Long-term prophylaxis should be considered based upon multiple parameters, including attack frequency, comorbidities, patient preferences, access to emergency care.[1]
- Berinert (c1 esterase inhibitor, human), ecallantide, icatibant, and Ruconest (c1 esterase inhibitor, recombinant) are all FDA approved for the acute attacks of HAE.
- Berinert (c1 esterase inhibitor, human), Cinryze (c1 esterase inhibitor, human), Haegarda (c1 esterase inhibitor, human), icatibant, lanadelumab-flyo, and Ruconest (c1 esterase inhibitor, recombinant) are approved for patient self-administration after training by a health care professional.

	Clinical Notes
	• Ecallantide is not approved for self- administration and should only be administered by a doctor or nurse with medical support to manage serious allergic reactions and HAE. [1]Farkas, H, Zuraw B. Hereditary angioedema (due to C1 inhibitor deficiency): General care and long-term prophylaxis. In Saini S (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2022 [cited 2022 March 4]. Available from: http://www.utdol.com/utd/index.do.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Treatment of acute attacks of hereditary angioedema (HAE) (Berinert, icatibant, Kalbitor, Ruconest)
- Prophylaxis against angioedema attacks in patients with HAE (Cinryze, Haegarda, Orladeyo, Takhyzro)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate

and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Berinert, icatibant, Kalbitor, Ruconest

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an allergist or immunologist or consult notes from an allergist or immunologist regarding the diagnosis are provided; **and**
  - appropriate dosing.
- For recertification, documentation of the use or expiration of a previously approved product is required.

Cinryze, Haegarda, Orladeyo, Takhzyro

- Documentation of all the following is required:
  - appropriate diagnosis; **and**
  - prescriber is an allergist or immunologist or consult notes from an allergist or immunologist regarding the diagnosis are provided; **and**
  - one of the following:
    - member has > one HAE event/30 days; **or**
    - member has a history of recurrent laryngeal attacks; **and**
  - appropriate dosing.

MassHealth Evaluation Criteria

Table 61 - Gastrointestinal Drugs – Antidiarrheals, Constipation, and Miscellaneous Gastrointestinal Agents

Drug Category: Gastrointestinal

Medication Class/Individual Agents: Antidiarrheals, Antispasmodics, Bile Acid Agents, Bowel Preparations, Constipation Agents

I. Prior-Authorization Requirements

Gastrointestinal Drugs – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
bezlotoxumab	Zinplava	PA	
bifidobacterium infantis	Align	PA - ≥ 21 years	
fecal microbiota spores, live-brpk	Vowst	PA	
fecal microbiota, live-jslm	Rebyota	PA	
lactobacillus rhamnosus GG	Culturelle	PA - ≥ 21 years	
saccharomyces boulardii	Florastor	PA - ≥ 21 years	
teduglutide injection	Gattex	PA	BP

Gastrointestinal Drugs – Constipation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aluminum hydroxide			*, A90
bisacodyl enema, suppository			*, A90
bisacodyl tablet			*, M90
calcium polycarbophil			*, M90
dextrin			*, A90
docusate / benzocaine enema	Enemeez Plus		A90
docusate sodium capsule, tablet			*, M90
docusate sodium enema	Enemeez		A90
docusate sodium solution, syrup			*, A90
lactulose packet		PA	
lactulose solution			A90
linaclotide	Linzess		
lubiprostone	Amitiza	PA	M90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Alosetron

- Alosetron is a selective 5-HT3 receptor antagonist used to treat irritable bowel syndrome (IBS).
- Due to the risk of serious gastrointestinal complications, providers prescribing alosetron must be enrolled in Lotronex Prescribing Program and document a signed physician-patient agreement.

Opium tincture

- Opium tincture is not recommended for use in children and caution is recommended for use in the elderly.

Bowel Preparation Agents

- All preparations are considered equally efficacious; however, certain products may have the advantage of reduced side effects or lower fluid requirements.

Gastrointestinal Drugs – Constipation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
magnesium salts			*, A90
methylcellulose			*, A90
methylnaltrexone	Relistor	PA	
mineral oil			*, A90
naldemedine	Symproic	PA	
naloxegol	Movantik	PA	
plecanatide	Trulance	PA	
polyethylene glycol 3350			*, A90
prucalopride	Motegrity	PA	
psyllium capsule			*, M90
psyllium powder			*, A90
sennosides syrup			*, A90
sennosides tablet			*, M90
tenapanor 50 mg tablet	Ibsrela	PA	

Gastrointestinal Drugs – Antispasmodics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dicyclomine	Bentyl		# , A90
hyoscyamine oral			A90

Gastrointestinal Drugs – Bile Acid Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
chenodiol		PA	A90
cholic acid	Cholbam	PA	
maralixibat	Livmarli	PA	
obeticholic acid	Ocaliva	PA	
odevixibat	Bylvay	PA	
ursodiol 200 mg, 400 mg capsule		PA	A90
ursodiol 250 mg tablet	Urso		# , A90
ursodiol 300 mg capsule			A90
ursodiol 500 mg tablet	Urso Forte		# , A90

Gastrointestinal Drugs – Bowel Preparation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
polyethylene glycol / sodium sulfate /	Suflave	PA	

Gastrointestinal Drugs – Bowel Preparation Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
potassium chloride / magnesium sulfate / sodium chloride			
polyethylene glycol-electrolyte solution			A90
polyethylene glycol-electrolyte solution-Golytely	Golytely		# , A90
polyethylene glycol-electrolyte solution-Moviprep	Moviprep		BP, A90
polyethylene glycol-electrolyte solution-Plenvu	Plenvu		
sodium phosphate	Osmoprep		
sodium picosulfate / magnesium oxide / anhydrous citric acid-Clenpiq	Clenpiq	PA	
sodium sulfate / magnesium sulfate / potassium chloride	Sutab	PA	
sodium sulfate / potassium sulfate / magnesium sulfate	Suprep		BP, A90

Gastrointestinal Drugs – Antidiarrhea Medications			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alosetron	Lotronex	PA	A90
bismuth subsalicylate			*, A90
crofelemer	Mytesi	PA	
difenoxin / atropine	Motofen	PA	
diphenoxylate / atropine	Lomotil		#
eluxadoline	Viberzi	PA	
loperamide			*
opium tincture		PA	

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Alagille syndrome (Bylvay, Livmarli)
- Bile acid synthesis disorders due to single enzyme defects with or without familial hypertriglyceridemia (Cholbam)
- Bowel preparation prior to colonoscopy procedure or surgery (Clenpiq, Suflave, Sutab)
- Chronic idiopathic constipation (lactulose packet, lubiprostone, Motegrity, Trulance)
- Gallstones (chenodiol, ursodiol)
- IBS with constipation (Ibsrela, lactulose packet, lubiprostone, Trulance)
- Opioid-induced constipation in adults with chronic, non-cancer pain (lubiprostone, Movantik, Relistor, Symproic)
- Opioid-induced constipation in palliative care members (lactulose packet, Relistor)
- Peroxisomal disorders with or without familial hypertriglyceridemia (Cholbam)
- Prevention of gallstone formation (ursodiol)
- Prevention of recurrent Clostridium difficile infection (Rebyota, Vowst)
- Primary biliary cholangitis (Ocaliva)
- Progressive familial intrahepatic cholestasis (Bylvay)
- Severe and chronic diarrhea-predominant IBS (alosetron, Viberzi)
- Short bowel syndrome (Gattex)
- Symptomatic relief of non-infectious diarrhea in adult members with HIV/AIDS on anti-retroviral therapy (Mytesi)
- Treatment of chronic diarrhea (Motofen, opium tincture)
- Recurrent Clostridium difficile infection (Zinplava)

Non-FDA-approved, for example:

- Cerebrotendinous xanthomatosis (chenodiol)
- Hepatic encephalopathy (lactulose packet)
- Pediatric requests for chronic idiopathic constipation or irritable bowel syndrome with constipation (lubiprostone)

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month,

per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Align, Culturelle, Florastor ≥ 21 years of age
- Documentation of the following is required for the diagnosis of antibiotic associated diarrhea (prophylaxis):
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to two or contraindication to all of the following: alosetron, bismuth subsalicylate, diphenoxylate/atropine, loperamide; **and**
  - current antibiotic therapy.
- Documentation of the following is required for the diagnosis of bacterial overgrowth:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to one of the following: amoxicillin-clavulanic acid, ciprofloxacin, doxycycline, metronidazole, neomycin, tetracycline, trimethoprim-sulfamethoxazole, rifaximin.
- Documentation of the following is required for the diagnosis of chronic constipation:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to three or contraindication to all of the following: docusate, fiber supplementation/bulk-forming laxatives, lubiprostone or Linzess or Motegrity or Trulance, osmotic laxatives, saline laxatives, stimulant laxatives.
- Documentation of the following is required for the diagnosis of C. difficile associated diarrhea:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to one or contraindication to all of the following: fidaxomicin, metronidazole, rifaximin, oral vancomycin.
- Documentation of the following is required for the diagnosis of irritable bowel syndrome associated with constipation (IBS-C):
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to two or contraindication to all of the following: docusate, fiber supplementation/bulk-forming laxatives, lubiprostone or Linzess or Trulance, osmotic laxatives, saline laxatives, stimulant laxatives.
- Documentation of the following is required for the diagnosis of irritable bowel syndrome associated with diarrhea (IBS-D):
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to two or contraindication to all of the following: antibiotic (rifaximin), anti-diarrheal, antispasmodic, bile acid sequestrant, tricyclic antidepressant (TCA).
- Documentation of the following is required for the diagnosis of recurrent vaginitis:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ seven days of therapy) or adverse reaction within the last 90 days to two or contraindication to all of the following: butoconazole, clindamycin, clotrimazole, fluconazole, metronidazole, miconazole, terconazole.

alosetron
- Documentation of the following is required:
  - appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- prescriber is a gastroenterologist or consultation notes from a gastroenterologist are provided; **and**
- appropriate dosing (0.5 mg twice daily initial, up to 1 mg twice daily maintenance); **and**
- inadequate response or adverse reaction to three or contraindication to all of the following: bile acid sequestrant, bismuth subsalicylate, bulk-forming agent, diphenoxylate/atropine, loperamide, TCAs.

Bylvay

- Documentation of the following is required for diagnosis of progressive familial intrahepatic cholestatis (PFIC):
  - appropriate diagnosis; **and**
  - genetic testing does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of BSEP-3; **and**
  - member is ≥ three months of age; **and**
  - presence of moderate to severe pruritus; **and**
  - no evidence of portal hypertension or decompensated cirrhosis; **and**
  - no history of liver transplant; **and**
  - no history of biliary diversion surgery within the past six months; **and**
  - inadequate response, adverse reaction, or contraindication to ursodiol 30 mg/kg/day; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: cholestyramine 4 g/day, rifampin 10 mg/kg/day; **and**
  - member's current weight; **and**
  - appropriate dosing.

- Documentation of the following is required for diagnosis of Alagille syndrome:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - genetic testing documenting JAG1 or NOTCH2 deletion or genetic testing confirming mutation in GAA gene; **and**
  - member has moderate to severe pruritus caused by cholestasis; **and**
  - prescriber is a specialist (hepatologist, gastroenterologist, or Alagille syndrome specialist) or consult notes from a specialist are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: bile acid sequestrant, naltrexone, rifampin, sertraline, ursodiol; **and**
  - inadequate response, adverse reaction, or contraindication to Livmarli; **and**
  - member's current weight; **and**
  - appropriate dosing.

chenodiol

- Documentation of the following is required for a diagnosis of cerebrotendinous xanthomatosis (CTX):
  - appropriate diagnosis; **and**
  - results of molecular genetic testing confirming the diagnosis of cerebrotendinous xanthomatosis; **and**
  - appropriate dosing or documentation that the member is stable on a lower or higher dose; **and**
  - member’s current weight.

- Documentation of the following is required for a diagnosis of gallstones:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to an ursodiol product; **and**
  - member's current weight.

Cholbam

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- member is ≥ three weeks of age; **and**
- member's current weight.

Clenpiq, Suflave, Sutab

- Documentation of the following is required:
  - one of the following:
    - inadequate response or adverse reaction to one bowel prep product available without PA; **or**
    - medical necessity for the requested product.

Gattex

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - dependence on parenteral nutrition or intravenous fluids for at least one year; **and**
  - appropriate dosing.

Ibsrela

- Documentation of the following is required for diagnosis of IBS with constipation
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ two units/day; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - inadequate response, adverse reaction, or contraindication to lubiprostone; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Linzess and Trulance.

lactulose packet

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction or contraindication to lactulose solution.

Livmarli

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ three months of age; **and**
  - genetic testing documenting JAG1 or NOTCH2 deletion or genetic testing confirming mutation in GAA gene; **and**
  - member has moderate to severe pruritus caused by cholestasis; **and**
  - prescriber is a specialist (hepatologist, gastroenterologist, or Alagille syndrome specialist) or consult notes from a specialist are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: bile acid sequestrant, naltrexone, rifampin, sertraline, ursodiol; **and**
  - member's current weight; **and**
  - appropriate dosing.

lubiprostone

- Documentation of the following is required for members ≥ 18 years of age:
  - appropriate diagnosis; **and**

- inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
- for a diagnosis of IBS with constipation or chronic idiopathic constipation, inadequate response or adverse reaction to one or contraindication to both of the following: Linzess and Trulance; **and**
- appropriate dosing.

- Documentation of the following is required for members ≥ three years of age and <18 years of age:
  - diagnosis of chronic idiopathic constipation or irritable bowel syndrome with constipation; **and**
  - prescriber is a specialist in gastroenterology; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - appropriate dosing.

Motegrity, Movantik, Symproic

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one unit/day; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - inadequate response, adverse reaction, or contraindication to lubiprostone; **and**
  - for Motegrity, inadequate response or adverse reaction to one or contraindication to both of the following: Linzess and Trulance; **and**
  - for a compounded formulation of Motegrity, appropriate dosing.

Motofen

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to diphenoxylate/atropine; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: bismuth subsalicylate and loperamide.

Mytesi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: bismuth subsalicylate, diphenoxylate/atropine, loperamide; **and**
  - requested quantity is ≤ two units/day.

Non-preferred Probiotics

- Documentation of the following is required:
  - Diagnosis of one of the following:
    - antibiotic associated diarrhea (prophylaxis); **or**
    - bacterial overgrowth; **or**
    - chronic constipation; **or**
    - C. difficile associated diarrhea; **or**
    - irritable bowel syndrome with constipation; **or**

- irritable bowel syndrome with diarrhea; **or**
- recurrent vaginitis; **and**

- member must meet all criteria as written above for the listed diagnosis; **and**
- inadequate response, adverse reaction, or contraindication to all of the following: Align, Culturelle, Florastor.

Ocaliva

- Documentation of the following is required:
  - appropriate diagnosis of primary biliary cholangitis supported by laboratory testing results and medical records documenting two of the following:
    - alkaline phosphatase elevation; **or**
    - presence of antimitochondrial antibody; **or**
    - histopathologic evidence of cholangitis and destruction of small or medium-sized bile ducts on biopsy, if performed; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - alkaline phosphatase > upper limit of normal; **or**
    - total bilirubin > upper limit of normal; **and**
  - one of the following:
    - inadequate response to ursodiol at a dose of 13 to 15 mg/kg/day for at least one year and request is for use with ursodiol 13 to 15 mg/kg/day; **or**
    - adverse reaction or contraindication to ursodiol; **and**
  - one of the following:
    - member does not have cirrhosis; **or**
    - member has compensated cirrhosis without evidence of portal hypertension; **and**
  - requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - request is for initiation of treatment and requested dose is 5 mg once daily; **or**
    - request is for continuation of treatment beyond three months and both of the following:
      - if request is for continuation of treatment beyond 12 months, one of the following:
        - if alkaline phosphatase was > upper limit of normal at baseline, alkaline phosphatase < 1.67-times upper limit of normal; **or**
        - ≥ 15% decrease in alkaline phosphatase; **or**
        - if total bilirubin was > upper limit of normal at baseline, total bilirubin ≤ upper limit of normal; **or**
        - clinical rationale for continued treatment; **and**
      - one of the following:
        - requested dose is 10 mg once daily; **or**
        - requested dose and/or frequency is ≤ 10 mg once daily and one of the following:
          - positive response to therapy at current dose (defined as alkaline phosphatase < 1.67-times upper limit of normal, total bilirubin ≤ upper limit of normal, and ≥ 15% decrease in alkaline phosphatase); **or**
          - clinical rationale for not titrating the dose to 10 mg once daily.

opium tincture

- Documentation of the following is required:
  - diagnosis of chronic diarrhea; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: bismuth subsalicylate, diphenoxylate/atropine, loperamide.

Rebyota

- Documentation of the following is required:
  - diagnosis for prevention of recurrent Clostridium difficile infection with ≥ two episodes of Clostridium difficile infection following initial infection (≥ three total episodes of CD including initial infection); **and**
  - prescriber is an infectious disease specialist or gastroenterologist or consult notes from a specialist are provided; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction or contraindication to Zinplava; **and**
  - medical necessity for requested agent instead of fecal microbiota transplant via other methods (e.g., IND protocol, stool banks); **and**
  - requested quantity is ≤ single dose.

Relistor
- Documentation of the following is required for diagnosis of opioid induced constipation with advanced illness receiving palliative care:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes(bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - for the injection formulation, medical necessity for the requested formulation instead of tablet formulation.
- Documentation of the following is required for diagnosis of opioid induced constipation with chronic non-cancer pain:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes(bulk-forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Movantik and Symproic; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Linzess and lubiprostone; **and**
  - for the injection formulation, medical necessity for the requested formulation instead of tablet formulation.

Trulance
- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ one unit/day; **and**
  - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **and**
  - inadequate response, adverse reaction, or contraindication to Linzess.

ursodiol 200 mg, 400 mg
- Documentation of the following is required for the diagnosis of gallstones:
  - appropriate diagnosis; **and**
  - member is not a candidate for cholecystectomy; **and**
  - medical necessity for the requested agent instead of an ursodiol product available without PA; **and**
  - member's current weight.
- Documentation of the following is required for the prevention of gallstone formation:
  - appropriate diagnosis; **and**
  - medical necessity for the requested agent instead of an ursodiol product available without PA.

Viberzi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a gastroenterologist or provides consult notes from a gastroenterologist; **and**
  - requested quantity is ≤ two units/day; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: bile acid sequestrant, bismuth subsalicylate, bulk-forming agent, diphenoxylate/atropine, loperamide, TCAs.

Vowst

- Documentation of the following is required:
  - diagnosis for prevention of recurrent Clostridium difficile infection with ≥ two episodes of Clostridium difficile infection following initial infection (≥ three total episodes of CD including initial infection); **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is an infectious disease specialist or gastroenterologist or consult notes from a specialist are provided; **and**
  - inadequate response, adverse reaction, or contraindication to Zinplava; **and**
  - medical necessity for requested agent instead of fecal microbiota transplant via other methods (IND protocol, stool banks); **and**
  - requested quantity is ≤ 12 capsules for one course of therapy.

Zinplava

- Documentation of the following is required:
  - diagnosis of recurrent Clostridium difficile infection with ≥ 1 episode of Clostridium difficile infection following initial infection; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - requested quantity is ≤ a single dose; **and**
  - requested medication will be used in combination with an antibiotic being used for the treatment of Clostridium difficile infection including at least one of the following: fidaxomicin, metronidazole, rifaximin, or vancomycin.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 62 - Gout Agents

Drug Category: Gout Agents

Medication Class/Individual Agents: Gout Agents

I. Prior-Authorization Requirements

Anti-Gout Agents				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
allopurinol 100 mg, 300 mg tablet	Zyloprim		# , M90	**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** **allopurinol:** • This agent can be started during an acute attack if appropriate anti-inflammatory prophylaxis has been started or after the acute flare has resolved. • If a patient is already being treated with allopurinol, the agent should not be discontinued during an acute attack. • Serum urate levels begin to fall within two days of allopurinol administration and reach stable levels in one to two weeks. • The therapeutic goal of urate lowering therapy is to promote urate dissolution and prevent crystal formation. This is achieved by maintaining the serum urate level at ≤ 6 mg/dL. **colchicine capsule, solution:** • FDA approved for prophylaxis of gout flares in adults. **colchicine tablet:** • FDA approved for treatment of acute gout flares in adults, prophylaxis of gout flares in adults, and treatment of Familial Mediterranean Fever. • The FDA approved dosing for acute gout is: 1.2 mg orally at the first sign of a flare followed by 0.6 mg one hour later; maximum dose is 1.8 mg over 1 hour (3
allopurinol 200 mg tablet		PA	M90	
colchicine capsule	Mitigare	PA	BP, A90	
colchicine solution	Gloperba	PA		
colchicine tablet	Colcrys		# , A90	
febuxostat	Uloric	PA	M90	
pegloticase	Krystexxa	PA	MB	
probenecid			M90	
probenecid / colchicine			M90	

	Clinical Notes
	tablets per acute attack). **febuxostat:** • A xanthine oxidase inhibitor but unlike allopurinol, it is not a purine-based analogue. • Elimination occurs through hepatic metabolism and renal dose adjustment is unnecessary in patients with mild to moderate renal dysfunction. **pegloticase:** • A recombinant modified mammalian uricase enzyme indicated for the treatment of chronic gout in adults refractory to conventional therapy. • This agent is not recommended for the treatment of asymptomatic hyperuricemia. **probenecid:** • A uricosuric agent that promotes renal clearance of uric acid in the proximal tubule. • The agent is known to increases urinary calcium excretion in gout patients and should be avoided in patients with prior nephrolithiasis.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Gout (allopurinol 200 mg tablet, colchicine capsule, febuxostat, Gloperba, Krystexxa)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

allopurinol 200 mg tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - medical necessity for use of the requested agent instead of two allopurinol 100 mg tablets available without PA; **and**
  - medical records documenting inadequate response or adverse reaction to two allopurinol 100 mg tablets available without PA.

colchicine capsule

- Documentation of all of the following is required for gout prophylaxis in combination with urate lowering therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member will be initiated on a urate lowering treatment with allopurinol, febuxostat, or probenecid; **and**
  - clinical rationale for use of the requested agent instead of colchicine tablet.
- Documentation of all of the following is required for gout prophylaxis without urate lowering therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to allopurinol 600 mg/day for four weeks; **or**
    - adverse reaction or contraindication to allopurinol; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to febuxostat 80 mg/day, or 40 mg/day if creatinine clearance (CrCL) < 30 mL/min, for four weeks; **or**
    - adverse reaction or contraindication to febuxostat; **and**
  - clinical rationale for use of the requested agent instead of colchicine tablet.
- For recertification, documentation of a diagnosis of tophaceous gout is required.

febuxostat

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**

- member is ≥ 18 years of age; **and**
- one of the following:
  - inadequate response (defined by serum urate levels > 6.0 mg/dL) to allopurinol 600 mg/day for four weeks; **or**
  - adverse reaction or contraindication to allopurinol; **and**
- one of the following:
  - requested quantity is ≤ one tablet/day; **or**
  - medical necessity for exceeding quantity limit.

Gloperba

- Documentation of all of the following is required for gout prophylaxis in combination with urate lowering therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member will be initiated on a urate lowering treatment with allopurinol, febuxostat, or probenecid; **and**
  - medical necessity for the use of a solution formulation.
- Documentation of all of the following is required for gout prophylaxis without urate lowering therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to allopurinol 600 mg/day for four weeks; **or**
    - adverse reaction or contraindication to allopurinol; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to febuxostat 80 mg/day, or 40 mg/day if CrCL < 30 mL/min, for four weeks; **or**
    - adverse reaction or contraindication to febuxostat; **and**
  - medical necessity for the use of a solution formulation.
- For recertification, documentation of a diagnosis of tophaceous gout is required.

Krystexxa

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to allopurinol 600 mg/day for four weeks; **or**
    - adverse reaction or contraindication to allopurinol; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to febuxostat 80 mg/day, or 40 mg/day if CrCL < 30 mL/min, for four weeks; **or**
    - adverse reaction or contraindication to febuxostat; **and**
  - one of the following:
    - inadequate response (defined by serum urate levels > 6.0 mg/dL) to a uricosuric agent in combination with allopurinol or febuxostat for four weeks; **or**
    - adverse reaction or contraindication to a uricosuric agent.

MassHealth Evaluation Criteria

Table 63 - Dermatologic Agents - Topical Chemotherapy, Genital Wart Treatment, and Miscellaneous Dermatologic Agents

Drug Category: Dermatologic Agents

Medication Class/Individual Agents: Topical Chemotherapy, Genital Wart Treatment, and Miscellaneous Dermatologic Agents

I. Prior-Authorization Requirements

Dermatologic Agents – Actinic Keratosis			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aminolevulinic acid	Ameluz	PA	MB
aminolevulinic acid	Levulan	PA	MB
diclofenac 3% gel			A90
fluorouracil 0.5% cream	Carac		BP, A90

Dermatologic Agents – Genital Wart Treatment			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
podofilox gel	Condylox		BP, A90
podofilox solution			A90
sinecatechins	Veregen	PA	

Dermatologic Agents – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aluminum chloride	Drysol	PA	
cantharidin	Ycanth	PA	MB
doxepin cream-Prudoxin	Prudoxin	PA	
doxepin cream-Zonalon	Zonalon	PA	
glycopyrronium cloth	Qbrexza	PA	

Dermatologic Agents – Actinic Keratosis and Superficial Basal Cell Carcinoma			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fluorouracil 5% cream	Efudex		BP, A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Actinic keratosis:

- Treatment includes destructive therapies, topical medications, and photodynamic therapy.

Basal Cell Carcinoma:

- The NCCN guideline on Basal Cell and Squamous Cell Skin Cancers, recommends that in patients with low-risk, superficial basal cell skin cancer, where surgery or radiation is contraindicated or impractical, topical therapies such as fluorouracil, imiquimod, photodynamic therapy, or cryotherapy can be considered. The guideline does not specify any agent as preferred.[1]

Genital Warts:

- Treatment involves one of three major approaches: chemical or physical destruction, immunologic therapy, or surgical excision.
- The preferred approach depends upon the number and extent of the lesions.
- In general, no one treatment appears to be significantly more efficacious versus another.

Moderate pruritus:

- Doxepin cream is FDA-approved for the short-term (up

Dermatologic Agents – Actinic Keratosis and Superficial Basal Cell Carcinoma			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fluorouracil solution			A90

Dermatologic Agents – Actinic Keratosis and Genital Wart Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
imiquimod 2.5%, 3.75% cream	Zyclara	PA	BP, A90

Dermatologic Agents – Actinic Keratosis, Superficial Basal Cell Carcinoma and Genital Wart Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
imiquimod 5% cream			A90

Clinical Notes

to eight days) management of moderate pruritus in adults with atopic dermatitis or lichen simplex chronicus.

[1]NCCN Clinical Practice Guidelines in Oncology. Basal Cell Skin Cancer [guideline on the Internet]. 2017 Sept 18 [cited 2018 *May 30*]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Actinic keratosis (Ameluz, imiquimod 3.75% cream, Levulan, Zyclara)
- External genital/perianal warts (imiquimod 3.75% cream, Veregen)
- Hyperhydrosis (Drysol)
- Moderate-to-severe pruritus (doxepin cream)
- Molluscum contagiosum (Ycanth)
- Primary axillary hyperhidrosis (Qbrexza)

non-FDA approved, for example:

- Craniofacial hyperhidrosis (Qbrexza)

- Palmar or plantar hyperhidrosis (Qbrexza)

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Ameluz and Levulan

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: topical fluorouracil, topical imiquimod, cryosurgery; **and**
  - requested agent will be used in conjunction with photodynamic therapy; **and**
  - for Ameluz, inadequate response, adverse reaction, or contraindication to Levulan used in conjunction with photodynamic therapy.
- For recertification, medical necessity for use beyond 12 weeks.

doxepin cream

- Documentation of all of the following is required:
  - diagnosis of moderate-to-severe pruritus; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to three or contraindication to all of the following: capsaicin cream, lidocaine patch, one potent or superpotent topical corticosteroid, systemic therapy (antihistamines, SSRIs, SNRIs, anticonvulsants), topical calcineurin inhibitor (tacrolimus, pimecrolimus); **and**
  - one of the following:
    - requested quantity is ≤ 45 grams/30 days; **or**
    - all of the following:
      - requested quantity is > 45 grams/30 days; **and**

- adverse reaction or inadequate response to one systemic therapy; **and**
- medical necessity for exceeding the quantity limit.

Drysol
- Documentation of all of the following is required:
  - diagnosis of hyperhidrosis; **and**
  - inadequate response, adverse reaction, or contraindication to an OTC antiperspirant.

imiquimod 3.75% cream for External Genital/Perianal Warts
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to topical imiquimod 5% cream; **or**
    - medical necessity for use of imiquimod 3.75% instead of imiquimod 5%; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical podofilox, podophyllum resin applied by a provider.

imiquimod 3.75% cream and Zyclara for Actinic Keratosis
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response or adverse reaction to topical imiquimod 5% cream; **or**
    - medical necessity for use of imiquimod 2.5% or 3.75% instead of imiquimod 5%; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: topical fluorouracil solution, topical fluorouracil cream; **or**
    - medical necessity for use of the requested agent instead of topical fluorouracil.

Qbrexza
- Documentation of all of the following is required:
  - diagnosis of craniofacial hyperhidrosis, primary axillary hyperhidrosis, or palmar or plantar hyperhidrosis; **and**
  - member is ≥ nine years of age; **and**
  - inadequate response, adverse reaction, or contraindication to aluminum chloride solution; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to Botox; **or**
    - clinical rationale for use of the requested agent instead of Botox; **and**
  - requested quantity is ≤ one unit/day.

Veregen for External Genital/Perianal Warts
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical podofilox, podophyllum resin applied by a provider.

Ycanth
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:

    - itching, pain, or bleeding associated with lesions; **or**
    - member is immunocompromised; **or**
    - concomitant bacterial infection; **or**
    - risk of spread to contacts (i.e., siblings, daycare); **and**
- member is ≥ two years of age; **and**
- prescriber is a dermatologist or consult notes from a dermatologist are provided; **and**
- inadequate response or adverse reaction to one or contraindication to all of the following: cryotherapy, curettage, podofilox; **and**
- requested dose is ≤ eight applicators/12 weeks.

MassHealth Evaluation Criteria
Table 64 - Asthma/Allergy Monoclonal Antibodies

Drug Category: Respiratory Tract Agents

Medication Class/Individual Agents: Immunologic Agents

I. Prior-Authorization Requirements

Asthma/Allergy Monoclonal Antibodies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
benralizumab	Fasenra	PA	
dupilumab	Dupixent PD	PA	
mepolizumab	Nucala	PA	
omalizumab	Xolair	PA	
reslizumab	Cinqair	PA	MB
tezepelumab-ekko	Tezspire	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Benralizumab

- Benralizumab is a humanized monoclonal antibody (IgG1, κ-class) that directly binds to the alpha subunit of the human interleukin-5 receptor (IL-5Rα). It is indicated for the add-on maintenance treatment of members aged 12 years and older with severe asthma, and with an eosinophilic phenotype.
- This agent is initially administered under the care of a healthcare professional. Thereafter, this injectable medication can be self-administered using the autoinjector.
- Benralizumab is given subcutaneously (SC) at an initial dose of 30 mg every four weeks for three doses, then 30 mg every eight weeks.

Dupilumab

- Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin (IL)-4 and IL-13 signaling by binding to the IL-4Rα subunit for these complexes. Blocking IL-4Rα with dupilumab inhibits IL-4 and IL-13 cytokine-induced inflammatory responses, including the release of proinflammatory cytokines, chemokines, nitric oxide, and

	Clinical Notes

	immunoglobulin E (IgE); however, the exact mechanism of action for dupilumab in treating asthma has not been definitively identified.
	• It is indicated in :
	  • members aged six years and older with moderate-to-severe eosinophilic asthma as add-on maintenance therapy, oral corticosteroid (OC)-dependent asthma as add-on maintenance therapy;
	  • members aged six months and older with moderate-to-severe atopic dermatitis (AD) not controlled with topical therapies;
	  • add-on therapy in adults with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP);
	  • members one year and older, weighing at least 15 kg with eosinophilic esophagitis;
	  • adults with prurigo nodularis.
	• Dupilumab is initially administered under the care of a healthcare professional. Thereafter, this injectable medication can be self-administered.
	
	Omalizumab
	• Omalizumab is a recombinant monoclonal antibody that selectively binds to human immunoglobulin E (IgE).
	• It is indicated:
	  • for moderate-to-severe persistent asthma in members ≥ six years of age with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids (ICS);
	  • for chronic idiopathic urticaria in members ≥ 12 years of age who remain symptomatic despite histamine-1 (H1) antihistamine treatment;
	  • for add-on maintenance treatment of nasal polyps in adults with inadequate response to intranasal corticosteroids;
	  • for the reduction of allergic reactions (Type 1), including anaphylaxis, that may occur with accidental exposure to one or more foods in members one year of age and older with IgE-mediated food allergy.
	• Omalizumab carries a black-box warning highlighting the risk of anaphylaxis and thus should be administered by a healthcare professional initially for three doses before determining if individuals are appropriate for self-administration.

	Clinical Notes
	Mepolizumab • Mepolizumab is a humanized interleukin-5 (IL-5) antagonist monoclonal antibody indicated for add-on maintenance treatment of members aged six years and older with severe asthma, and with an eosinophilic phenotype. In addition, this agent is FDA-approved for the treatment of adults with eosinophilic granulomatosis with polyangiitis (EGPA) and for the treatment of adult and pediatric members aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ six months without an identifiable non-hematologic secondary cause, and most recently for add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adults with inadequate response to intranasal corticosteroids. • This medication is administered by SC injection every four weeks. • It is suggested that this agent be administered by a healthcare professional for anyone < 12 years of age. Members aged 12 years and older should initially receive their injection under the guidance of a healthcare professional. Following proper training, members can then self-inject using the prefilled autoinjector or prefilled syringe. **Reslizumab** • Reslizumab is another humanized IL-5 antagonist monoclonal antibody indicated for add-on maintenance treatment of adults aged 18 years and older with severe asthma, and with an eosinophilic phenotype. • This agent should be administered in a healthcare setting by a healthcare professional. • It is given via an intravenous infusion at a dosage of 3 mg/kg once every four weeks. • Reslizumab carries a black-box warning highlighting the risk of anaphylaxis. **Tezepelumab** • Tezepelumab is a first-in-class monoclonal antibody that blocks the action of thymic stromal lymphopoietin (TSLP). This agent is approved as add-on maintenance treatment of individuals 12 years of age and older with severe asthma. **Treatment Guidelines for the Management of Persistent**

	Clinical Notes
	Severe Asthma • The National Heart, Lung, and Blood Institute (NHLBI) guidelines recommend consideration of omalizumab as an adjunctive therapy in members five to 11 years of age with persistent asthma that is inadequately controlled with daily and as needed combination of low-to-medium dose ICS-formoterol. In addition, it recommends that members who are being considered for omalizumab therapy are referred to an asthma specialist.[1] • According to the 2014 International European Respiratory Society/American Thoracic Society (ERS/ATS) guidelines, persistent severe asthma afflicts five to ten percent of all asthma members.[2] It is important to differentiate these individuals based on their subgroups or phenotypes whenever possible. Eosinophilic asthma is one such subgroup of severe asthma. Members with severe asthma with an eosinophilic phenotype have both recurrent exacerbations and eosinophilic airway inflammation, which plays a significant part in airway remodeling, hyperresponsiveness, and mucus accumulation. • Currently, the Global Initiative for Asthma (GINA) guidelines recommend the use of ICS-formoterol as the preferred maintenance treatment for adults and adolescents ≥ 12 years of age. • GINA recommends the use of low-dose ICS for children ≤ 11 years of age. The addition of a leukotriene receptor agonist (LTRA) can be considered for some children. • For children six to 11 years of age inadequately controlled with low-dose ICS or low-dose ICS plus LTRA, consideration can be given to starting low-dose ICS-formoterol, increasing ICS to medium dose, or starting very low-dose ICS-formoterol. • GINA also recommends consideration for phenotypic assessment for potential add-on biologic (e.g., anti-IgE, anti-IL5/5R, or anti-IL4R therapy) in severe cases of asthma not adequately controlled on maintenance inhalers.[3] **Treatment Guidelines for the Management of Chronic Urticaria** • The European Academy of Allergy and Clinical Immunology/Global Allergy and Asthma European Network/European Dermatology Forum/World Allergy Organization (2009) and the American Academy of

	Clinical Notes
	Allergy, Asthma and Immunology (2014) recommend that omalizumab be considered in members with refractory chronic urticaria who have failed first-line treatment options.[4,5] **Treatment Guidelines for the Management of CRSwNP** • Current guidelines for management of CRSwNP highlight intranasal corticosteroids (INS) as the cornerstone of maintenance treatment. Nasal saline irrigations, shorts courses of oral corticosteroids, or leukotriene antagonists can be used as adjunctive therapy to INS. Sinus surgery is generally reserved for those who have failed to respond to medical therapy. The American Academy of Allergy, Asthma, & Immunology (AAAAI) 2020 have included dupilumab in their recommendation as a potential treatment option for CRSwNP but have yet to include the other FDA-approved agents.[6] The EPOS 2020 steering group advises to use dupilumab or mepolizumab in individuals with CRSwNP who have not improved despite other medical or surgical options. Data was not sufficient to advise on the use of anti-IgE in CRSwNP at the time of publication.[7] [1]National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group: 2020 Focused Updates to the Asthma Management Guidelines. National Heart Lung and Blood Institute. 2020 Dec [cited 2022 Mar 31]. Available from: https://www.nhlbi.nih.gov/health-topics/all-publications-and-resources/2020-focused-updates-asthma-management-guidelines. [2]Chung KF, Wenzel SE, Brozek JL, Bush A, Castro M, Sterk PJ, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. Feb 2014;43(2):343-73. [3]Global Strategy for Asthma Management and Prevention. [guideline on the internet]. Bethesda (MD): Global Initiative for Asthma (GINA); 2023 [cited 2024 Feb 22]. Available from: https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf. [4]Bernstein JA, Lang DM, Khan DA, Craig T, Dreyfus D, Hsieh F, et al. The diagnosis and management of acute and

	Clinical Notes
	chronic urticaria: 2014 update. J Allergy Clin Immunol. 2014;133(5):1270-7. [5]Zuberbier T, Aberer W, Asero R, Bindslev-Jensen C, Brzoza Z, Canonica GW, Church MK, Gimenez-Arnau AM, et al. EAACI/GA2LEN/EDF/WAO guideline for the definition, classification, diagnosis and management of urticaria: the 2013 revision and update. Allergy. 2018 Jul;73(7):1393-1414. [6]Dykewicz, MS, Wallace, DV, Amrol, DJ, Baroody, FM, Bernstein, JA, et al. Rhinitis 2020: A Practice parameter update. J Allerg Clinical Immun. 2020 Oct. 146(4):721-767. Available from:https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/Rhinitis-2020-A-practice-parameter-update.pdf. [7]Fokkens WJ, Lund VJ, Hopkins C, Hellings PW, Kern R, Reitsma S, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2020. 2020 Feb;58(29): 1-481. Available from: https://www.rhinologyjournal.com/Rhinology_issues/manuscript_2353.pdf.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Chronic idiopathic urticaria
- Eosinophilic granulomatosis with polyangiitis
- Hypereosinophilic syndrome
- IgE-mediated food allergy
- Moderate-to-severe allergy-related asthma
- Moderate-to-severe eosinophilic asthma
- Moderate-to-severe atopic dermatitis (AD)
- Nasal polyps
- Oral corticosteroid (OCS)-dependent asthma
- Severe Asthma

non-FDA-approved, for example:

- systemic mastocytosis

Note: The above list may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Cinqair

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - member is symptomatic despite receiving **one** of the following:
    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 400 cells/μL, elevated sputum eosinophils or FeNO); **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing (3 mg/kg intravenously every 28 days).

Dupixent

- Documentation of all of the following is required for moderate-to-severe AD:
  - appropriate diagnosis; **and**
  - member is ≥ six months of age; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, or dermatologist) or consult notes from a specialist are provided; **and**
  - inadequate response or adverse reaction to one superpotent or potent topical corticosteroid, or contraindication to all superpotent or potent topical corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: topical tacrolimus, Eucrisa; **and**

- appropriate dosing.

- Documentation of all of the following is required for nasal polyps:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - one of the following:
    - inadequate response or adverse reaction to one oral corticosteroid; **or**
    - inadequate response or adverse reaction to one intranasal corticosteroid; **or**
    - inadequate response or adverse reaction to prior nasal surgery; **or**
    - contraindication to both oral corticosteroids and intranasal corticosteroids; **and**
  - appropriate dosing (300 mg subcutaneously every 14 days); **and**
  - requested agent will be used as adjunctive therapy.
- Documentation of all of the following is required for moderate-to-severe eosinophilic asthma or OCS-dependent asthma:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - member is symptomatic despite receiving **one** of the following:
    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - one of the following:
    - evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 150 cells/μL, elevated sputum eosinophils or FeNO); **or**
    - member is receiving chronic oral corticosteroids; **or**
    - member has concomitant AD or CRSwNP; **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing.
- Documentation of all the following is required for prurigo nodularis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, dermatologist) or consult notes from a specialist are provided; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to all potent or superpotent topical corticosteroids; **or**
    - inadequate response or adverse reaction to one or contraindication to all intralesional corticosteroids; **or**
    - inadequate response, adverse reaction, or contraindication to phototherapy; **and**
  - appropriate dosing (loading dose of 600 mg subcutaneously followed by 300 mg subcutaneously every other week).
- Documentation of all the following is required for eosinophilic esophagitis:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - prescriber is a specialist (e.g., allergist, hematologist, immunologist, gastroenterologist) or consult notes from a specialist are provided; **and**
  - member weighs ≥ 15 kg; **and**
  - inadequate response (defined as ≥ 60 days of therapy) or adverse reaction to one or contraindication to all proton pump inhibitors; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to both of the following: budesonide, fluticasone propionate; **and**
  - appropriate dosing.

SmartPA: Claims for Dupixent (dupilumab) 300 mg/2 mL at a quantity ≤ two syringes/28 days will usually process and pay at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Dupixent for at least 84 days out of the last 120 days and a MassHealth history of medical claims for moderate to severe atopic dermatitis, moderate to severe eosinophilic asthma, nasal polyps, or prurigo nodularis. Claims for Dupixent (dupilumab) 300 mg/2 mL at a quantity ≤ four syringes/28 days will usually process and pay at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Dupixent for at least 84 days out of the last 120 days and a MassHealth history of medical claims for eosinophilic esophagitis. Claims for Dupixent (dupilumab) 200 mg/1.14 mL at a quantity ≤ two syringes/28 days will usually process and pay at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Dupixent for at least 84 days out of the last 120 days and a MassHealth history of medical claims for moderate to severe atopic dermatitis or moderate to severe eosinophilic asthma. Claims for Dupixent (dupilumab) 100 mg/0.67 mL at a quantity ≤ two syringes/28 days will usually process and pay at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Dupixent for at least 84 days out of the last 120 days and a MassHealth history of medical claims for moderate to severe eosinophilic asthma.

Fasenra

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - member is symptomatic despite receiving **one** of the following:
    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 150 cells/μL, elevated sputum eosinophils or FeNO); **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing (30 mg every four weeks for three doses, then 30 mg every eight weeks).

SmartPA: Claims for Fasenra will usually pay at the pharmacy without a PA request if the member has a history of medical claims for severe eosinophilic asthma and paid MassHealth pharmacy claims for Fasenra for at least 84 days out of the last 120 days. †

Nucala

- Documentation of all of the following is required for severe eosinophilic asthma:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - member is symptomatic despite receiving **one** of the following:
    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 150 cells/μL, elevated sputum eosinophils or FeNO); **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing (100 mg subcutaneously every four weeks if 12 years of age or older; 40 mg subcutaneously every four weeks if six to 11 years of age).
- Documentation of all of the following is required for eosinophilic granulomatosis with polyangiitis:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to all systemic glucocorticoids; **and**

- inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to both of the following: azathioprine, methotrexate; **and**
- prescriber is a specialist (e.g., allergist, cardiologist, hematologist, immunologist, pulmonologist, rheumatologist, etc.) or consult notes from a specialist are provided; **and**
- appropriate dosing (300 mg subcutaneously every four weeks).

- Documentation of all of the following is required for hypereosinophilic syndrome:
  - appropriate diagnosis; **and**
  - diagnosis without an identifiable non-hematologic secondary cause; **and**
  - member is ≥ 12 years of age; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to all systemic glucocorticoids; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to all of the following: hydroxyurea, methotrexate, interferon alfa; **and**
  - prescriber is a specialist (e.g., allergist, cardiologist, GI, hematologist, immunologist, pulmonologist, etc.) or consult notes from a specialist are provided; **and**
  - appropriate dosing (300 mg subcutaneously every four weeks).
- Documentation of all of the following is required for nasal polyps:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to all oral corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all intranasal corticosteroids; **and**
  - appropriate dosing; **and**
  - requested agent will be used as adjunctive therapy.

SmartPA: Claims for Nucala at a quantity ≤ one vial/28 days will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Nucala for at least 84 days out of the last 120 days and a MassHealth history of medical claims for severe eosinophilic asthma. Claims for Nucala at a quantity ≤ three vials/28 days will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for Nucala for at least 84 days out of the last 120 days and a MassHealth history of medical claims for eosinophilic granulomatosis with polyangiitis or hypereosinophillic syndrome. †

Tezspire

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - member is symptomatic despite receiving **one** of the following:
    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - appropriate dosing.

SmartPA: Claims for Tezspire will usually pay at the pharmacy without a PA request if the member has a history of medical claims for severe persistent asthma and paid MassHealth pharmacy claims for Tezspire for at least 84 days out of the last 120 days. †

Xolair

- Documentation of all of the following is required for chronic idiopathic urticaria:

- appropriate diagnosis; **and**
- member is ≥ 12 years of age; **and**
- inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to at least two or contraindication to all histamine$_1$ antihistamines; **and**
- inadequate response (defined as ≥ 14 days of therapy); adverse reaction, or contraindication to a histamine$_1$ antihistamine in combination with a histamine$_2$ antihistamine; **and**
- for the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial formulation; **and**
- appropriate dosing; **and**
- prescriber is an allergist/immunologist or dermatologist or consult notes from a specialist are provided.

- Documentation of all of the following is required for IgE-mediated food allergy:
  - appropriate diagnosis; **and**
  - prescriber is an allergist or immunologist or consult notes from an allergist or immunologist are provided; **and**
  - member is ≥ one year of age; **and**
  - baseline serum IgE between 30 IU/mL to 1,850 IU/mL; **and**
  - evidence of specific allergic sensitivity (i.e., positive skin test or radioallergosorbent test [RAST] for IgE); **and**
  - appropriate dosing; **and**
  - for the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial formulation.
- Documentation of all of the following is required for moderate-to-severe allergy-related asthma:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - member is symptomatic despite receiving **one** of the following:
    - combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
    - combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as separate inhalers; **or**
    - chronic oral corticosteroids; **and**
  - baseline serum IgE between 30 IU/mL to 700 IU/mL; **and**
  - evidence of specific allergic sensitivity (i.e., positive skin test or radioallergosorbent test [RAST] for IgE); **and**
  - prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - for the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial formulation; **and**
  - appropriate dosing (75 to 375 mg subcutaneously every two to four weeks; not exceeding six units/28 days for the 150 mg vial, four units/28 days for the 150 mg or 300 mg syringe/auto-injection, and two units/28 days for the 75 mg syringe/auto-injection).
- Documentation of all of the following is required for nasal polyps:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or consult notes from a specialist are provided; **and**
  - inadequate response or adverse reaction to one or contraindication to all oral corticosteroids; **and**
  - inadequate response or adverse reaction to one or contraindication to all intranasal corticosteroids; **and**
  - appropriate dosing; **and**
  - for the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial; **and**
  - requested agent will be used as adjunctive therapy
- Documentation of all of the following is required for systemic mastocytosis:
  - appropriate diagnosis; **and**
  - prescriber is a specialist (e.g., hematologist, oncologist, allergist/immunologist) or consult notes from a specialist are provided; **and**

- appropriate dosing; **and**
- for the 150 mg or 300 mg syringe or auto-injection, medical necessity for the requested formulation instead of the vial; **and**
- inadequate response, adverse reaction, or contraindication to all of the following: corticosteroids, histamine$_1$ antihistamine and histamine$_2$ antihistamine.

SmartPA: Claims for Xolair at a quantity ≤ six units/28 days for the 150 mg vial, and ≤ two units/28 days for the 75 mg syringe/auto-injection will usually process at the pharmacy without a PA request if the member has a MassHealth history of medical claims for moderate-to-severe allergy-related asthma and a history of paid MassHealth pharmacy claims for Xolair for at least 84 days out of the last 120 days. †

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 65 - Enzyme and Metabolic Disorder Therapies

Drug Category: Endocrine and Metabolic Agents

Medication Class/Individual Agents: Enzyme and Metabolic Disorder Therapies

I. Prior-Authorization Requirements

Enzyme and Metabolic Disorder Therapies – Injectable Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ADAMTS13, recombinant-krhn	Adzynma	PA	
agalsidase beta	Fabrazyme	PA	
alglucosidase alfa	Lumizyme	PA	MB
asfotase alfa	Strensiq	PA	
avalglucosidase alfa-ngpt	Nexviazyme	PA	MB
cipaglucosidase alfa-atga	Pombiliti	PA	MB
elapegademase-lvlr	Revcovi	PA	
elosulfase alfa	Vimizim	PA	MB
galsulfase	Naglazyme	PA	MB
idursulfase	Elaprase	PA	MB
imiglucerase	Cerezyme	PA	MB
laronidase	Aldurazyme	PA	MB
olipudase alfa-rpcp	Xenpozyme	PA	MB
pegunigalsidase alfa-iwxj	Elfabrio	PA	
pegvaliase-pqpz	Palynziq	PA	
plasminogen, human-tvmh	Ryplazim	PA	
taliglucerase alfa	Elelyso	PA	MB
velaglucerase alfa	Vpriv	PA	MB
velmanase alfa-tycv	Lamzede	PA	MB
vestronidase alfa-vjbk	Mepsevii	PA	MB

Enzyme and Metabolic Disorder Therapies – Oral Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alpelisib-Vijoice	Vijoice	PA	
carglumic acid	Carbaglu [PD]	PA	BP, A90
glycerol phenylbutyrate	Ravicti	PA	
leniolisib	Joenja	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Lysosomal storage disorders are caused by a deficiency or absence of required enzymes. The consequence is an accumulation of compounds that are normally degraded, causing cell and organ dysfunction. Before the development of enzyme replacement therapy, management of these conditions consisted of supportive care and treatment of the complications.
- A number of exogenously supplied enzymes are available for lysosomal storage disorders, including adenosine deaminase (ADA) deficiency, Gaucher disease, Fabry disease, Hunter syndrome, hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthetase, hypophosphatasia, lysosomal acid lipase deficiency, mucopolysaccharidosis type I, IVA, VI, and VII, non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) type B or A/B and Pompe disease.
- Pancreatic enzyme replacement is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions. Multiple formulations of pancreatic enzymes exist with different combinations of lipase, protease, and amylase; however, these enzymes may differ in their effects. Members should be reevaluated after any changes in enzyme preparation or

Enzyme and Metabolic Disorder Therapies – Oral Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
migalastat	Galafold	PA	
miglustat 65 mg	Opfolda	PA	
mitapivat	Pyrukynd	PA	
pancrelipase-Creon DR	Creon DR		
pancrelipase-Pertzye DR	Pertzye DR		
pancrelipase-Viokace	Viokace		
pancrelipase-Zenpep DR	Zenpep DR		
penicillamine capsule	Cuprimine		BP, A90
penicillamine tablet	Depen		# , A90
sacrosidase	Sucraid	PA	
sapropterin	Kuvan	PA	
sodium phenylbutyrate granules	Pheburane	PA	
sodium phenylbutyrate pellets for suspension	Olpruva	PA	
sodium phenylbutyrate powder, tablet	Buphenyl		BP, A90
trientine 250 mg capsule	Syprine		BP, A90
trientine 300 mg tablet	Cuvrior	PA	
trientine 500 mg capsule		PA	A90
triheptanoin	Dojolvi	PA	
uridine triacetate	Xuriden	PA	

Enzyme and Metabolic Disorder Therapies – Substrate Replacement/Reduction Therapies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
eliglustat	Cerdelga	PA	
fosdenopterin	Nulibry	PA	MB
miglustat 100 mg	Zavesca	PA	BP
sebelipase alfa	Kanuma	PA	MB

Clinical Notes

dose.

- Molybdenum cofactor deficiency (MoCD) is a rare genetic disorder that results from one of several single gene defects in the biosynthetic pathway of molybdenum cofactor. About two-thirds of members have MoCD type A, which involves mutations in molybdenum cofactor synthesis gene 1 (MOSC1). Prior to the approval of fosdenopterin, the only available treatment options included supportive care and therapies directed towards complications arising from the disease.
- Pyruvate kinase deficiency is an inherited red blood cell enzyme disorder that causes chronic hemolysis. Affected individuals are either homozygous for a single pathogenic mutation or compound heterozygous for two different pathogenic variants affecting the function of the pyruvate kinase enzyme in red blood cells and liver. Mitapivat is a pyruvate kinase activator that acts by allosterically binding to the pyruvate kinase tetramer and increasing pyruvate kinase activity.
- PIK3CA-Related Overgrowth Spectrum (PROS) is considered a rare disease that includes a group of genetic disorders, which leads to overgrowth of various body parts due to PIK3CA mutations. Alpelisib is small-molecule inhibitor of phosphatidylinositol-3 kinase (PI3K). Mutations in the gene for PI3K lead to PI3Ka and Akt activation, tumor generation, and cellular transformation. Activating these mutations lead to a range of malformations and overgrowths known as PROS. Alpelisib can inhibit the phosphorylation of PI3K and Akt to prevent further activity in the pathway.
- ASMD is a rare autosomal recessive liposomal storage disease that results in a deficiency in the enzyme acid sphingomyelinase (ASM), which is required to metabolize sphingomyelin, a fatty acid. As a result, sphingomyelin accumulates in cells within major organs. Prior to the approval of olipudase alpha-rpcp, the only available treatment options included supportive care and therapies directed towards complications arising from the disease. Olipudase alfa-rpcp is the first and only FDA-approved drug to treat the underlying pathology of ASMD. This drug does not cross the blood-brain barrier; therefore, it is not expected to modulate the CNS manifestations of ASMD.
- Plasminogen deficiency (PLGD) type 1, also referred to as hypoplasminogenemia, is an ultra-rare, autosomal

	Clinical Notes
	recessive disorder that can impair normal tissue and organ function which can lead to blindness. Individuals with PLGD type 1 lack the enzyme plasminogen and develop thick lesions in the mucous membranes of their body. There have been no standardized treatments for patients with PLGD due to the rarity of the disease, and plasminogen human-tvhm is the first and only product FDA-approved for the treatment of PLGD type 1.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Acid sphingomyelinase deficiency (ASMD) (Xenpozyme)
- Activated phosphoinositide 3-kinase delta (PI3Kd) syndrome (APDS) (Joenja)
- Adenosine deaminase severe combined immunodeficiency (ADA-SCID) (Revcovi)
- Alpha-mannosidosis (Lamzede)
- Congenital sucrase-isomaltase deficiency (Sucraid)
- Congenital thrombocytopenic purpura (cTTP) (Adzynma)
- Fabry disease (Elfabrio, Fabrazyme, Galafold)
- Gaucher Disease Type 1 (Cerdelga, Cerezyme, Elelyso, miglustat, Vpriv)
- Hemolytic anemia with pyruvate kinase deficiency (Pyrukynd)
- Hereditary orotic aciduria (Xuriden)
- Hunter Syndrome (Elaprase)
- Hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthetase (NAGS) (carglumic acid)
- Hyperammonemia due to propionic aciduria (PA) or methylmalonic aciduria (MMA) (carglumic acid)
- Hypophosphatasia (Strensiq)
- Late-onset Pompe Disease (Opfolda, Pombiliti)
- Long-chain fatty acid oxidation disorders (LC-FAOD) (Dojolvi)
- Lysosomal acid lipase deficiency (Kanuma)

- Molybdenum cofactor deficiency (MoCD) Type A (Nulibry)
- Mucopolysaccharidosis I (Aldurazyme)
- Mucopolysaccharidosis IVA (Morquio A syndrome) (Vimizim)
- Mucopolysaccharidosis VI (Naglazyme)
- Mucopolysaccharidosis VII (Sly syndrome) (Mepsevii)
- Phenylketonuria (Palynziq, sapropterin)
- PIK3CA-Related Overgrowth Spectrum (PROS) (Vijoice)
- Plasminogen deficiency (PLGD), Type 1 (Ryplazim)
- Pompe disease (Lumizyme, Nexviazyme)
- Urea cycle disorder (Olpruva, Pheburane, Ravicti)
- Wilson's disease (Cuvrior, trientine 500 mg capsule)

Non-FDA approved, for example:

- Acute hyperammonemia in isovaleric aciduria (carglumic acid)

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Adzynma

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - prescriber is a hematologist, oncologist, or intensive care specialist or consult notes from a specialist are provided; **and**
  - copy of genetic test confirming diagnosis of cTTP; **and**
  - requested agent will not be used concurrently with fresh frozen plasma; **and**
  - appropriate dosing; **and**
  - member's current weight.

Aldurazyme

- Documentation of all of the following is required:

- appropriate diagnosis; **and**
- results from genetic testing showing mutations in IDUA gene or an enzyme assay test showing reduced lysosomal alpha-L-iduronidase activity in peripheral blood leukocytes, plasma, or cultured fibroblasts; **and**
- prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
- member's current weight.

carglumic acid

- Documentation of all of the following is required for hyperammonemia due to NAGS deficiency:
  - appropriate diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - results from genetic test or an enzyme assay test supporting the diagnosis.
- Documentation of all of the following is required for hyperammonemia due to PA or MMA:
  - appropriate diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - results from genetic testing, medical records, or lab results supporting the diagnosis; **and**
  - elevated ammonia levels > 60 µmol/L.
- Documentation of all of the following is required for acute hyperammonemia in isovaleric aciduria (IVA):
  - appropriate diagnosis; **and**
  - medical records and/or laboratory testing results supporting the diagnosis of IVA; **and**
  - abnormally elevated baseline ammonia levels (e.g., > 60 µmol/L); **and**
  - appropriate dosing.

Cerdelga

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - results from enzyme assay test showing reduced activity of glucocerebrosidase; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member is not currently receiving enzyme replacement therapy.

Cerezyme and Vpriv

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic test confirming mutation in GBA gene or an enzyme assay test showing reduced activity of the enzyme glucocerebrosidase; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

Cuvrior

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥18 years of age; **and**
  - member has stable disease; **and**
  - member is tolerant to penicillamine; **and**
  - contraindication to penicillamine; **and**
  - inadequate response, adverse reaction, or contraindication to trientine 250 mg capsule; **and**
  - requested medication will not be taken concurrently with penicillamine; **and**
  - appropriate dosing.

Dojolvi

- Documentation of all of the following is required:

- diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD); **and**
- results from genetic testing or molecular analysis to confirm diagnosis (e.g., CPT I or II, LCHAD, TFP, VLCAD deficiency); **and**
- prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
- trial with a diet consisting of low-fat, high-carbohydrates, and avoidance of fasting; **and**
- member's current caloric intake.

Elaprase

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic testing confirming mutation in IDS gene or iduronate-2-sulfatase assay test showing reduced or absent activity in the serum, white blood cells, or fibroblasts; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

Elelyso

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic test confirming mutation in GBA gene or an enzyme assay test showing reduced activity of the enzyme glucocerebrosidase; **and**
  - member is ≥ four years of age; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

Elfabrio and Fabrazyme

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - results from an enzyme assay test showing reduced or absent α-galactosidase A (α-GAL) enzyme activity in plasma, leukocytes, tears, or biopsied tissue; **or**
    - Genetic testing confirming mutation in GAL gene; **or**
    - Biomarker demonstrating an increase in Gb3 concentration; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight; **and**
  - for Elfabrio, inadequate response, adverse reaction, or contraindication to Fabrazyme.

Joenja

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - prescriber is a specialist (e.g., pediatrician, hematologist/oncologist, or allergist/immunologist), or consult notes from a specialist are provided; **and**
  - results from genetic testing confirming mutation in the PIK3CD or PIK3R1 genes; **and**
  - member's weight is ≥ 45 kg; **and**
  - appropriate dosing.

Galafold

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - results from an enzyme assay test showing reduced or absent α-galactosidase A (α-GAL) enzyme activity in plasma, leukocytes, tears, or biopsied tissue; **and**
  - member has GLA variants which are amenable to treatment with the requested agent; **and**

- requested quantity is ≤ 15 units/30 days.

Kanuma

- Documentation of all of the following is required:
  - diagnosis of lysosomal acid lipase deficiency; **and**
  - one of the following:
    - lab assay documenting low lysosomal acid lipase activity; **or**
    - genetic testing confirming full or partial loss of LAL gene; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight.

Lamzede

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 3 years of age; **and**
  - copy of a genetic test confirming diagnosis of alpha-mannosidosis (e.g., mutation of MAN2B1 gene); **and**
  - baseline measurements for all of the following tests:
    - one of the following motor function tests:
      - 3-minute stair climb test; **or**
      - 6-minute walk test; **and**
    - serum oligosaccharides; **and**
    - forced vital capacity; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

Lumizyme

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - results from acid maltase enzyme alpha-glucosidase (GAA) assay test showing reduced or absent activity from cultured skin fibroblasts; **or**
    - lymphocyte testing; **or**
    - blood spot assay; **or**
    - genetic testing confirming mutation in GAA gene; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

Mepsevii

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic testing showing mutations in the beta glucuronidase gene; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

miglustat

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - results from enzyme assay test showing reduced activity of glucocerebrosidase; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - contraindication to enzyme replacement therapy.

Naglazyme

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from an enzyme assay test showing reduced arylsulfatase B (ASB) enzyme activity in leukocytes or fibroblasts along with elevated urine glycosaminoglycan (GAG) levels; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

Nexviazyme

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - results from GAA assay test showing reduced or absent activity from cultured skin fibroblasts; **or**
    - lymphocyte testing; **or**
    - blood spot assay; **or**
    - genetic testing confirming mutation in GAA gene; **and**
  - member is ≥ one year of age; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight; **and**
  - for members weighing < 30 kg, contraindication to Lumizyme.

Nulibry

- Documentation of all of the following is required:
  - appropriate diagnosis confirmed by genetic testing; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - member's current weight.

Olpruva

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic test or an enzyme assay test supporting the diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: sodium phenylbutyrate powder, sodium phenylbutyrate tablet; **and**
  - inadequate response, adverse reaction, or contraindication to Pheburane.

Opfolda

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight is ≥ 40 kg; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - one of the following:
    - results from GAA assay test showing reduced or absent activity from cultured skin fibroblasts; **or**
    - lymphocyte testing; **or**
    - blood spot assay; **or**
    - genetic testing confirming mutation in GAA gene; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Lumizyme, Nexviagzyme; **and**
  - requested agent will be used in combination with Pombiliti.

Palynziq

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - blood phenylalanine concentrations > 600 micromol/L; **and**
  - medication will be used in conjunction with a phenylalanine-restricted diet; **and**
  - inadequate response, adverse reaction, or contraindication to sapropterin.

Pheburane

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic test or an enzyme assay test supporting the diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: sodium phenylbutyrate powder, sodium phenylbutyrate tablet.

Pombiliti

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - member's current weight is ≥ 40 kg; **and**
  - member is ≥ 18 years of age; **and**
  - appropriate dosing; **and**
  - one of the following:
    - results from GAA assay test showing reduced or absent activity from cultured skin fibroblasts; **or**
    - lymphocyte testing; **or**
    - blood spot assay; **or**
    - genetic testing confirming mutation in GAA gene; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: Lumizyme, Nexviagzyme; **and**
  - requested agent will be used in combination with Opfolda.

Pyrukynd

- Documentation of all of the following is required:
  - diagnosis of hemolytic anemia with pyruvate kinase deficiency; **and**
  - member is ≥ 18 years of age; **and**
  - results from genetic testing confirming mutation in PKLR gene or lab testing showing reduced or absent activity of pyruvate kinase; **and**
  - prescriber is a specialist in genetic diseases, hematology, or metabolic diseases or consultation notes from a specialist are provided; **and**
  - hemoglobin (Hb) ≤ 10 g/dL (dated within the last 60 days); **and**
  - requested quantity is ≤ two units/day.

Ravicti

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - results from genetic test or an enzyme assay test supporting the diagnosis; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided; **and**
  - appropriate dosing; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: sodium phenylbutyrate powder, sodium phenylbutyrate tablet, Olpruva, Pheburane.

Revcovi

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - laboratory results documenting one of the following:
    - absent ADA enzymatic activity in lysed erythrocytes; **or**
    - elevated levels of adenosine and deoxyadenosine in the urine and plasma; **or**
    - a marked increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates; **or**
    - a significant decrease in ATP concentration in red blood cells; **or**
    - absent or extremely low levels of N adenosylhomocysteine hydrolase in red blood cells; **or**
    - severe T cell deficiency manifested by lymphopenia and poor T cell responses to mitogens and antigens; **or**
    - absent thymic shadow on chest radiograph; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

Ryplazim

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - history of lesions (external and/or internal) and symptoms consistent with a diagnosis of PLGD type 1; **and**
  - baseline plasminogen activity level ≤ 45%; **and**
  - one of the following:
    - results from genetic testing showing mutations in PLG gene; **or**
    - member has plasminogen antigen levels ≤ 9 mg/dL; **and**
  - requested dose is ≤ 6.6 mg/kg every two to four days.

sapropterin

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - documentation that medication will be used in conjunction with a phenylalanine-restricted diet; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

Strensiq

- Documentation of all of the following is required:
  - diagnosis of perinatal-onset, infantile-onset, or juvenile-onset hypophosphatasia; **and**
  - genetic testing confirming mutation in ALPL gene; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

Sucraid

- Documentation of all of the following is required:
  - diagnosis of congenital sucrase-isomaltase deficiency (CSID); **and**
  - results from small bowel biopsy or breath hydrogen test showing reduced or absent enzyme activity or sucrase breath test; **and**
  - prescriber is a specialist in genetic or metabolic diseases, a gastroenterologist, or consult notes from a specialist or gastroenterologist are provided; **and**
  - member's current weight.

trientine 500 mg capsule

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response, adverse reaction, or contraindication to penicillamine; **and**
  - medical necessity for the 500 mg capsule instead of trientine 250 mg capsule; **and**
  - requested medication will not be taken concurrently with penicillamine; **and**
  - requested quantity is ≤ four capsules/day.

Vijoice

- Documentation of all of the following is required:
  - diagnosis of PROS with congenital or early childhood onset; **and**
  - member is ≥ two years of age; **and**
  - overgrowth is sporadic and mosaic (i.e., patchy, irregular); **and**
  - results from genetic testing showing evidence of a mutation in the PIK3CA gene; **and**
  - appropriate dosing; **and**
  - medical records documenting one of the following:
    - spectrum categorization defined as having at least two of the following:
      - adipose, muscle, nerve, or skeletal overgrowth; **or**
      - capillary, venous, arteriovenous, or lymphatic vascular malformations; **or**
      - epidermal nevus; **or**
    - isolated features defined as having one of the following:
      - large isolated lymphatic malformation; **or**
      - isolated macrodactyly or overgrown splayed feet/hands, overgrown limbs; **or**
      - truncal adipose overgrowth; **or**
      - bilateral hemimegalencephaly/dysplastic megalencephaly/focal cortical dysplasia type 2; **or**
      - epidermal nevus; **or**
      - seborrheic keratoses; **or**
      - benign lichenoid keratoses.

Vimizim

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ five years of age; **and**
  - results from an enzyme assay test showing reduced N-acetylgalactosamine-6-sulfatase activity in blood and/or skin cells; **and**
  - prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; **and**
  - member's current weight.

Xenpozyme

- Documentation of all of the following is required:
  - diagnosis of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) type B or ASMD type A/B; **and**
  - prescriber is a specialist (e.g., medical geneticist or a specialist familiar with lysosomal storage disorders) or consult notes from a specialist are provided; **and**
  - one of the following:
    - for members ≥ 18 years of age, both of the following:
      - DLco ≤ 70% of predicted normal value; **and**
      - spleen volume ≥ 6 MN; **or**
    - for members < 18 years of age, spleen volume ≥ 5 MN; **and**
  - member does not have acute or rapidly progressing neurologic abnormalities; **and**
  - both of the following:
    - member does not require invasive ventilatory support; **and**
    - member does not require noninvasive ventilatory support while awake for > 12 hours a day; **and**
  - member's current weight; **and**
  - appropriate dosing.
- For recertification, documentation of all of the following is required:
  - improvement from baseline in DLco and spleen volume; **and**
  - updated member weight.

Xuriden

- Documentation of all of the following is required:

- diagnosis of hereditary orotic aciduria (HOA); and
- genetic testing confirming mutation in UMPS gene; and
- prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided; and
- member's current weight.

MassHealth Evaluation Criteria
Table 66 - Antibiotics and Anti-Infectives – Injectable

Drug Category: Infectious Disease Agents

Medication Class/Individual Agents: Antibiotics and Anti-Infectives – Injectable

I. Prior-Authorization Requirements

Antibiotics: Injectable – Fluoroquinolones

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
ciprofloxacin injection, suspension, 250 mg, 500 mg, 750 mg tablet	Cipro		# , A90	Delafloxacin requires PA because of safety concerns and to ensure appropriate utilization.
delafloxacin injection	Baxdela	PA		
levofloxacin			A90	
moxifloxacin injection	Avelox			

Antibiotics: Injectable – Cephalosporins

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
cefazolin				Cefiderocol, ceftazidime/avibactam, and ceftolozane/tazobactam require PA because of safety concerns and to ensure appropriate utilization.
cefepime				
cefiderocol	Fetroja	PA		
cefotaxime	Claforan		#	
cefotetan				
cefoxitin				
ceftaroline	Teflaro		BP	
ceftazidime				
ceftazidime / avibactam	Avycaz	PA		
ceftolozane / tazobactam	Zerbaxa	PA		
ceftriaxone				
cefuroxime sodium				

Anti-Infectives: Injectable – Not Otherwise Classified

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
artesunate		PA		• Dalbavancin, dalfopristin/quinupristin, lefamulin, linezolid, oritavancin, tedizolid, telavancin, and tigecycline require PA to ensure appropriate utilization and due to safety concerns. • These antibiotics are approved for indications such as
azithromycin	Zithromax		# , A90	
aztreonam injection	Azactam		#	
chloramphenicol			MB	
clindamycin capsule, injection,	Cleocin		# , A90	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
oral solution				complicated and uncomplicated skin and skin structure infections, intra-abdominal infections, pneumonia, bacteremia, endocarditis along with vancomycin-resistant *Enterococci* (VRE) infections. • In addition, many of the agents have activity against methicillin-resistant *Staphylococcus aureus* (MRSA) infection. • Intravenous (IV) artesunate is the recommended treatment for severe malaria. It is given at a dose of 2.4 mg/kg at 0, 12 and 24 hours. Artesunate should be continued until parasite density is ≤ 1% and the patient is able to tolerate oral medications. If IV artesunate is not readily available, oral antimalarials such as artemether/lumefantrine or atovaquone/proguanil are recommended until IV artesunate is procured. [1] 1. Centers for Disease Control and Prevention. Malaria Treatment Guidelines, 2021 [guideline on the Internet]. Atlanta (GA): CDC; 2021 [cited 2021 Nov 19]; Available from: https://www.cdc.gov/malaria/diagnosis_treatment/clinicians1.html.
colistimethate sodium injection	Coly-Mycin M		#	
dalbavancin	Dalvance	PA		
daptomycin	Cubicin		#	
daptomycin				
erythromycin injection	Erythrocin			
isoniazid			A90	
lincomycin	Lincocin		#	
linezolid injection	Zyvox	PA		
metronidazole injection	Metro		#	
oritavancin	Kimyrsa	PA		
oritavancin	Orbactiv	PA		
rifampin	Rifadin		# , A90	
sulfamethoxazole / trimethoprim injection				
tedizolid injection	Sivextro	PA		
telavancin	Vibativ	PA		
tigecycline	Tygacil	PA		
vancomycin injection				

Antibiotics: Injectable – Penicillins

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
ampicillin			A90	
ampicillin / sulbactam	Unasyn		#	
nafcillin				
oxacillin				
penicillin G 0.6 million, 1.2 million, 2.4 million units	Bicillin LA			
penicillin G 5 million, 20 million units	Pfizerpen		#	
penicillin G benzathine / penicillin G procaine	Bicillin CR			
piperacillin / tazobactam	Zosyn		#	

Antibiotics: Injectable – Carbapenems

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
ertapenem	Invanz		#	Imipenem/cilastatin/relebactam and meropenem/vaborbactam require PA because of safety concerns and to ensure appropriate utilization.
imipenem / cilastatin	Primaxin		#	
imipenem / cilastatin / relebactam	Recarbrio	PA		
meropenem				
meropenem / vaborbactam	Vabomere	PA		

Antibiotics: Injectable – Tetracyclines

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
doxycycline hyclate injection				Eravacycline and omadacycline require PA because of safety concerns and to ensure appropriate utilization.
eravacycline	Xerava	PA		
minocycline injection	Minocin			
omadacycline injection	Nuzyra	PA		

Antibiotics: Injectable – Aminoglycosides

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amikacin				Plazomicin requires prior authorization (PA) because of safety concerns and to ensure appropriate utilization.
gentamicin injection				
plazomicin	Zemdri	PA		
streptomycin				
tobramycin injection				

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Infections (site and location vary by indication for requested agent)

Non-FDA-approved, for example:

- Infections (site and location vary by indication for requested agent)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

artesunate for the treatment of malaria

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - appropriate dose and frequency.

Avycaz, Fetroja, Recarbrio, and Zerbaxa for the treatment of hospital-acquired (nosocomial) bacterial pneumonia (HABP) or ventilator-associated bacterial pneumonia (VABP) infections caused by susceptible Gram-negative organisms

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication (e.g., culture is not susceptible) to all of the following:
    - aminoglycosides (gentamicin, amikacin, tobramycin); **or**
    - aztreonam; **or**
    - cefepime; **or**
    - ceftazidime; **or**
    - ciprofloxacin or levofloxacin; **or**
    - imipenem/cilastatin; **or**
    - meropenem; **or**
    - piperacillin/tazobactam.

Avycaz, Fetroja, Recarbrio, and Vabomere for the treatment of carbapenem-resistant enterobacterales

- Documentation of the following is required:
  - appropriate diagnosis; **and**

- one of the following:
  - culture is resistant to ertapenem and meropenem (if cultures can be obtained); **or**
  - suspected resistance to ertapenem and meropenem and susceptibility testing is not able to be performed.

Avycaz, Recarbrio, tigecycline, Xerava, and Zerbaxa for the treatment of complicated intra-abdominal infections (cIAI)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for tigecycline or Zerbaxa, member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication (e.g., culture is not susceptible) to all of the following:
    - combination therapy with aztreonam and metronidazole and vancomycin; **or**
    - combination therapy with metronidazole and cefepime; **or**
    - combination therapy with metronidazole and cefotaxime; **or**
    - combination therapy with metronidazole and ceftazidime; **or**
    - combination therapy with metronidazole and ceftriaxone; **or**
    - combination therapy with metronidazole and ciprofloxacin; **or**
    - combination therapy with metronidazole and levofloxacin; **or**
    - doripenem; **or**
    - ertapenem; **or**
    - imipenem/cilastatin; **or**
    - meropenem; **or**
    - moxifloxacin; **or**
    - piperacillin/tazobactam; **and**
  - for Avycaz or Zerbaxa, the requested agent is being utilized concurrently with metronidazole.

Avycaz, Fetroja, Recarbrio, Vabomere, Zemdri, and Zerbaxa for the treatment of complicated urinary tract infections (cUTI)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Vabomere, Zemdri, or Zerbaxa, member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication (e.g., culture is not susceptible) to all of the following:
    - amikacin; **or**
    - ampicillin/sulbactam; **or**
    - aztreonam; **or**
    - cefepime; **or**
    - ceftazidime; **or**
    - ceftriaxone; **or**
    - ciprofloxacin or levofloxacin; **or**
    - ertapenem; **or**
    - gentamicin; **or**
    - imipenem/cilastatin; **or**
    - meropenem; **or**
    - piperacillin/tazobactam.

Baxdela injection and Nuzyra injection for the treatment of non-MRSA community acquired bacterial pneumonia (CABP) infections

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to Teflaro; **and**
  - inadequate response or adverse reaction to a regimen containing one or contraindication to all of the following:
    - amoxicillin; **or**
    - amoxicillin/clavulanate; **or**
    - ampicillin/sulbactam; **or**

- azithromycin; **or**
- cefotaxime; **or**
- cefpodoxime; **or**
- ceftriaxone; **or**
- cefuroxime; **or**
- clarithromycin; **or**
- doxycycline; **or**
- levofloxacin; **or**
- moxifloxacin.

Baxdela injection, Kimyrsa, Nuzyra injection, and Orbactiv for the treatment of non-MRSA skin and soft tissue infections (SSTIs)

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to Teflaro; **and**
  - one of the following:
    - organism susceptibility to the requested agent; **or**
    - culture cannot be obtained due to the nature of the infection; **and**
  - for Baxdela or Nuzyra, one of the following:
    - inadequate response to one regimen available without PA; **or**
    - adverse reaction, contraindication, or culture is resistant to all regimens available without PA; **and**
  - for Kimyrsa or Orbactiv, inadequate response, adverse reaction, or contraindication (e.g., culture not susceptible) to all of the following: ceftaroline, daptomycin, vancomycin; **and**
  - for Kimyrsa, clinical rationale for use instead of Orbactiv.

Baxdela injection, Dalvance, Kimyrsa, linezolid injection, Nuzyra injection, Orbactiv, Sivextro injection, tigecycline, and Vibativ for the treatment of MRSA SSTIs

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Baxdela, Kimyrsa, Nuzyra, Orbactiv, Sivextro, or Vibativ, member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication (e.g., culture not susceptible) to all of the following: ceftaroline, daptomycin, vancomycin; **and**
  - for tigecycline, one of the following:
    - inadequate response, adverse reaction, or contraindication to all other available agents that treat MRSA SSTIs; **or**
    - culture is resistant to all other available agents that treat MRSA SSTIs (if cultures can be obtained); **and**
  - for Kimyrsa, clinical rationale for use instead of Orbactiv.

Please note: Adverse events caused by vancomycin, such as red-man syndrome (rate-related infusion reaction) or renal (kidney) adverse events, such as increased serum creatinine or microalbuminuria, are also associated with Vibativ, and renal events in particular are higher with Vibativ. Thus, these specific adverse reactions are not appropriate clinical rationale for selecting Vibativ over vancomycin.

Dalvance for MRSA osteomyelitis or MRSA bacteremia

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - clinical rationale for use of requested agent instead of vancomycin.

Dalvance, linezolid injection, Sivextro injection, tigecycline, and Vibativ for the treatment of non-MRSA/non-VRE infections

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Sivextro or Vibativ, member is ≥ 18 years of age; **and**
  - one of the following:
    - organism susceptibility to the requested agent; **or**

- culture cannot be obtained due to the nature of the infection; **and**
- one of the following:
  - inadequate response, adverse reaction, or contraindication to vancomycin; **or**
  - culture is resistant to vancomycin (if cultures can be obtained).

Please note: Adverse events caused by vancomycin, such as red-man syndrome (rate-related infusion reaction) or renal (kidney) adverse events, such as increased serum creatinine or microalbuminuria, are also associated with Vibativ, and renal events in particular are higher with Vibativ. Thus, these specific adverse reactions are not appropriate clinical rationale for selecting Vibativ over vancomycin.

Dalvance or Vibativ for VRE infection or suspected VRE infection

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to linezolid; **or**
    - culture is resistant to linezolid (if cultures can be obtained).

linezolid injection for the treatment of MRSA bone/joint infections

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to vancomycin; **or**
    - culture is resistant to vancomycin (if cultures can be obtained); **or**
    - member has a history of MRSA infections that have not responded to vancomycin in the past.

linezolid injection, Sivextro injection, and tigecycline for the treatment of VRE infections

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for Sivextro, member is is ≥ 18 years of age; **and**
  - for Sivextro or tigecycline, one of the following:
    - inadequate response, adverse reaction, or contraindication to linezolid; **or**
    - culture is resistant to linezolid (if cultures can be obtained).

linezolid injection for the treatment of MRSA central nervous system (CNS) infections

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to vancomycin; **or**
    - culture is resistant to vancomycin (if cultures can be obtained); **or**
    - member has a history of MRSA infections that have not responded to vancomycin in the past.

linezolid injection and Vibativ for the treatment of HABP infections caused by MRSA or suspected MRSA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to vancomycin; **or**
    - culture is resistant to vancomycin (if cultures can be obtained); **or**
    - member has a history of MRSA infections that have not responded to vancomycin in the past; **and**
  - if the request is for Vibativ, both of the following:
    - member is ≥ 18 years of age; **and**
    - one of the following:
      - inadequate response, adverse reaction, or contraindication to linezolid; **or**
      - culture is resistant to linezolid (if cultures can be obtained); **or**
      - member has a history of MRSA infections that have not responded to linezolid in the past.

Please note: Adverse events caused by vancomycin, such as red-man syndrome (rate-related infusion reaction) or renal (kidney) adverse events, such as increased serum creatinine or microalbuminuria, are also associated with Vibativ, and renal events in particular are higher with Vibativ. Thus, these specific adverse reactions are not appropriate clinical rationale for selecting Vibativ over vancomycin.

Vibativ for the treatment of VABP infections caused by MRSA or suspected MRSA

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is is ≥ 18 years of age; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to vancomycin; **or**
    - culture is resistant to vancomycin (if cultures can be obtained); **or**
    - member has a history of MRSA infections that have not responded to vancomycin in the past; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to linezolid; **or**
    - culture is resistant to linezolid (if cultures can be obtained); **or**
    - member has a history of MRSA infections that have not responded to linezolid in the past.

Please note: Adverse events caused by vancomycin, such as red-man syndrome (rate-related infusion reaction) or renal (kidney) adverse events, such as increased serum creatinine or microalbuminuria, are also associated with Vibativ, and renal events in particular are higher with Vibativ. Thus, these specific adverse reactions are not appropriate clinical rationale for selecting Vibativ over vancomycin.

MassHealth Evaluation Criteria
Table 67 - Antiviral Agents

Drug Category: Antiviral Agents

Medication Class/Individual Agents: Antiviral Agents

I. Prior-Authorization Requirements

Antiviral Agents – Topical			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acyclovir / hydrocortisone	Xerese		
acyclovir cream	Zovirax		BP
acyclovir ointment	Zovirax		#
penciclovir	Denavir		BP

Antiviral Agents – Oral and Injectable			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
acyclovir capsule, tablet			A90
acyclovir injection			
acyclovir suspension	Zovirax		# , A90
cidofovir			
famciclovir			A90
foscarnet			MB
ganciclovir injection			
letermovir	Prevymis	PA	
maribavir	Livtencity	PA	
valacyclovir	Valtrex		# , A90
valganciclovir powder for oral solution	Valcyte	PA	BP, A90
valganciclovir tablet	Valcyte		# , A90

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- The 2015 Centers for Disease Control and Prevention (CDC) sexually transmitted diseases treatment guidelines state that topical antiviral therapy offers minimal clinical benefit for the treatment of genital herpes and does not recommend their use.[1]
- The CDC guidelines recommend the use of oral antiviral agents, including acyclovir, famciclovir, and valacyclovir for recurrent and suppressive therapy in genital herpes.[1]
- Oral antiviral agents (acyclovir, famciclovir and valacyclovir) are available without PA.
- Acyclovir is also available as an oral suspension.
- Letermovir therapy is limited to 100 days post-transplant.

[1]Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines [homepage on the Internet]. Atlanta: Centers for Disease Control and Prevention: 2015 [updated 2015 Jun 5]; [cited 2018 May 31]. Available from: https://www.cdc.gov/std/tg2015/tg-2015-print.pdf

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (Prevymis, valganciclovir powder for oral solution)
- Prophylaxis of CMV infection post-solid organ transplant (valganciclovir powder for oral solution)
- Treatment of CMV infection post-transplant that is refractory to standard treatment in adult and pediatric patients ≥ 12 years of age and who weigh ≥ 35 kg (Livtencity)
- Treatment of CMV retinitis (valganciclovir powder for oral solution)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, application frequency, and tube size.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Livtencity

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - member weight is ≥35 kg; **and**

- prescriber is an infectious disease specialist or consultation notes from an infectious disease specialist are provided; **and**
- appropriate dosing; **and**
- member will not be receiving concurrent antiviral therapy with cidofovir, foscarnet, ganciclovir, or valganciclovir; **and**
- one of the following:
  - inadequate response or adverse reaction to ganciclovir or valganciclovir; **or**
  - contraindication to cidofovir, foscarnet, ganciclovir, and valganciclovir; **or**
  - both of the following:
    - contraindication to both ganciclovir and valganciclovir; **and**
    - inadequate response or adverse reaction to cidofovir or foscarnet.

Prevymis

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response, adverse reaction, or contraindication to valganciclovir; **and**
  - member is at high risk for CMV reactivation; **and**
  - for tablet, requested quantity is ≤ one tablet/day; **and**
  - for the injection formulation, medical necessity for use of the requested formulation instead of the tablet formulation.

valganciclovir powder for oral solution

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - for a diagnosis of CMV retinitis, member is ≥ 18 years of age; **and**
  - medical necessity for the use of a solution formulation as noted by one of the following:
    - member utilizes tube feeding (G-tube/J-tube); **or**
    - member has a swallowing disorder or condition affecting ability to swallow; **or**
    - member is < 13 years of age; **and**
  - requested quantity is ≤ 18 mL/day.

MassHealth Evaluation Criteria
Table 68 - Thrombocytopenic Agents

Drug Category: Blood and Circulation

Medication Class/Individual Agents: Thrombocytopenic Agents

I. Prior-Authorization Requirements

Thrombocytopenic Agents – Thrombopoietin Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
avatrombopag	Doptelet	PA	
eltrombopag choline	Alvaiz	PA	
eltrombopag olamine	Promacta	PA	BP
lusutrombopag	Mulpleta	PA	
romiplostim	Nplate	PA	MB

Thrombocytopenic Agents – Monoclonal Antibody			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
caplacizumab-yhdp	Cablivi	PA	

Thrombocytopenic Agents – Tyrosine Kinase Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fostamatinib	Tavalisse	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Thrombopoietin agonists are approved for the treatment of refractory thrombocytopenia in those patients who have had an insufficient response to corticosteroids, immunoglobulin, or splenectomy.
- Eltrombopag is also approved for the treatment of severe aplastic anemia and thrombocytopenia in the setting of hepatitis C.
- Romiplostim is also approved for the treatment of hematopoietic syndrome of acute radiation syndrome.
- These agents are not approved for the normalization of platelet counts and should only be used in those whose clinical condition is associated with a high risk of bleeding.
- Fostamatinib is a tyrosine kinase inhibitor with demonstrated activity against spleen tyrosine kinase (SYK). It is approved for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.
- Avatrombopag and lusutrombopag are indicated for the treatment of thrombocytopenia in adults with chronic liver disease (CLD) who are scheduled to undergo a procedure.
  - For avatrombopag, dosing should begin 10-to-13 days

	Clinical Notes
	before scheduled procedure. Patients should undergo their procedure five-to-eight days after the last dose. • For lusutrombopag, dosing should begin eight-to-14 days before scheduled procedure. Patients should undergo their procedure two-to-eight days after the last dose. • Avatrombopag is also indicated for thrombocytopenia in adults with chronic ITP who have had insufficient response to a previous treatment. • Caplacizumab-yhdp is a novel humanized immunoglobulin (nanobody) that works by targeting platelet (PLT) aggregation through binding to von Willebrand factor (vWF) and inhibiting interaction between vWF and PLTs. It is approved for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange (PEX) and immunosuppressive therapy. This agent should be administered upon initiation of PEX and continued once daily for 30 days following the last daily PEX.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- aTTP (Cablivi)
- Chronic, relapsed, or refractory ITP (Alvaiz, Doptelet, Nplate, Promacta, Tavalisse)
- Hematopoietic syndrome of acute radiation ayndrome (HS-ARS)/acute exposure to myelosuppressive doses of radiation (Nplate)
- Severe aplastic anemia (Alvaiz, Promacta)
- Thrombocytopenia due to CLD in a member scheduled to undergo a procedure (Doptelet, Mulpleta)
- Thrombocytopenia in the setting of hepatitis C with interferon therapy (Alvaiz, Promacta)

Non-FDA-approved, for example:

- Thrombocytopenia in the setting of hepatitis C independent of interferon therapy (Promacta)

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Alvaiz

- Documentation of the following is required for a diagnosis of chronic, relapsed, or refractory ITP:
  - appropriate diagnosis; **and**
  - member is ≥ six years of age; **and**
  - one of the following:
    - platelet count < 30,000 cells/mcL; **or**
    - medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding); **and**
  - requested dose is ≤ 54 mg/day; **and**
  - medical necessity for use instead of Promacta; **and**
  - for Alvaiz 9 mg, requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: corticosteroid, immunoglobulin; **or**
    - member has had a splenectomy.

- Documentation of the following is required for a diagnosis of severe aplastic anemia:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - platelet count < 50,000 cells/mcL; **and**
  - requested dose is ≤ 108 mg/day; **and**
  - medical necessity for use instead of Promacta; **and**
  - for Alvaiz 9 mg, requested quantity is ≤ one unit/day; **and**
  - inadequate response, adverse reaction, or contraindication to immunosuppressive therapy with anti-thymocyte globulin (ATG); **and**
  - inadequate response, adverse reaction, or contraindication to immunosuppressive therapy with cyclosporine.

- Documentation of the following is required for a diagnosis of thrombocytopenia in the setting of hepatitis C with interferon therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**

- requested dose is ≤ 72 mg/day; **and**
- medical necessity for use instead of Promacta; **and**
- for Alvaiz 9 mg, requested quantity is ≤ one unit/day; **and**
- one of the following:
  - member intends to initiate therapy with interferon and current platelet count is ≤ 75,000 cells/mcL; **or**
  - both of the following:
    - member has already begun interferon therapy and platelet count supports continued use; **and**
    - member has met criteria for continued interferon therapy based on treatment futility protocols per most recent PA for hepatitis antiviral agents.

Cablivi

- Documentation of the following is required for a diagnosis of aTTP:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested agent will be used initially in conjunction with immunosuppressive therapy; **and**
  - requested quantity is ≤ one unit/day after initial bolus injection.

Doptelet

- Documentation of the following is required for a diagnosis of chronic, relapsed, or refractory ITP:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - platelet count < 30,000 cells/mcL; **or**
    - medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding); **and**
  - inadequate response, adverse reaction, or contraindication to eltrombopag; **and**
  - requested quantity is ≤ two units/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: corticosteroid, immunoglobulin; **or**
    - member has had a splenectomy.

- Documentation of the following is required for a diagnosis of thrombocytopenia due to CLD in a member scheduled to undergo a procedure:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - platelet count < 50,000 cells/mcL; **and**
  - one of the following:
    - if platelet count is 40,000 to < 50,000 cells/mcL, requested dose is 40 mg (two tablets) once daily for five days; **or**
    - if platelet count is less than 40,000 cells/mcL, requested dose is 60 mg (three tablets) once daily for five days.

Mulpleta

- Documentation of the following is required for a diagnosis of thrombocytopenia due to CLD in a member scheduled to undergo a procedure:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - platelet count < 50,000 cells/mcL; **and**
  - inadequate response, adverse reaction, or contraindication to Doptelet; **and**
  - requested dose is 3 mg once daily for a maximum of seven days.

Nplate

- Documentation of the following is required for a diagnosis of chronic, relapsed, or refractory ITP:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - one of the following:
    - platelet count < 30,000 cells/mcL; **or**
    - medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding); **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: corticosteroid, immunoglobulin; **or**
    - member has had a splenectomy; **and**
  - inadequate response, adverse reaction, or contraindication to eltrombopag.

- Documentation of the following is required for a diagnosis of HS-ARS/acute exposure to myelosuppressive doses of radiation:
  - appropriate diagnosis; **and**
  - requested dose is 10 mcg/kg for a one-time administration.

Promacta

- Documentation of the following is required for a diagnosis of chronic, relapsed, or refractory ITP:
  - appropriate diagnosis; **and**
  - member is ≥ one year of age; **and**
  - one of the following:
    - platelet count < 30,000 cells/mcL; **or**
    - medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding); **and**
  - requested dose is ≤ 75 mg/day; **and**
  - for Promacta 12.5 mg, requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: corticosteroid, immunoglobulin; **or**
    - member has had a splenectomy.

- Documentation of the following is required for a diagnosis of severe aplastic anemia:
  - appropriate diagnosis; **and**
  - member is ≥ two years of age; **and**
  - platelet count < 50,000 cells/mcL; **and**
  - requested dose is ≤ 150 mg/day; **and**
  - for Promacta 12.5 mg, requested quantity is ≤ one unit/day; **and**
  - one of the following:
    - inadequate response, adverse reaction, or contraindication to immunosuppressive therapy with anti-thymocyte globulin (ATG) and cyclosporine; **or**
    - member is treatment naïve and the requested agent will be used in combination with ATG and cyclosporine.

- Documentation of the following is required for a diagnosis of thrombocytopenia in the setting of hepatitis C with interferon therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is ≤100 mg/day; **and**
  - for Promacta 12.5 mg, requested quantity is ≤ one unit/day; **and**

- one of the following:
  - member intends to initiate therapy with interferon and current platelet count is ≤ 75,000 cells/mcL; **or**
  - both of the following:
    - member has already begun interferon therapy and platelet count supports continued use; **and**
    - member has met criteria for continued interferon therapy based on treatment futility protocols per most recent PA for hepatitis antiviral agents.

- Documentation of the following is required for a diagnosis of thrombocytopenia in the setting of hepatitis C independent of interferon therapy:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested dose is ≤100 mg/day; **and**
  - for Promacta 12.5 mg, requested quantity is ≤ one unit/day; **and**
  - current platelet count is ≤ 75,000 cells/mcL; **and**
  - member is not currently using interferon therapy and does not intend to begin therapy; **and**
  - inadequate response, adverse reaction, or contraindication to immunoglobulin.

Tavalisse

- Documentation of the following is required for a diagnosis of chronic, relapsed, or refractory ITP:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - platelet count < 30,000 cells/mcL; **or**
    - medical necessity for platelet elevation (upcoming surgery, peptic ulcer disease or condition that may predispose member to bleeding); **and**
  - inadequate response, adverse reaction, or contraindication to eltrombopag; **and**
  - requested quantity is ≤ two units/day; **and**
  - one of the following:
    - inadequate response or adverse reaction to one or contraindication to both of the following: corticosteroid, immunoglobulin; **or**
    - member has had a splenectomy.

MassHealth Evaluation Criteria

Table 69 - Barbiturates, Benzodiazepines, and Miscellaneous Antianxiety Agents

Drug Category: Central Nervous System

Medication Class/Individual Agents: Barbiturates, Benzodiazepines, and Miscellaneous Antianxiety Agents

I. Prior-Authorization Requirements

Benzodiazepines

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
alprazolam	Xanax	PA - < 6 years	#	• Extended-release and orally disintegrating benzodiazepine formulations require prior authorization (PA) due to the availability of less-costly dosage formulations. • For additional information regarding the management of benzodiazepine powders for compounding, please see: Table 79 - Pharmaceutical Compounds.
alprazolam extended-release	Xanax XR	PA - < 6 years and PA > 2 units/day	#	
alprazolam orally disintegrating tablet		PA		
chlordiazepoxide		PA - < 6 years		
clonazepam 0.125 mg, 0.25 mg, 0.5 mg, 1 mg orally disintegrating tablet		PA - < 6 years and PA > 3 units/day		
clonazepam 2 mg orally disintegrating tablet		PA - < 6 years and PA > 2 units/day		
clonazepam tablet	Klonopin	PA - < 6 years	#	
clorazepate		PA		
diazepam injection				
diazepam solution, tablet	Valium	PA - < 6 years	#	
estazolam		PA - < 6 years and PA > 1 unit/day		
flurazepam		PA		
lorazepam extended-release	Loreev XR	PA		
lorazepam injection	Ativan		#	
lorazepam solution, tablet	Ativan	PA - < 6 years	#	
midazolam injection			MB	
midazolam syrup		PA - < 6 years		
oxazepam		PA		
quazepam	Doral	PA		
remimazolam	Byfavo	PA	MB	
temazepam 22.5 mg	Restoril	PA		
temazepam 7.5 mg, 15 mg, 30 mg	Restoril	PA - < 6 years and PA > 1 unit/day	#	
triazolam	Halcion	PA - < 6 years and	#	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
		PA > 1 unit/day	

Antianxiety Agents – Not Otherwise Classified

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amitriptyline / chlordiazepoxide		PA		
buspirone		PA - < 6 years	A90	
chlordiazepoxide / clidinium	Librax	PA		
meprobamate		PA		

Barbiturates

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
phenobarbital 100 mg injection	Sezaby		MB	
phenobarbital 65 mg / mL, 130 mg / mL injection			MB	
phenobarbital tablet, solution				

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Alcohol withdrawal syndrome (alprazolam ER, clorazepate, oxazepam)
- Anxiety, panic disorder, skeletal muscle spasm, or seizure (benzodiazepines excluding chlordiazepoxide/clidinium)
- Anxiety (Loreev XR, meprobamate)
- Emotional and somatic factors in gastrointestinal disorders (chlordiazepoxide/clidinium)
- Adjunctive therapy in peptic ulcer, irritable bowel syndrome, and acute enterocolitis (chlordiazepoxide/clidinium)
- Induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less (Byfavo)
- Insomnia (estazolam, flurazepam, quazepam, temazepam, triazolam)
- Seizure disorder (clorazepate, oxazepam)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

alprazolam extended-release > two units/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested dose cannot be consolidated; **and**
  - medical records documenting titration of medication up to current dose; **and**
  - clinical rationale for dosing higher than FDA approved limits.

alprazolam orally disintegrating tablet

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - requested dose cannot be consolidated; **and**
  - medical necessity for an orally disintegrating tablet (ODT) formulation as indicated by both of the following:
    - member has a g-tube, dysphagia, or swallowing difficulties; **and**
    - member is currently not using other oral medications.

Byfavo

- Documentation of all of the following is required:
  - the agent will be used for induction and maintenance of procedural sedation; **and**
  - inadequate response, adverse reaction, or contraindication to intravenous midazolam; **and**
  - appropriate dosing.

chlordiazepoxide/amitriptyline

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical necessity for the use of the combination product instead of the commercially available separate agents.

SmartPA: Claims for chlordiazepoxide/amitriptyline will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims for the requested agent for at least 90 days of therapy out of the last 120 days.†

chlordiazepoxide/clidinium

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - requested quantity is ≤ eight units/day; **and**
  - prescriber is a gastrointestinal specialist or consult notes from a gastroenterology office are provided; **and**
  - inadequate response or adverse reaction to two or contraindication to all anticholinergic/antispasmodics; **and**
  - inadequate response or adverse reaction to one or contraindication to all SSRIs; **and**
  - inadequate response or adverse reaction to one or contraindication to all non-benzodiazepine anxiolytics; **and**
  - inadequate response or adverse reaction to one other benzodiazepine; **and**
  - requested medication will be used as an adjunctive therapy; **and**
  - for a diagnosis of peptic ulcer, all of the following:
    - inadequate response (defined as ≥ four weeks of therapy) or adverse reaction to two proton pump inhibitors, or contraindication to all proton pump inhibitors; **and**
    - requested treatment duration is ≤ 12 weeks; **and**
    - for H. pylori-positive peptic ulcer, an inadequate response to one four-week course of appropriate combination therapy; **or**
  - for a diagnosis of irritable bowel syndrome with constipation, both of the following:
    - inadequate response or adverse reaction to two or contraindication to all of the following: Linzess, lubiprostone, Trulance; **and**
    - inadequate response, adverse reaction, or contraindication to one agent from three of the four traditional laxative therapy classes (bulk forming laxatives, osmotic laxatives, saline laxatives, stimulant laxatives); **or**
  - for a diagnosis of irritable bowel syndrome with diarrhea, inadequate response or adverse reaction to five or contraindication to all of the following: bile acid sequestrants, bismuth subsalicylate, bulk-forming laxatives, diphenoxylate/atropine, loperamide, Xifaxan; **or**
  - for a diagnosis of acute enterocolitis, all of the following:
    - inadequate response, adverse reaction, or contraindication to both of the following: bismuth subsalicylate, loperamide; **and**
    - requested treatment duration ≤ three days.

clonazepam 0.125 mg, 0.25 mg, 0.5 mg, and 1 mg orally disintegrating tablet > three units/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or psychiatrist, or consult notes from a neurologist or psychiatrist are provided; **and**
  - requested dose cannot be consolidated within quantity limits; **and**
  - medical records documenting titration of medication up to current dose; **and**
  - clinical rationale for dosing higher than the FDA approved limits.

clonazepam 2 mg orally disintegrating tablet > two units/day

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neurologist or psychiatrist, or consult notes from a neurologist or psychiatrist are provided; **and**
  - requested dose cannot be consolidated within the quantity limit; **and**
  - medical records documenting titration of medication up to current dose; **and**
  - clinical rationale for dosing higher than the FDA approved limits.

clorazepate and oxazepam

- Documentation of all of the following is required
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all benzodiazepines: alprazolam, chlordiazepoxide,

clonazepam, diazepam, lorazepam.

SmartPA: Claims for clorazepate and oxazepam will usually process at the pharmacy without a PA request if the member has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 days of therapy out of the last 120 days.†

estazolam, flurazepam, temazepam 7.5 mg, 15 mg, and 30 mg, quazepam, and triazolam 0.125 mg > one unit/day

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of all of the following is required:
  - diagnosis of insomnia; **and**
  - requested dose cannot be consolidated; **and**
  - medical necessity for exceeding the quantity limit noted by all of the following:
    - inadequate response to the established quantity limit; **and**
    - higher dose was effective in alleviating symptoms; **and**
    - for requests exceeding the FDA-approved maximum dose, inadequate response or adverse reaction to two alternatives for sleep (one must be a non-benzodiazepine hypnotic):
      - non-benzodiazepine hypnotics: eszopiclone, zaleplon, zolpidem (IR or ER); **or**
      - other alternatives: Belsomra, Dayvigo, diphenhydramine, doxepin capsule, doxepin tablet, melatonin, Quvivq, Rozerem, trazodone.

flurazepam and quazepam

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an inadequate response or adverse reaction to all of the following hypnotic benzodiazepines: estazolam, temazepam 7.5, 15, or 30 mg, triazolam; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - medical necessity for > one unit/day.

Loreev XR

- Documentation of all of the following is required
  - appropriate diagnosis; **and**
  - medical records documenting stability with lorazepam tablets in three evenly divided daily doses; **and**
  - one of the following:
    - medical records documenting inadequate response or adverse reaction to two intermediate/long- or long-acting benzodiazepines; **or**
    - contraindication to all other long-acting benzodiazepines; **and**
  - requested quantity is ≤ one unit/day.

meprobamate

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction to two or contraindication to all benzodiazepines (Please note, up to two one-month provisional approvals may be allowed for members who are stabilized on the requested medication to avoid risk of withdrawal).
- For recertification requests, documentation of all of the following is required:
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to three or contraindication to all of the following: buspirone, SSRI, SNRI, TCA; **and**
  - clinical rationale for continued therapy with meprobamate.

temazepam 22.5 mg

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction or inadequate response to all of the following hypnotic benzodiazepines:
    - estazolam; **and**
    - temazepam 7.5 mg, 15 mg, or 30 mg; **and**
    - triazolam; **and**
  - one of the following:
    - requested quantity is ≤ one unit/day; **or**
    - all of the following
      - inadequate response to 30 mg/day; **and**
      - medical records documenting titration of medication up to current dose; **and**
      - clinical rationale for dosing higher than the FDA approved limits.

triazolam 0.25 mg > one unit/day
- Documentation of all of the following is required:
  - diagnosis of insomnia; **and**
  - inadequate response to 0.25 mg/day.

Brand-name products (Ativan, Klonopin, Xanax)
- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - medical records documenting an adverse reaction or inadequate response to a generic equivalent of the requested product; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one other non-hypnotic benzodiazepine; **and**
  - requested dose cannot be consolidated within the quantity limit.

Benzodiazepine Polypharmacy ***(overlapping pharmacy claims for two or more benzodiazepines [excludes clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations] for at least 60 days within a 90-day period)*** **for members ≥ 18 years of age**
- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for a sleep diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a neurologist, sleep medicine specialist, or psychiatrist, or consultation notes from specialist are provided; **and**
    - clear treatment plan (i.e., medication name(s), dose, frequency); **and**
    - severity of sleep diagnosis outlined; **and**
    - intended treatment duration and prescriber follow-up plan noted; **and**
    - one of the following:
      - cross-titration/taper of benzodiazepine therapy (Please note, six-month provisional approval may be allowed for members who are cross-titrating or tapering from one agent to another); **or**
      - both of the following:
        - inadequate response, adverse reaction, or contraindication to all alternative hypnotics indicated for diagnosis: eszopiclone, zaleplon, zolpidem (IR or ER), an orexin receptor antagonist (Belsomra, Dayvigo, Quviviq), Rozerem, Silenor or doxepin capsules; **and**
        - the benzodiazepine regimen includes one short acting benzodiazepine agent and one long-acting benzodiazepine agent (Please note, up to two one-month provisional approvals may be allowed for members whose regimens include two short-acting or two long-acting benzodiazepine agents and all other criteria are met).

- Documentation of the following is required for a psychiatric diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - clear treatment plan (i.e., diagnosis intended to treat, medication name(s), dose, frequency); **and**
    - severity of psychiatric condition outlined; **and**
    - intended treatment duration and prescriber follow-up plan noted; **and**
    - one of the following:
      - cross-titration/taper of benzodiazepine therapy (Please note, six-month provisional approval may be allowed for members who are cross-titrating or tapering from one agent to another); **or**
      - both of the following:
        - inadequate response or adverse reaction to three (trials must include at least one SSRI and one SNRI, unless classes are contraindicated) or contraindication to all of the following: buspirone (for the diagnosis of GAD only), mirtazapine, SNRI, SSRI, TCA, Trintellix, vilazodone; **and**
        - the benzodiazepine regimen includes one short acting benzodiazepine agent and one long-acting benzodiazepine agent (Please note, up to two one-month provisional approvals may be allowed for members whose regimens include two short-acting or two long-acting benzodiazepine agents and all other criteria are met).

Please note, up to two one-month provisional approvals may be allowed for members who are stabilized on the requested medication(s) to avoid risk of destabilization.

- Documentation of the following is required for a musculoskeletal diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - clear treatment plan (i.e., diagnosis intended to treat, medication name(s), dose, frequency); **and**
    - severity of musculoskeletal condition outlined; **and**
    - intended treatment duration and prescriber follow-up plan noted; **and**
    - one of the following:
      - cross-titration/taper of benzodiazepine therapy (Please note, six-month provisional approval may be allowed for members who are cross-titrating or tapering from one agent to another); **or**
      - both of the following:
        - inadequate response or adverse reaction to three or contraindication to all of the following skeletal muscle relaxants: chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, orphenadrine; **and**
        - the benzodiazepine regimen includes one short-acting benzodiazepine agent and one long-acting benzodiazepine agent (Please note, up to two one-month provisional approvals may be allowed for members whose regimens include two short-acting or two long-acting benzodiazepine agents and all other criteria are met).

Please note, up to two one-month provisional approvals may be allowed for members who are stabilized on the requested medication(s) to avoid risk of destabilization.

- Documentation of the following is required for a seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**

- member has a history of severe risk of harm to self or others; **or**
- all of the following:
  - appropriate diagnosis; **and**
  - clear treatment plan (i.e., diagnosis intended to treat, medication name(s), dose, frequency); **and**
  - intended treatment duration and prescriber follow-up plan noted; **and**
  - one of the following:
    - stability on the requested regimen; **or**
    - cross-titration/taper of benzodiazepine therapy (Please note, six-month provisional approval may be allowed for members who are cross-titrating or tapering from one agent to another); **or**
    - both of the following:
      - inadequate response or adverse reaction to three anticonvulsants; **and**
      - the benzodiazepine regimen includes one short-acting benzodiazepine agent and one long-acting benzodiazepine agent.

Please note, up to two one-month provisional approvals may be allowed for members who are stabilized on the requested medication(s) to avoid risk of destabilization.

- Documentation of the following is required for both a seizure and psychiatric diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - clear treatment plan (i.e., diagnosis intended to treat, medication name(s), dose, frequency); **and**
    - intended treatment duration and prescriber follow-up plan noted; **and**
    - one of the following:
      - stability on the requested regimen; **or**
      - cross-titration/taper of benzodiazepine therapy (Please note, six-month provisional approval may be allowed for members who are cross-titrating or tapering from one agent to another); **or**
      - all of the following:
        - inadequate response or adverse reaction to three anticonvulsants; **and**
        - inadequate response or adverse reaction to three (trials must include at least one SSRI and one SNRI, unless classes are contraindicated) or contraindication to all of the following: buspirone (for the diagnosis of GAD only), mirtazapine, SNRI, SSRI, TCA, Trintellix, vilazodone; **and**
        - the benzodiazepine regimen includes one short-acting benzodiazepine agent and one long-acting benzodiazepine agent.

Please note, up to two one-month provisional approvals may be allowed for members who are stabilized on the requested medication(s) to avoid risk of destabilization.

Concomitant Opioid and Benzodiazepine Polypharmacy *(pharmacy claims for ≥ 15 days supply for one or more opioid(s) [new to therapy] and one or more benzodiazepine(s) [clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations are not included] for ≥ 15 days supply within the past 45-day period.)*

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of all of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - appropriate diagnosis for the benzodiazepine; **and**
  - appropriate diagnosis for the opioid; **and**
  - one of the following:

- member's treatment is currently managed by palliative care; **or**
- member is currently in hospice or is transitioning to hospice; **or**
- member is currently being treated for sickle cell disease or cancer pain; **or**
- if the benzodiazepine is being used for a psychiatric diagnosis, an inadequate response (defined as ≥ 4 weeks of therapy), or adverse reaction to three antidepressants, or contraindication to all antidepressants; **or**
- if the benzodiazepine is being used for a musculoskeletal diagnosis, an inadequate response, or adverse reaction to three skeletal muscle relaxants (e.g., cyclobenzaprine, chlorzoxazone, metaxalone, methocarbamol, orphenadrine), or a contraindication to all skeletal muscle relaxants; **or**
- if the benzodiazepine is being used for a sleep disorder, an inadequate response, or adverse reaction to three non-benzodiazepine sleep medications, or a contraindication to all non-benzodiazepine sleep medications; **or**
- if the benzodiazepine is being used for a seizure disorder, member is stable on a non-benzodiazepine anticonvulsant; **or**
- treatment plan to taper off or taper down from benzodiazepine therapy; **or**
- treatment plan to taper off opioid therapy; **or**
- clinical rationale for the concomitant use of opioids and benzodiazepines; **and**

- member will be co-prescribed naloxone.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Behavioral Health Medication Polypharmacy (*pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, and viloxazine] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period*) for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist (including psychiatric nurse practitioners) neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.
- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**

- prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist (including psychiatric nurse practitioners) neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation; **and**
- one of the following:
  - member has a seizure diagnosis only; **or**
  - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
  - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
  - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and**
  - one off the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Benzodiazepine Polypharmacy ***(overlapping pharmacy claims for two or more benzodiazepines [hypnotic benzodiazepine agents, clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations are not included] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a seizure diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current benzodiazepines and corresponding diagnoses; **and**
    - one of the following:
      - cross-titration/taper of benzodiazepine therapy; **or**
      - clinical rationale for use of ≥ two benzodiazepines of different chemical entities.

buspirone for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**

- treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
- prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation.

Benzodiazepine *(hypnotic benzodiazepine agents are not included)* for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a seizure diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding indications; **and**
    - prescriber is a specialist (e.g. psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

SmartPA: Claims for mood stabilizers or benzodiazepines will usually process at the pharmacy without a PA request if the member is < six years of age, has a history of MassHealth medical claims for seizure, and does not have a history of MassHealth medical claims for psychiatric diagnoses and/or other diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain).†

Hypnotic agents in members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for members with a diagnosis of insomnia with other behavioral health comorbidities, excluding ADHD/ASD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis of insomnia without behavioral health comorbidities or insomnia with comorbid ASD:

- treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
- prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
- if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation; **and**
- inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to melatonin.

- Documentation of the following is required for members with a diagnosis of insomnia with comorbid ADHD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation; **and**
  - inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - inadequate response (defined by ≥ 10 days of therapy), adverse reaction, or contraindication to clonidine.

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 70 - Progesterone Agents

Drug Category: Endocrine/Metabolic Agents

Medication Class/Individual Agents: Progesterone agents

I. Prior-Authorization Requirements

Progesterone Agents				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
hydroxyprogesterone caproate injection		PA		**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** • On April 6, 2023 the Food and Drug Administration (FDA) announced a final decision to withdraw the approval of Makena (hydroxyprogesterone caproate, HPC, 17-OHPC) and effective immediately Makena and its generics are no longer approved.[1] • The American Academy of Obstetricians and Gynecologists has updated the Clinical Guidance for the Use of Progesterone Supplementation for the Prevention of Recurrent Preterm Birth noting that hydroxyprogesterone caproate is not recommended for the primary prevention of preterm birth in patients with a history of spontaneous preterm birth.[2] • Preterm birth is a significant public health issue in the United States. According to the March of Dimes, preterm birth or the birth of a baby at less than 37 weeks of gestation affects one in ten babies born in the United States. Although the causes of spontaneous preterm birth are often unknown, a leading risk factor is history of prior preterm birth, pregnancy of multiples, and abnormalities associated with the uterus or cervix.[3] • Hydroxyprogesterone caproate injection is ONLY indicated in non-pregnant women for the treatment of advanced adenocarcinoma of the uterine corpus (Stage III or IV), in the management of amenorrhea (primary or
progesterone gel	Crinone	PA		
progesterone vaginal insert	Endometrin	PA		

	Clinical Notes
	secondary) and abnormal uterine bleeding, as a test for endogenous estrogen production and for the production of secretory endometrium and desquamation.[4] [1]FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena [press release on the Internet]. Rockville (MD): Food and Drug Administration (US); 2023 April 6 [cited 2023 Apr 6]. Available from: https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena. [2]American College of Obstetricians and Gynecologists. Updated Clinical Guidance for the Use of Progesterone Supplementation for the Prevention of Recurrent Preterm Birth. 2023 [Practice Advisory on the internet] [cited 2023 Apr 12]. Available from: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/04/updated-guidance-use-of-progesterone-supplementation-for-prevention-of-recurrent-preterm-birth. [3]Preterm labor and premature birth [webpage on the Internet]. March of Dimes; 2016 Mar 1 [cited 2021 Oct 16]. Available from: http://www.marchofdimes.org/complications/preterm-labor-and-premature-birth.aspx [4]Hydroxyprogesterone caproate [package insert on the Internet]. Morgantown (WV): Mylan Institutional LLC; 2021 Nov [cited 2023 April 13]. Available from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0919b927-c57c-40ae-88a8-39e9efe4f677

II. Therapeutic Uses

FDA-approved, for example:

- Advanced adenocarcinoma of the uterine corpus
- Management of amenorrhea (primary and secondary)
- Production of secretory endometrium and desquamation
- Progestin challenge for the diagnosis of secondary amenorrhea
- Test for endogenous estrogen production

Non-FDA-approved, for example:

- Maintenance of pregnancy/placental support through gestational week 12 after positive pregnancy test
- Prevention of miscarriage with history of recurrent miscarriages through gestational week 12
- Prevention of spontaneous preterm birth

- Short cervix

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Crinone

- Documentation of all the following is required for requests for Crinone 4% or 8% gel for progestin challenge for the diagnosis of secondary amenorrhea:
  - appropriate diagnosis; **and**
  - inadequate response or adverse drug reaction to one or contraindication to all of the following: medroxyprogesterone, norethindrone, progesterone capsule; **and**
  - requested dose is ≤ six doses; **and**
  - for the 8% gel, inadequate response or adverse reaction to the 4% gel.
- Documentation of all the following is required for requests for Crinone 8% gel for all other diagnoses:
  - indication of one of the following:
    - prevention of spontaneous preterm birth with one of the following:
      - both of the following:
        - history of spontaneous singleton delivery and/or premature rupture of membranes; **and**
        - gestational age ≥ 18 weeks to < 23 weeks; **and**
      - both of the following: diagnosis of short cervix and gestational age ≥ 18 weeks to < 23 weeks; **or**
    - maintenance of pregnancy/placental support through gestational week 12 after positive pregnancy test; **or**
    - prevention of miscarriage with history of recurrent miscarriages through gestational week 12; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: compounded progesterone suppository, progesterone injection, oral progesterone capsule, Endometrin (progesterone vaginal insert); **and**
  - appropriate dosing and treatment duration.

Endometrin

- Documentation of all the following is required for the diagnosis of prevention of spontaneous preterm birth:
  - appropriate diagnosis; and
  - gestational age ≥ 18 weeks to < 23 weeks; and
  - one of the following:
    - member has a history of spontaneous singleton delivery and/or premature rupture of membranes; or
    - short cervix.

hydroxyprogesterone caproate injection

- Documentation of all the following is required:
  - indication of one of the following:
    - treatment of advanced adenocarcinoma of the uterine corpus (stage III or IV); **or**
    - management of amenorrhea (primary and secondary); **or**
    - member requires a test for endogenous estrogen production; **or**
    - production of secretory endometrium and desquamation; **and**
  - appropriate dosing.

Please note: The MassHealth agency does not pay for any drug when used to promote fertility as described in 130 CMR 406.413(B) "Limitations on Coverage of Drugs – Drug Exclusions" (see link below).
https://www.mass.gov/regulations/130-CMR-406000-pharmacy-services

MassHealth Evaluation Criteria
Table 71 - Pediatric Behavioral Health

Drug Category: Behavioral Health

Medication Class/Individual Agents: various

I. Prior-Authorization Requirements

Pediatric Behavioral Health – Second-Generation (Atypical) Antipsychotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
aripiprazole extended-release injection	Abilify Asimtufii	PA	
aripiprazole extended-release injection	Abilify Maintena	PA	
aripiprazole lauroxil 1,064 mg	Aristada PD	PA - < 10 years and PA > 1 injection/56 days	
aripiprazole lauroxil 441 mg, 662 mg, 882 mg	Aristada PD	PA - < 10 years and PA > 1 injection/28 days	
aripiprazole lauroxil 675 mg	Aristada Initio PD	PA - < 10 years and PA > 1 injection/28 days	
aripiprazole orally disintegrating tablet		PA	A90
aripiprazole solution		PA - < 10 years or ≥ 18 years and PA > 25 mL/day	A90
aripiprazole tablet	Abilify	PA - < 10 years and PA > 2 units/day	# , A90
aripiprazole tablet with sensor	Abilify Mycite	PA	
asenapine sublingual tablet	Saphris	PA	A90
asenapine transdermal	Secuado	PA	
brexpiprazole	Rexulti	PA	
cariprazine	Vraylar PD	PA	
clozapine orally disintegrating tablet		PA	A90
clozapine suspension	Versacloz	PA	A90
clozapine tablet	Clozaril	PA - < 10 years	# , A90
iloperidone	Fanapt	PA	
lumateperone	Caplyta	PA	

Clinical Notes

Please note: For a comprehensive list of all behavioral health medications included in the Pediatric Behavioral Health Medication Initiative, please see Appendix I below. The member will need to meet all criteria for the requested agent as specified in the respective medication class guideline, if applicable.

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- The American Academy of Child and Adolescent Psychiatry Practice Parameter on the use of Psychotropic Medications in Children and Adolescents encourages a complete medical and psychiatric evaluation before initiation of pharmacotherapy, a psychosocial and psychopharmacological treatment and monitoring strategy, and member and family education about the treatment plan.[1]
- A treatment and monitoring plan is essential to properly assess therapy response and adverse effects upon initiation, dose optimization, and discontinuation. Appropriate follow-up allows for opportunities to educate the member and family/caregiver and to address treatment plan concerns.[1]
- Evidence-based and age-appropriate psychosocial treatments should be tried prior to psychopharmacologic

Pediatric Behavioral Health – Second-Generation (Atypical) Antipsychotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
lurasidone 20 mg, 40 mg, 60 mg, 120 mg	Latuda	PA - < 10 years and PA > 1 unit/day	# , A90
lurasidone 80 mg	Latuda	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 15 mg orally disintegrating tablet	Zyprexa Zydis	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 15 mg, 20 mg tablet	Zyprexa	PA - < 10 years and PA > 2 units/day	# , A90
olanzapine 2.5 mg, 5 mg, 7.5 mg, 10 mg tablets	Zyprexa	PA - < 10 years and PA > 3 units/day	# , A90
olanzapine 210 mg, 300 mg extended-release injection	Zyprexa Relprevv	PA - < 10 years and PA > 2 injections/28 days	
olanzapine 405 mg extended-release injection	Zyprexa Relprevv	PA - < 10 years and PA > 1 injection/28 days	
olanzapine 5 mg, 10 mg, 20 mg orally disintegrating tablet	Zyprexa Zydis	PA - < 10 years and PA > 1 unit/day	# , A90
paliperidone 1.5 mg, 3 mg, 9 mg tablet	Invega	PA - < 10 years and PA > 1 unit/day	# , A90
paliperidone 6 mg tablet	Invega	PA - < 10 years and PA > 2 units/day	# , A90
paliperidone extended-release 1-month injection	Invega Sustenna PD	PA - < 10 years, PA > 2 injections/28 days within the first 28 days of therapy and PA > 1 injection/28 days after 28 days of therapy	
paliperidone extended-release 3-month injection	Invega Trinza PD	PA - < 10 years and PA > 1 injection/84 days	
paliperidone extended-release 6-month injection	Invega Hafyera PD	PA - < 10 years and PA > 1 injection/168 days	
quetiapine	Seroquel	PA - < 10 years and PA > 3 units/day	# , A90
quetiapine extended-release	Seroquel XR	PA - < 10 years and PA > 2 units/day	# , A90
risperidone 0.25		PA - < 10 years	A90

Clinical Notes

treatments in pediatric members as clinically appropriate.[2] Pharmacological treatments should be reserved for members who have not responded to psychological treatment and if benefits outweigh the risks associated with treatment.[3]

- Psychotherapy in combination with pharmacotherapy may lead to more favorable outcomes compared to either treatment alone.[4,5] Member and family/caregiver education about the importance of both interventions is essential.[6]
- With initial treatment non-response, dose optimization or switching to an alternative agent should be considered prior to polypharmacy when clinically appropriate.[7] Prescribers should have clear rationale for use of medication combinations to treat a condition, multiple comorbidities, and/or adverse effects resulting from therapy.[1] At this time there is limited evidence supporting the use of medication polypharmacy from the same medication class, especially in the pediatric and adolescent population.[1]
- Refractory members and those considered as being a risk to self or others should be referred to a specialist provider.[7]

References:

[1] Walkup J, Work Group on Quality Issues. Practice parameter on the use of psychotropic medication in children and adolescents. J Am Acad Child Adolesc Psychiatry. 2009 Sep;48(9):961-973. doi: 10.1097/CHI.0b013e3181ae0a08. PMID: 19692857.

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[3] Anderson IM, Ferrier IN, Baldwin RC, Cowen PJ, Howard L, Lewis G, et al. Evidence-based guidelines for treating depressive disorders with antidepressants: a revision of the 2000 British Association for the Psychopharmacology guidelines. J Psychopharmacology. 2008;22(4):343-96.

[4] Walkup JT, Albano AM, Piacentini J, et al. Cognitive behavioral therapy, sertraline, or a combination in childhood anxiety. N Engl J Med 2008;359(26):2753-66.

[5] March J, Silva S, Petrycki S, CurryJ, Wells K, Fairbank J, et al. Fluoxetine, cognitive-behavioral therapy and their

Pediatric Behavioral Health – Second-Generation (Atypical) Antipsychotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
mg, 0.5 mg, 1 mg, 2 mg orally disintegrating tablet		and PA > 2 units/day	
risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg tablets	Risperdal	PA - < 10 years and PA > 3 units/day	# , A90
risperidone 12.5 mg, 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection-Risperdal Consta	Risperdal Consta	PA - < 10 years and PA > 2 injections/28 days	BP
risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection	Uzedy PD	PA - < 10 years and PA > 1 injection/56 days	
risperidone 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection-Rykindo	Rykindo	PA	
risperidone 3 mg, 4 mg orally disintegrating tablet		PA	A90
risperidone 4 mg tablet	Risperdal	PA - < 10 years and PA > 4 units/day	# , A90
risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection	Uzedy PD	PA - < 10 years and PA > 1 injection/28 days	
risperidone 90 mg, 120 mg extended-release subcutaneous injection	Perseris PD	PA - < 10 years and > 1 injection/28 days	
risperidone solution	Risperdal	PA - < 10 years and PA > 16 mL/day	# , A90
ziprasidone capsule	Geodon	PA - < 10 years and PA > 2 units/day	# , A90

Clinical Notes

combination for adolescents with depression: treatment for adolescents with depression (TADS) randomized controlled -trial. JAMA.2004;292(7):807-20.

[6] Stroeh O and Trivedi H. Appropriate and judicious use of psychotropic medications in youth. Child Adolesc Psychiatric Clin N Am. 2012;21:703-11.

[7] Balwin DS, Anderson IM, Nutt DJ, Allqulander C, Bandelow B, den Boer JA, et al. Evidence-based pharmacological treatment of anxiety disorders, post-traumatic stress disorder and obsessive-compulsive disorder: a revision of the 2005 guidelines from the British Association for Psychopharmacology. J Psychopharmacology. 2014;28(5):403-39.

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Short- and Intermediate-Acting Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphetamine salts	Adderall	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
amphetamine sulfate		PA	
amphetamine sulfate orally disintegrating tablet	Evekeo ODT	PA	
dexmethylphenidate	Focalin	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg tablet		PA	
dextroamphetamine 5 mg, 10 mg tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
dextroamphetamine 5 mg, 10 mg, 15 mg capsule	Dexedrine Spansule	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#
dextroamphetamine solution		PA - < 3 years or ≥ 21 years and PA > 40 mL/day	
methamphetamine	Desoxyn	PA	
methylphenidate chewable tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
methylphenidate oral solution	Methylin oral solution	PA - < 3 years or ≥ 21 years and PA > 30 mL/day	#
methylphenidate sustained-release tablet		PA - < 3 years or ≥ 21 years and PA > 3 units/day	
methylphenidate-Ritalin	Ritalin	PA - < 3 years or ≥ 21 years and PA > 3 units/day	#

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Long-Acting Amphetamine Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphetamine extended-release 1.25 mg/mL oral suspension		PA	
amphetamine extended-release 2.5 mg/mL oral suspension	Dyanavel XR	PA	

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Long-Acting Amphetamine Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amphetamine extended-release chewable tablet	Dyanavel XR	PA	
amphetamine extended-release orally disintegrating tablet	Adzenys XR-ODT	PA	
amphetamine salts extended-release-Adderall XR	Adderall XR	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
amphetamine salts extended-release-Mydayis	Mydayis	PA	
lisdexamfetamine capsule	Vyvanse	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
lisdexamfetamine chewable tablet	Vyvanse	PA	BP

Pediatric Behavioral Health – Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
armodafinil	Nuvigil	PA - < 6 years and PA > 1 unit/day	#
donepezil 10 mg tablet	Aricept	PA - < 6 years and PA > 2 units/day	# , A90
donepezil 5 mg, 23 mg tablet	Aricept	PA - < 6 years and PA > 1 unit/day	# , A90
donepezil orally disintegrating tablet		PA - < 6 years and PA > 1 unit/day	A90
donepezil patch	Adlarity	PA	
memantine / donepezil extended-release	Namzaric	PA	
memantine extended-release	Namenda XR	PA - < 6 years and PA > 1 unit/day	# , A90
memantine solution		PA	A90
memantine tablet	Namenda	PA - < 6 years and PA > 2 units/day	# , A90
memantine titration pack	Namenda	PA - < 6 years and PA > 49 units/28 days	A90
modafinil 100 mg	Provigil	PA - < 6 years and PA > 1.5 units/day	#
modafinil 200 mg	Provigil	PA - < 6 years and PA > 2 units/day	#
naltrexone tablet		PA - < 6 years	A90
prazosin	Minipress	PA - < 6 years	# , M90

Pediatric Behavioral Health – Hypnotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
daridorexant	Quviviq	PA	
doxepin tablet		PA	A90
estazolam		PA - < 6 years and PA > 1 unit/day	
eszopiclone	Lunesta	PA - < 6 years and PA > 1 unit/day	#
flurazepam		PA	
lemborexant	Dayvigo	PA	
suvorexant	Belsomra	PA	
temazepam 22.5 mg	Restoril	PA	
temazepam 7.5 mg, 15 mg, 30 mg	Restoril	PA - < 6 years and PA > 1 unit/day	#
triazolam	Halcion	PA - < 6 years and PA > 1 unit/day	#
zaleplon		PA - < 6 years and PA > 1 unit/day	
zolpidem 1.75 mg, 3.5 mg sublingual tablet		PA	
zolpidem 10 mg tablet	Ambien	PA - < 6 years and PA > 1 unit/day	#
zolpidem 5 mg tablet	Ambien	PA - < 6 years and PA > 1.5 units/day	#
zolpidem 5 mg, 10 mg sublingual tablet	Edluar	PA	
zolpidem 7.5 mg capsule		PA	
zolpidem extended -release tablet	Ambien CR	PA - < 6 years and PA > 1 unit/day	#

Pediatric Behavioral Health – Antidepressants - Tricyclic Antidepressants (TCA)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline tablet		PA - < 6 years	A90
amoxapine		PA	A90
clomipramine	Anafranil	PA	A90
desipramine	Norpramin	PA	A90
doxepin capsule, oral concentrate		PA - < 6 years	A90
imipramine hydrochloride		PA - < 6 years	A90
imipramine pamoate		PA	A90
nortriptyline	Pamelor	PA - < 6 years	# , A90
protriptyline		PA	A90

Pediatric Behavioral Health – Antidepressants - Tricyclic Antidepressants (TCA)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
trimipramine		PA	A90

Pediatric Behavioral Health – Antidepressants - Norepinephrine/Dopamine Reuptake Inhibitors (NDRI)

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
bupropion hydrobromide extended-release	Aplenzin	PA	
bupropion hydrochloride extended-release 150 mg, 300 mg tablet	Wellbutrin XL	PA - < 6 years and PA > 1 unit/day	# , A90
bupropion hydrochloride extended-release 450 mg tablet	Forfivo XL	PA	A90
bupropion hydrochloride immediate-release		PA - < 6 years	A90
bupropion hydrochloride sustained-release-Wellbutrin SR	Wellbutrin SR	PA - < 6 years	# , A90
bupropion hydrochloride sustained-release-Zyban	Zyban	PA - < 6 years	# , A90

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Long-Acting Methylphenidate Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes
dexmethylphenidate extended-release	Focalin XR	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
dextroamphetamine transdermal	Xelstrym	PA	
methylphenidate extended-release 72 mg tablet		PA	
methylphenidate extended-release chewable tablet	Quillichew ER	PA	
methylphenidate extended-release	Quillivant XR	PA	

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Long-Acting Methylphenidate Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
oral suspension			
methylphenidate extended-release orally disintegrating tablet	Cotempla XR-ODT	PA	
methylphenidate extended-release, CD		PA	
methylphenidate extended-release-Aptensio XR	Aptensio XR	PA	
methylphenidate extended-release-Concerta	Concerta	PA - < 3 years or ≥ 21 years and PA > 2 units/day	BP
methylphenidate extended-release-Jornay PM	Jornay PM	PA	
methylphenidate extended-release-Relexxii	Relexxii	PA	
methylphenidate transdermal	Daytrana	PA - < 3 years or ≥ 21 years and PA > 1 unit/day	BP
methylphenidate-Ritalin LA	Ritalin LA	PA	
serdexmethylphenidate / dexmethylphenidate	Azstarys	PA	

Pediatric Behavioral Health – Mood Stabilizers			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
carbamazepine extended-release	Carbatrol	PA - < 6 years	# , A90
carbamazepine extended-release	Equetro	PA - < 6 years	
carbamazepine extended-release	Tegretol XR	PA - < 6 years	BP, A90
carbamazepine-Tegretol	Tegretol	PA - < 6 years	# , A90
divalproex extended-release	Depakote ER	PA - < 6 years	# , A90
divalproex immediate-release	Depakote	PA - < 6 years	# , A90
divalproex sprinkle capsule	Depakote	PA - < 6 years	BP, A90
eslicarbazepine	Aptiom	PA	
gabapentin	Neurontin	PA - < 6 years and	#

Pediatric Behavioral Health – Mood Stabilizers			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
capsule, solution, tablet		PA > 3600 mg/day	
gabapentin enacarbil	Horizant	PA - < 6 years and PA > 1200 mg/day	BP
gabapentin extended-release	Gralise	PA	
lamotrigine dispersible tablet	Lamictal	PA - < 6 years	# , A90
lamotrigine extended-release tablet	Lamictal XR	PA	A90
lamotrigine extended-release tablet starter kit	Lamictal XR	PA	
lamotrigine orally disintegrating tablet	Lamictal ODT	PA	A90
lamotrigine orally disintegrating tablet starter kit	Lamictal ODT	PA	
lamotrigine tablet	Lamictal	PA - < 6 years	# , A90
lamotrigine tablet starter kit	Lamictal	PA	
lithium	Lithobid	PA - < 6 years	# , A90
oxcarbazepine extended-release	Oxtellar XR	PA	BP
oxcarbazepine suspension	Trileptal	PA - < 6 years	BP, A90
oxcarbazepine tablet	Trileptal	PA - < 6 years	# , A90
pregabalin	Lyrica	PA - < 6 years and PA > 600 mg/day	#
pregabalin extended-release	Lyrica CR	PA	BP
topiramate extended-release capsule-Qudexy XR	Qudexy XR	PA - < 6 years	BP, A90
topiramate extended-release capsule-Trokendi XR	Trokendi XR	PA	BP, A90
topiramate solution	Eprontia	PA	
topiramate sprinkle capsule	Topamax	PA - < 6 years	# , A90
topiramate tablet	Topamax	PA - < 6 years	# , A90
valproic acid	Depakene	PA - < 6 years	# , A90

Pediatric Behavioral Health – Antianxiety Agents - Benzodiazepines			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
alprazolam	Xanax	PA - < 6 years	#
alprazolam extended-release	Xanax XR	PA - < 6 years and PA > 2 units/day	#
alprazolam orally disintegrating tablet		PA	
chlordiazepoxide		PA - < 6 years	
clonazepam 0.125 mg, 0.25 mg, 0.5 mg, 1 mg orally disintegrating tablet		PA - < 6 years and PA > 3 units/day	
clonazepam 2 mg orally disintegrating tablet		PA - < 6 years and PA > 2 units/day	
clonazepam tablet	Klonopin	PA - < 6 years	#
clorazepate		PA	
diazepam solution, tablet	Valium	PA - < 6 years	#
lorazepam extended-release	Loreev XR	PA	
lorazepam solution, tablet	Ativan	PA - < 6 years	#
midazolam syrup		PA - < 6 years	
oxazepam		PA	
quazepam	Doral	PA	

Pediatric Behavioral Health – Antidepressants - NMDA Receptor Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dextromethorphan / bupropion	Auvelity	PA	
esketamine	Spravato	PA	

Pediatric Behavioral Health – Antidepressants - Selective Serotonin Reuptake Inhibitors (SSRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
citalopram capsule		PA	A90
citalopram solution, tablet	Celexa	PA - < 6 years	# , A90
escitalopram	Lexapro	PA - < 6 years	# , A90
fluoxetine 10 mg,		PA - < 6 years	A90

Pediatric Behavioral Health – Antidepressants - Selective Serotonin Reuptake Inhibitors (SSRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
20 mg tablet for premenstrual dysphoric disorder			
fluoxetine 10 mg, 20 mg, 40 mg capsule, solution	Prozac	PA - < 6 years	# , A90
fluoxetine 60 mg tablet		PA	A90
fluoxetine 90 mg delayed-release capsule		PA	A90
fluvoxamine extended-release		PA	A90
fluvoxamine immediate-release		PA - < 6 years	A90
paroxetine controlled-release	Paxil CR	PA	A90
paroxetine hydrochloride	Paxil	PA - < 6 years	# , A90
sertraline capsule		PA	A90
sertraline oral concentrate, tablet	Zoloft	PA - < 6 years	# , A90

Pediatric Behavioral Health – Antidepressants - Serotonin/Norepinephrine Reuptake Inhibitors (SNRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
desvenlafaxine extended-release		PA	A90
desvenlafaxine succinate extended-release	Pristiq	PA - < 6 years and PA > 1 unit/day	# , A90
duloxetine 20 mg, 30 mg, 60 mg capsule	Cymbalta	PA - < 6 years	# , A90
duloxetine 40 mg capsule		PA	A90
duloxetine sprinkle capsule	Drizalma	PA	
levomilnacipran	Fetzima	PA	
venlafaxine besylate extended -release tablet		PA	A90
venlafaxine extended-release capsule	Effexor XR	PA - < 6 years	# , A90
venlafaxine		PA	A90

Pediatric Behavioral Health – Antidepressants - Serotonin/Norepinephrine Reuptake Inhibitors (SNRI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
hydrochloride extended-release tablet			
venlafaxine immediate-release		PA - < 6 years	A90

Pediatric Behavioral Health – Antidepressants - Monoamine Oxidase Inhibitors (MAOI)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
isocarboxazid	Marplan	PA	
phenelzine	Nardil	PA - < 6 years	# , A90
selegiline transdermal patch	Emsam	PA	
tranylcypromine		PA - < 6 years	A90

Pediatric Behavioral Health – First-Generation (Typical) Antipsychotics			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline / perphenazine		PA	A90
chlorpromazine		PA - < 10 years	A90
fluphenazine		PA - < 10 years	A90
haloperidol	Haldol	PA - < 10 years	# , A90
loxapine capsule	Loxitane	PA - < 10 years	# , A90
molindone		PA - < 10 years	A90
perphenazine		PA - < 10 years	A90
pimozide	Orap	PA - < 10 years	# , A90
thioridazine		PA - < 10 years	A90
thiothixene	Navane	PA - < 10 years	# , A90
trifluoperazine		PA - < 10 years	A90

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
atomoxetine	Strattera	PA - < 6 years	# , A90
clonidine extended -release 0.1 mg		PA - < 3 years and PA > 4 units/day	A90

Pediatric Behavioral Health – Cerebral Stimulants and Miscellaneous Agents - Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
tablet			
guanfacine extended-release	Intuniv	PA - < 3 years	# , A90
viloxazine	Qelbree	PA	

Pediatric Behavioral Health – Second-Generation (Atypical) Antipsychotic and Opioid Antagonist			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
olanzapine / samidorphan	Lybalvi	PA	

Pediatric Behavioral Health – Antidepressants - Noradrenergic and Specific Serotonergic Antidepressants (NaSSA)			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
mirtazapine	Remeron	PA - < 6 years	# , A90
mirtazapine orally disintegrating tablet	Remeron Sol Tab	PA	A90

Pediatric Behavioral Health – Second-Generation (Atypical) Antipsychotic-Selective Serotonin Reuptake Inhibitor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
olanzapine / fluoxetine	Symbyax	PA	A90

Pediatric Behavioral Health – Antidepressants - Serotonin Modulators			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nefazodone		PA - < 6 years	A90
trazodone 300 mg tablet		PA	A90
trazodone 50 mg, 100 mg, 150 mg		PA - < 6 years	A90
vilazodone	Viibryd	PA	A90
vortioxetine	Trintellix	PA	

Pediatric Behavioral Health – Antidepressants – Gamma-Aminobutyric (GABA)-A Receptor Positive Modulator			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
zuranolone	Zurzuvae PD	PA	

Pediatric Behavioral Health – Alpha Agonists			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
clonidine extended -release 0.17 mg tablet		PA	A90
clonidine patch		PA	A90
clonidine tablet		PA - < 3 years	A90
guanfacine		PA - < 3 years	A90

Pediatric Behavioral Health – Antianxiety Agents - Not Otherwise Classified			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
amitriptyline / chlordiazepoxide		PA	
buspirone		PA - < 6 years	A90
meprobamate		PA	

This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

M90 Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- Anxiety
- Attention Deficit Hyperactivity Disorder (ADHD)
- Bipolar disorder
- Depression

- Hyperactivity associated with autism spectrum disorder (ASD)
- Psychotic disorders
- Schizophrenia
- Tourette Disorder

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28-days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

In addition to individual drug PA criteria where applicable, some behavioral health medications are subject to additional polypharmacy and age limit restrictions.

Please note: The member will need to meet all criteria for the requested agent as specified in the respective medication class table, if applicable.

Behavioral Health Medication Polypharmacy *(pharmacy claims for any combination of four or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, and viloxazine] within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant; or, pharmacy claims for any combination of five or more behavioral health medications [as defined above] within a 45-day period)* for members < 18 years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- For regimens including < two mood stabilizers (also includes regimens that do not include a mood stabilizer), documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**

- treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
- prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation.

- For regimens including ≥ two mood stabilizers, documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnoses; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation; **and**
    - one of the following:
      - member has a seizure diagnosis only; **or**
      - member has an appropriate psychiatric diagnosis, with or without seizure diagnosis, and one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **or**
      - member has a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **or**
      - member has psychiatric and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis, and that other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed, **and**
      - one of the following:
        - cross-titration/taper of mood stabilizer therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate.

Antidepressant Polypharmacy ***(overlapping pharmacy claims for two or more antidepressants for at least 60 days within a 90-day period, except esketamine)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:

- appropriate psychiatric diagnosis; **and**
- treatment plan including names of current antidepressants and corresponding diagnoses; **and**
- prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
- one of the following:
  - cross-titration/taper of antidepressant therapy; **or**
  - inadequate response (defined as four weeks of therapy) or adverse reaction to two monotherapy trials as clinically appropriate; **or**
  - antidepressant polypharmacy regimen of ≤ two antidepressants includes one of the following: bupropion, mirtazapine, trazodone, or zuranolone; **or**
  - one antidepressant in the regimen is indicated for a comorbid condition in which antidepressants may be clinically appropriate; **and**
- if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation.

SmartPA: Claims will usually process at the pharmacy without a PA request if the member is < 18 years of age and has a history of paid MassHealth pharmacy claims for two antidepressants (except esketamine) for at least 60 days of therapy out of the last 90 days and one or both agents are bupropion, trazodone, mirtazapine, or zuranolone.†

Antipsychotic Polypharmacy ***(overlapping pharmacy claims for two or more antipsychotics [includes first-generation and/or second-generation antipsychotics, except short-acting injectable formulations] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - treatment plan including name, dose, and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses; **and**
    - a comprehensive behavioral health plan (i.e. non-pharmacologic interventions) is in place; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - stage of treatment is acute, maintenance, or discontinuation; **and**
    - one of the following:
      - for acute stage (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects), one of the following:
        - cross-titration/taper of antipsychotic therapy; **or**
        - inadequate response or adverse reaction to two monotherapy trials as clinically appropriate; **or**
      - for maintenance stage (response to antipsychotic treatment with goal of remission or recovery), all of the following:
        - regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place; **and**
        - if member has been on the antipsychotic regimen for the past 12 months, clinical rationale for extended therapy including at least one of the following: previous efforts to reduce/simplify the antipsychotic regimen in the past 24 months resulted in symptom exacerbation; or family/caregiver does not support the antipsychotic regimen change at this time due to risk of exacerbation; or other significant barrier for antipsychotic therapy discontinuation; **or**
      - for discontinuation stage (clinically indicated that the antipsychotic regimen can likely be successfully tapered), cross-

titration/taper of antipsychotic therapy.

SmartPA: Claims for risperidone and aripiprazole will usually process at the pharmacy without a PA request if the member is ≥ six and < ten years of age and has a history of MassHealth medical claims for diagnosis of autism spectrum disorder.†

Benzodiazepine Polypharmacy ***(overlapping pharmacy claims for two or more benzodiazepines [hypnotic benzodiazepine agents, clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations are not included] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a seizure diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - treatment plan including names of current benzodiazepines and corresponding diagnoses; **and**
    - one of the following:
      - cross-titration/taper of benzodiazepine therapy; **or**
      - clinical rationale for use of ≥ two benzodiazepines of different chemical entities.

Cerebral Stimulant Polypharmacy ***(overlapping pharmacy claims for two or more cerebral stimulants [immediate-release and extended -release formulations of the same chemical entity are counted as one] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current cerebral stimulants and corresponding diagnoses; **and**
    - inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to monotherapy trial with a methylphenidate product; **and**
    - inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to monotherapy trial with an amphetamine product; **and**
    - clinical rationale for cerebral stimulant polypharmacy.

Mood Stabilizer Polypharmacy ***(overlapping pharmacy claims for three or more mood stabilizers [agents considered to be used only for seizure diagnoses are not included] for at least 60 days within a 90-day period)*** **for members < 18 years of age**

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for members with seizure diagnosis only:
  - appropriate diagnosis (seizure) without comorbid condition.

- Documentation of the following is required for members with psychiatric diagnoses, with or without seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**

- member has a history of severe risk of harm to self or others; **or**
- all of the following:
  - appropriate psychiatric diagnoses; **and**
  - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - one of the following:
    - cross-titration/taper of mood stabilizer therapy; **or**
    - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **and**
  - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain); **and**
    - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
    - other clinically appropriate therapies have been tried and failed; therefore, multiple mood stabilizers are needed.

- Documentation of the following is required for members with a psychiatric diagnosis and comorbid diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain), with or without seizure diagnosis:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - psychiatric diagnosis and diagnosis in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain); **and**
    - treatment plan including names of current mood stabilizers and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - other clinically relevant therapies have been tried and failed; therefore, multiple mood stabilizers are needed; **and**
    - one of the following:
      - cross-titration/taper of mood stabilizer therapy; **or**
      - inadequate response or adverse reaction to two monotherapy trials and/or multiple combination therapy trials as clinically appropriate; **and**
    - if member has been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

Antidepressant, armodafinil, buspirone, donepezil, memantine, meprobamate, modafinil, naltrexone, or prazosin for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

Antipsychotic for members < ten years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - for requests for aripiprazole or risperidone for members ≥ six years of age and < ten years of age, a diagnosis of ASD; **or**
  - all of the following:
    - complete medication treatment plan including name, dose, and frequency of all current behavioral health medications, associated target symptom(s), and behavioral health diagnoses; **and**
    - a comprehensive behavioral health treatment plan (i.e., non-pharmacological interventions) is in place; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - one of the following:
      - member is in acute stage of treatment (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects); **or**
      - all of the following:
        - member is in maintenance stage of treatment (response to antipsychotic treatment with goal of remission or recovery); **and**
        - regimen is effective, therapy benefits outweigh risks, and appropriate monitoring is in place; **and**
        - if member has been on the antipsychotic regimen for the past 12 months, clinical rationale for extended therapy including at least one of the following: previous efforts to reduce/simplify the antipsychotic regimen in the past 12 months resulted in symptom exacerbation; or family/caregiver does not support the antipsychotic regimen change at this time due to risk of exacerbation; or other significant barrier for antipsychotic therapy discontinuation; **or**
      - all of the following:
        - member is in discontinuation stage of treatment (clinically indicated that the antipsychotic regimen can likely be successfully tapered); **and**
        - cross-titration/taper of antipsychotic therapy.

Atomoxetine and viloxazine for members < six years of age

- Documentation of the following is required:

- one of the following:
  - member had a recent psychiatric hospitalization (within the last three months); **or**
  - member has a history of severe risk of harm to self or others; **or**
- all of the following:
  - appropriate diagnosis; **and**
  - treatment plan including names of current behavioral health medications and corresponding diagnoses; **and**
  - if member is < three years of age, prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided.

Benzodiazepine *(hypnotic benzodiazepine agents are not included)* or Mood Stabilizer *(agents considered to be used only for seizure diagnoses are not included)* for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a seizure diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - treatment plan including names of current behavioral health medications and corresponding indications; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
      - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
      - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
      - other significant barrier for therapy discontinuation.

SmartPA: Claims for mood stabilizers or benzodiazepines will usually process at the pharmacy without a PA request if the member is < six years of age, has a history of MassHealth medical claims for seizure, and does not have a history of MassHealth medical claims for psychiatric diagnoses and/or other diagnoses in which mood stabilizers may be clinically appropriate (e.g., migraine, neuropathic pain).†

Alpha$_2$ Agonist for members < three years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
    - member has a cardiovascular diagnosis only; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - treatment plan including names of current alpha$_2$ agonist(s) and corresponding diagnoses; **and**
    - clinical rationale for use of alpha$_2$ agonist in member < three years of age.

Cerebral Stimulant for members < three years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); **or**
    - member has a history of severe risk of harm to self or others; **or**
  - all of the following:
    - appropriate diagnosis; **and**
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
    - treatment plan including names of current cerebral stimulant(s) and corresponding diagnoses; **and**
    - clinical rationale for use of cerebral stimulant in member < three years of age; **and**
    - for requests for an amphetamine product, inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to a methylphenidate product.

Hypnotic agents for members < six years of age

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required for members with a diagnosis of insomnia with other behavioral health comorbidities, excluding ADHD/ASD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis of insomnia without behavioral health comorbidities or insomnia with comorbid ASD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**
  - inadequate response (defined by ≥ ten days of therapy), adverse reaction, or contraindication to melatonin; **and**
  - if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
    - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
    - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
    - other significant barrier for therapy discontinuation.

- Documentation of the following is required for members with a diagnosis of insomnia with comorbid ADHD:
  - treatment plan including name of current hypnotic agent and corresponding diagnosis; **and**
  - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; **and**
  - at least one behavioral intervention has been attempted (e.g., bedtime routine, extinction, fading, strategic napping, positive

reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques); **and**

- inadequate response (defined by ≥ ten days of therapy), adverse reaction, or contraindication to melatonin; **and**
- inadequate response (defined by ≥ ten days of therapy), adverse reaction, or contraindication to clonidine; **and**
- if member has been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation), at least one of the following:
  - previous efforts to reduce/simplify the regimen in the past 24 months resulted in symptom exacerbation; **or**
  - family/caregiver does not support the regimen change at this time due to risk of exacerbation; **or**
  - other significant barrier for therapy discontinuation.

The following behavioral health medications are included in the Pediatric Behavioral Health Medication Initiative:

Appendix I:

Pediatric Behavioral Health Medication Initiative Medication List[1]

Antidepressants		**Mood Stabilizers**	
amitriptyline	levomilnacipran	carbamazepine	lithium
amoxapine	mirtazapine	divalproex	oxcarbazepine
bupropion	nefazodone	gabapentin	pregabalin
citalopram	nortriptyline	lamotrigine	topiramate
clomipramine	paroxetine		valproic acid
desipramine	phenelzine	**Antianxiety Agents**	
desvenlafaxine	protriptyline	alprazolam	diazepam[3]
dextromethorphan/ bupropion	selegiline[2]	buspirone	lorazepam
doxepin	sertraline	chlordiazepoxide	meprobamate
duloxetine	tranylcypromine	chlordiazepoxide/ amitriptyline	midazolam[3]
escitalopram	trazodone	clonazepam	oxazepam
esketamine	trimipramine	clorazepate	
fluoxetine	venlafaxine	**Hypnotics**	
fluvoxamine	vilazodone	daridorexant	quazepam
imipramine	vortioxetine	doxepin[4]	suvorexant
isocarboxazid	zuranolone	estazolam	temazepam
Antipsychotics		eszopiclone	triazolam
aripiprazole	olanzapine	flurazepam	zaleplon
asenapine	olanzapine/fluoxetine	lemborexant	zolpidem
brexipiprazole	olanzapine/samidorphan	**Alpha$_2$ Agonists**	
cariprazine	paliperidone	clonidine	guanfacine
chlorpromazine	perphenazine	**Stimulants**	
clozapine	perphenazine/amitriptyline	amphetamine	lisdexamfetamine
fluphenazine	pimozide	dextroamphetamine	methamphetamine
haloperidol	quetiapine	dexmethylphenidate	methylphenidate
iloperidone	risperidone	dextroamphetamine/ amphetamine	serdexmethylphenidate/ dexmethylphenidate
loxapine	thioridazine	**Miscellaneous**	
lumateperone	thiothixene	armodafinil	modafinil

lurasidone	trifluoperazine	atomoxetine	naltrexone[5]
molindone	ziprasidone	donepezil	prazosin
		memantine	viloxazine

[1]Short-acting intramuscular injectable and intravenous formulations are excluded from the Pediatric Behavioral Health Medication Initiative requirements.

[2]Emsam (selegiline) is the only selegiline formulation included in the Pediatric Behavioral Health Medication Initiative.

[3]Nasal and rectal diazepam and nasal midazolam formulations are excluded from the Pediatric Behavioral Health Medication Initiative requirements.

[4]Doxepin tablet is classified as a hypnotic agent and the Pediatric Behavioral Health Medication Initiative requirements for antidepressants do not apply. Pediatric Behavioral Health Medication Initiative requirements for hypnotics apply.

[5]Vivitrol (naltrexone injection) is excluded from the Pediatric Behavioral Health Medication Initiative requirements.

†Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 72 - Agents not Otherwise Classified

Drug Category: Various

Medication Class/Individual Agents: Various

I. Prior-Authorization Requirements

Agents not Otherwise Classified – COVID-19 Related Medications

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

baricitinib COVID EUA - November 19, 2020 for members 2 to 17 years of age	Olumiant		MB	**Lagevrio**
				• Documentation of all of the following is required:
				  • indication for the treatment of COVID-19; **and**
				  • member is ≥ 18 years of age; **and**
				  • medical necessity for use of requested agent instead of Paxlovid; **and**
				  • appropriate dosing; **and**
				  • requested quantity is ≤ 40 units/treatment.
				
				Paxlovid > 20 units/claim
				• Documentation of all of the following is required:
				  • indication for the treatment of COVID-19; **and**
				  • member is ≥ 12 years of age; **and**
				  • medical necessity for exceeding standard dosing or duration recommendations.
				
				Pemgarda
				• Documentation of all of the following is required:
				  • indication for pre-exposure prophylaxis for COVID-19; **and**
				  • member is ≥ 12 years of age; **and**
				  • member weighs ≥ 40 kg; **and**
				  • one of the following:
				  • member has moderate-to-severe immune compromise due to a medical condition; **or**
				  • member has moderate-to-severe immune compromise due to the receipt of immunosuppressive medications or treatments; **and**
				• appropriate dosing.

baricitinib for members ≥ 18 years of age COVID	Olumiant		MB	
molnupiravir COVID EUA – December 23, 2021	Lagevrio	PA		
nirmatrelvir / ritonavir 150 mg-100 mg	Paxlovid	PA - < 12 years and PA > 20 units/claim		
nirmatrelvir / ritonavir 300-100 mg	Paxlovid	PA - < 12 years and PA > 30 units/claim		
pemivibart COVID EUA – March 22, 2024	Pemgarda	PA	MB	
remdesivir	Veklury		MB	
tocilizumab vial COVID	Actemra		MB	
vilobelimab COVID EUA - April 4, 2023	Gohibic		MB	

Agents not Otherwise Classified – Adrenocorticotropic Hormone

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

corticotropin	Acthar	PA		**Acthar and Cortrophin**
				• Documentation of the following is required for a diagnosis of infantile spasms:
				  • appropriate diagnosis; **and**
				  • member is < two years of age; **and**
				  • prescriber is a neurologist or consult notes from a neurologist are provided; **and**
				  • for Cortrophin, medical necessity for use instead of Acthar; **and**
				  • for initial therapy, one of the following:
				  • requested dose and duration is 20 units daily for two weeks followed by a taper over one week (specific taper must be documented); **or**
				  • requested dose and duration is 75 units/m^2 twice daily for two weeks [body surface area (BSA) must be documented] followed by a gradual taper over a two-week period (specific and appropriate taper must be documented); **or**
				  • for recertification, one of the following:
				  • inadequate response to 20 units daily for the initial two weeks, and request is for continuation of therapy at 40 units daily for four weeks followed by a taper over one week (specific taper must be documented); **or**
				  • history of relapse after previous treatment with corticotropin and medical necessity for retreatment.
				
				• Documentation of all of the following is required for a diagnosis of an acute exacerbation of multiple sclerosis:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a neurologist or consult notes from a neurologist are provided; **and**
				  • for Cortrophin, medical necessity for use instead of Acthar; **and**
				  • one of the following:
				  • requested dose and duration is 80 units daily for five days; **or**
				  • requested dose and duration is 80 to 120 units daily for two to three weeks; **and**
				  • medical records documenting inadequate response or adverse reaction to one or contraindication to both of the following: high-dose intravenous methylprednisolone, high-dose oral corticosteroids;

corticotropin	Cortrophin	PA		

	Clinical Notes
	and • for recertification for the same exacerbation, medical necessity for use beyond initial therapy, and requested dose and duration is ≤ 120 units daily for three weeks. • Documentation of all of the following is required for use to induce remission of proteinuria associated with idiopathic nephrotic syndrome: • appropriate diagnosis; **and** • etiology of proteinuria in nephrotic syndrome has been confirmed with renal biopsy; **and** • prescriber is a nephrologist or consult notes from a nephrologist are provided; **and** • for Cortrophin, medical necessity for use instead of Acthar; **and** • pretreatment proteinuria > 50 mg/kg per day or a spot urine sample with a total protein/creatinine ratio > 3 mg; **and** • pretreatment serum albumin < 3 g/dL (30 g/L); **and** • inadequate response, adverse reaction, or contraindication to all of the following: corticosteroids, calcineurin inhibitors (e.g., cyclosporine, tacrolimus), cyclophosphamide, mycophenolate, rituximab; **and** • requested dose is 40 or 80 units twice weekly for 12 to 24 weeks. • For recertification for use to induce remission of proteinuria associated with idiopathic nephrotic syndrome, documentation of all of the following is required: • prescriber is a nephrologist or consult notes from a nephrologist are provided; **and** • for Cortrophin, medical necessity for use instead of Acthar; **and** • current proteinuria or spot urine total protein/creatinine ratio; **and** • positive response to therapy as shown by improvements in proteinuria or spot urine total protein/creatinine ratio; **and** • total treatment duration is ≤ 24 weeks.

Agents not Otherwise Classified – Epinephrine Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

epinephrine 0.15 mg auto-injection -Epipen Jr	Epipen Jr		#	**Auvi-Q**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • for Auvi-Q 0.15 mg and 0.3 mg auto-injector, medical necessity for the use of the requested agent instead of alternatives available without PA; **and**
				  • for Auvi-Q 0.1 mg dose auto-injector, one of the following:
				  • member's current weight is <13 kg; **or**
				  • both of the following:
				  • member's current weight is 13 kg to <15 kg; **and**
				  • medical necessity for use of Auvi-Q 0.1 mg auto-injector.
				• For recertification, documentation that the member meets the criteria above is required.

epinephrine 0.3 mg auto-injection-Epipen	Epipen		#	
epinephrine auto-injection				
epinephrine auto-injection-Auvi-Q	Auvi-Q	PA		
epinephrine injection	Adrenalin			
epinephrine injection	Symjepi			

Agents not Otherwise Classified – Transthyretin Amyloidosis Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

eplontersen	Wainua	PA		**Amvuttra and Onpattro**
				• Documentation of all of the following is required for hereditary transthyretin-mediated (hATTR) amyloidosis:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • for Onpattro, member's current weight; **and**
				  • baseline polyneuropathy disability (PND) score of I, II, IIIa, or IIIb; **and**
				  • appropriate dosing.
				Tegsedi
				• Documentation of all of the following is required for hATTR amyloidosis:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a rheumatologist or neurologist or consult notes from a specialist are provided; **and**
				  • results from genetic testing showing mutations in the TTR gene; **and**
				  • inadequate response or adverse reaction to one or contraindication to both of the following: Amvuttra, Onpattro; **and**
				  • baseline PND score of I, II, IIIa, or IIIb; **and**
				  • appropriate dosing.
				Wainua
				• Documentation of all of the following is required for

inotersen	Tegsedi	PA		
patisiran	Onpattro PD	PA	MB	
vutrisiran	Amvuttra PD	PA	MB	

	Clinical Notes
	hATTR amyloidosis: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is a rheumatologist or neurologist or consult notes from a specialist are provided; **and** • results from genetic testing showing mutations in the TTR gene; **and** • baseline PND score of I, II, IIIa, or IIIb; **and** • appropriate dosing. MassHealth Drug Utilization Review will be reaching out to prescribers after Amvuttra or Onpattro PA approval to verify clinical effectiveness and for long-term monitoring of sustained response.

Agents not Otherwise Classified – Monoclonal Antibodies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
anifrolumab-fnia	Saphnelo	PA	MB	**Benlysta** • Documentation of all of the following is required for a diagnosis of lupus nephritis: • appropriate diagnosis; **and** • member is ≥ five years of age; **and** • member is receiving concurrent immunosuppressive therapy, excluding cyclophosphamide and biologics; **and** • appropriate dosing. • Documentation of all of the following is required for a diagnosis of systemic lupus erythematosus: • appropriate diagnosis; **and** • member is ≥ five years of age; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, cyclophosphamide, cyclosporine, leflunomide, methotrexate, mycophenolate; **and** • appropriate dosing. **Saphnelo** • Documentation of all of the following is required for a diagnosis of systemic lupus erythematosus: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: azathioprine, cyclophosphamide, cyclosporine, leflunomide,
belimumab auto-injection, prefilled syringe	Benlysta	PA		
belimumab vial	Benlysta	PA	MB	

	Clinical Notes
	methotrexate, mycophenolate; **and** • inadequate response, adverse reaction, or contraindication to Benlysta; **and** • appropriate dosing.

Agents not Otherwise Classified – Hormone Replacement Therapy

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
estradiol / progesterone	Bijuva	PA		**Bijuva** • Documentation of all of the following is required: • diagnosis of moderate to severe vasomotor symptoms due to menopause; **and** • medical necessity for the combination product instead of the commercially available separate agents.

Agents not Otherwise Classified – COVID-19 Test Kit Products

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
COVID-19 antigen self-test	Binaxnow	PA - > 2 tests/28 days		**All requests for COVID-19 antigen self-test kits at quantities above established quantity limits** • Documentation of the following is required: • Medical necessity for increased testing.
COVID-19 antigen self-test	Carestart	PA - > 2 tests/28 days		
COVID-19 antigen self-test	CVS COVID-19 At-Home Test	PA - > 2 tests/28 days		
COVID-19 antigen self-test	Flowflex	PA - > 2 tests/28 days		
COVID-19 antigen self-test	Genabio	PA - > 2 tests/28 days		
COVID-19 antigen self-test	Ihealth	PA - > 2 tests/28 days		
COVID-19 antigen self-test	Inteliswab	PA - > 2 tests/28 days		
COVID-19 antigen self-test	On-Go	PA - > 2 tests/28 days		
COVID-19 antigen self-test	Quickvue	PA - > 2 tests/28 days		

Agents not Otherwise Classified – Protein C Deficiency Agent

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
protein C concentrate	Ceprotin	PA	MB	**Ceprotin** • Documentation of all of the following is required: • diagnosis of inherited protein C deficiency; **and** • prescriber is a hematologist or consult notes from a hematologist are provided; **and** • inadequate response or adverse reaction to one or

	Clinical Notes
	contraindication to all of the following: Eliquis, dabigatran, Savaysa, warfarin, Xarelto; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: enoxaparin, fondaparinux, Fragmin.

Agents not Otherwise Classified – Oral, Injectable, and Miscellaneous Glycopyrrolate Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
glycopyrrolate 1 mg tablet	Robinul		# , A90	**Dartisla ODT** • Documentation of all of the following is required for a diagnosis of adjunctive therapy in treatment of peptic ulcer: • appropriate diagnosis; **and** • inadequate response, adverse reaction, or contraindication to glycopyrrolate tablets; **and** • medical necessity for use of orally disintegrating formulation as noted by one of the following: • member utilizes tube feeding (J-tube, G-tube); **or** • member has a swallowing disorder or condition affecting ability to swallow; **or** • member is < 13 years of age; **and** • requested quantity is ≤ three units/day. • Documentation of all of the following is required for a diagnosis of neurologic condition associated with drooling: • appropriate diagnosis; **and** • inadequate response, adverse reaction, or contraindication to glycopyrrolate tablets; **and** • appropriate dosing; **and** • medical necessity for use of orally disintegrating formulation as noted by one of the following: • member utilizes tube feeding (J-tube, G-tube); **or** • member has a swallowing disorder or condition affecting ability to swallow; **or** • member is < 13 years of age; **and** • inadequate response, adverse reaction, or contraindication to both of the following: glycopyrrolate tablets, scopolamine patches. **glycopyrrolate injection** • Documentation of all of the following is required for a diagnosis of adjunctive therapy in treatment of peptic ulcer:
glycopyrrolate 1.5 mg tablet		PA	A90	
glycopyrrolate 2 mg tablet	Robinul Forte		# , A90	
glycopyrrolate injection		PA		
glycopyrrolate oral solution	Cuvposa	PA	A90	
glycopyrrolate orally disintegrating tablet	Dartisla ODT	PA		

	Clinical Notes

	• appropriate diagnosis; **and**
	• medical necessity for use of an injection formulation as noted by one of the following:
	  • member utilizes tube feeding (J-tube, G-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • member is < 13 years of age.
	• Documentation of all of the following is required for a diagnosis of neurologic condition associated with drooling:
	  • appropriate diagnosis; **and**
	  • member's current weight; **and**
	  • medical necessity for use of an injection formulation as noted by one of the following:
	  • member utilizes tube feeding (J-tube, G-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • member is < 13 years of age; **and**
	  • inadequate response, adverse reaction, or contraindication to both of the following: glycopyrrolate tablets, scopolamine patches.
	
	glycopyrrolate oral solution
	• Documentation of all of the following is required:
	  • diagnosis of neurologic condition associated with drooling; **and**
	  • member's current weight; **and**
	  • medical necessity for use of a solution formulation as noted by one of the following:
	  • member utilizes tube feeding (J-tube, G-tube); **or**
	  • member has a swallowing disorder or condition affecting ability to swallow; **or**
	  • member is < 13 years of age; **and**
	  • for members ≥ 17 years of age, inadequate response or adverse reaction to one or contraindication to both of the following: scopolamine patches, trihexyphenidyl solution.
	
	glycopyrrolate 1.5 mg tablet
	• Documentation of the following is required:
	  • diagnosis of adjunctive therapy in treatment of peptic ulcer; **and**
	  • medical records documenting medical necessity for the 1.5 mg tablet instead of 1 mg or 2 mg tablet.

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

cysteamine 0.37% ophthalmic solution	Cystadrops	PA		**Cystaran, Cystadrops**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • appropriate dosing; **and**
				  • prescriber is a nephrologist or ophthalmologist.
				
				Procysbi
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • appropriate dosing; **and**
				  • prescriber is a nephrologist; **and**
				  • medical records documenting an inadequate response or adverse reaction to cysteamine immediate-release capsule; **and**
				  • for Procysbi granules, medical necessity for the requested formulation.
				• For recertification of Procysbi granules, documentation of continued medical necessity for the requested formulation.

cysteamine 0.44% ophthalmic solution	Cystaran	PA		
cysteamine delayed-release capsule	Procysbi	PA		
cysteamine delayed-release granule	Procysbi	PA		
cysteamine immediate-release capsule	Cystagon			

Agents not Otherwise Classified – Glycine-Proline-Glutamate Analog

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

trofinetide	Daybue	PA		**Daybue**
				• Documentation of all of the following is required for a diagnosis of classic or typical Rett syndrome:
				  • appropriate diagnosis; **and**
				  • member is ≥ two years of age; **and**
				  • prescriber is a neurologist or consult notes from a neurologist are provided; **and**
				  • results from genetic testing confirming a mutation in the MECP2 gene; **and**
				  • RTT Clinical Severity Scale (RTT-CSS) rating of 10 to 36; **and**
				  • Clinical Global Impression-Severity (CGI-S) score of ≥ four; **and**
				  • appropriate dosing.

Agents not Otherwise Classified – Complement Inhibitors and Miscellaneous Immunosuppressive Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
avacincaptad pegol	Izervay	PA	MB	**Empaveli**
avacopan	Tavneos	PA		

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
danicopan	Voydeya	PA		• Documentation of all of the following is required for a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH): • appropriate diagnosis; **and** • prescriber is a hematologist or consult notes from a specialist are provided; **and** • member is ≥ 18 years of age; **and** • appropriate dosing; **and** • inadequate response or adverse reaction to one or contraindication to both of the following: Soliris, Ultomiris; **and** • requested quantity is ≤ 160 mL/30 days. **Enjaymo** • Documentation of all of the following is required for the diagnosis of cold agglutinin disease (CAD): • appropriate diagnosis; **and** • prescriber is a hematologist or consult notes from a specialist are provided; **and** • member is ≥ 18 years of age; **and** • Hemoglobin (Hb) ≤ 10 g/dL (dated within the last 60 days); **and** • one of the following: • inadequate response, adverse reaction, or contraindication to a rituximab-containing regimen; **or** • requested agent is being used as a bridge therapy to initiate a rituximab-containing regimen; **and** • appropriate dosing. **Enspryng and Uplizna** • Documentation of all of the following is required for the diagnosis of neuromyelitis optica spectrum disorder (NMOSD): • appropriate diagnosis; **and** • prescriber is a neurologist or consult notes from a specialist are provided; **and** • a positive serologic test for anti-aquaporin 4 (AQP4); **and** • member is ≥ 18 years of age; **and** • appropriate dosing; **and** • for Uplizna, inadequate response, adverse reaction. or contraindication to Enspryng.
eculizumab	Soliris	PA	MB	
efgartigimod alfa-fcab	Vyvgart	PA	MB	
efgartigimod alfa-fcab and hyaluronidase-qvfc	Vyvgart Hytrulo	PA	MB	
inebilizumab-cdon	Uplizna	PA	MB	
iptacopan	Fabhalta	PA		
pegcetacoplan 1,080 mg/20 mL vial	Empaveli	PA		
pegcetacoplan 150 mg/mL vial	Syfovre	PA	MB	
pozelimab-bbfg	Veopoz	PA	MB	
ravulizumab-cwvz	Ultomiris	PA	MB	
rozanolixizumab-noli	Rystiggo	PA	MB	
satralizumab-mwge	Enspryng	PA		
sutimlimab-jome	Enjaymo	PA	MB	
zilucoplan	Zilbrysq	PA		

	Clinical Notes

	Fabhalta
	• Documentation of all of the following is required for a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH):
	  • appropriate diagnosis; **and**
	  • prescriber is a hematologist or consult notes from a specialist are provided; **and**
	  • member is ≥ 18 years of age; **and**
	  • appropriate dosing; **and**
	  • inadequate response or adverse reaction to one or contraindication to both of the following: Empaveli, Soliris, Ultomiris; **and**
	  • requested quantity is ≤ two units/day.
	
	Izervay and Syfovre
	• Documentation of all of the following is required for a diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD):
	  • appropriate diagnosis; **and**
	  • prescriber is an ophthalmologist; **and**
	  • member is ≥ 50 years of age; **and**
	  • absence of choroidal neovascularization (CNV or wet AMD) in the treatment eye; **and**
	  • normal luminance best corrected visual acuity (BCVA) ≥ 24 letters (20/230 Snellen equivalence); **and**
	  • total GA lesion area ≥ 2.5 and ≤ 17.5 mm2, with at least 1 lesion ≥ 1.25 mm2 if GA is multifocal; **and**
	  • presence of any pattern of hyperautoflorescence in the junctional zone of GA; **and**
	  • one of the following:
	  • for Izervay, requested dosing is 2 mg (0.1 mL) every 28 days; **or**
	  • for Syfovre, requested dosing is 15 mg (0.1 mL) once every 25 days to 60 days.
	• For recertification, documentation of all of the following is required for a diagnosis of GA secondary to AMD:
	  • positive response to therapy; **and**
	  • member has not developed nAMD (wet AMD); **and**
	  • for Izervay, total treatment duration ≤ 1 year; **and**
	  • for Syfovre, if requested dosing is ≥ every 60 days, prescriber has assessed using less frequent dosing.
	
	Rystiggo
	• Documentation of all of the following is required for a

	Clinical Notes

	diagnosis of generalized myasthenia gravis:
	• appropriate diagnosis; **and**
	• member is ≥ 18 years of age; **and**
	• member is AchR or MuSK antibody positive; **and**
	• prescriber is a neurologist or consult notes from specialist are provided; **and**
	• inadequate response, adverse reaction, or contraindication to pyridostigmine; **and**
	• one of the following:
	  • both of the following:
	  • member has severe disease requiring faster onset medication; **and**
	  • inadequate response, adverse reaction, or contraindication to IVIG or plasmapheresis with glucocorticoids; **or**
	  • inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclosporine, glucocorticoids, mycophenolate, tacrolimus; **and**
	• one of the following:
	  • inadequate response, adverse reaction, or contraindication to Vyvgart or Vyvgart Hytrulo; **or**
	  • member is MuSK antibody positive; **and**
	• appropriate dosing.
	
	Soliris
	• Documentation of all of the following is required for a diagnosis of atypical hemolytic-uremic syndrome (aHUS):
	  • appropriate diagnosis; **and**
	  • prescriber is a specialist (e.g., hematologist or nephrologist) or consult notes are provided; **and**
	  • appropriate dosing; **and**
	  • inadequate response, adverse reaction, or contraindication to Ultomiris.
	• Documentation of all of the following is required for a diagnosis of CD55-deficient protein-losing enteropathy (PLE), or complement hyperactivation, angiopathic thrombosis, and protein-losing enteropathy (CHAPLE) disease:
	  • appropriate diagnosis; **and**
	  • member is ≥ two months of age; **and**
	  • prescriber is a specialist in rare genetic or hematologic diseases or consult notes from specialist are

	Clinical Notes
	provided; **and** • results from genetic testing confirming a CD55 loss-of-function mutation; **and** • appropriate dosing. • For recertification, medical records documenting all of the following is required for a diagnosis of CD55-deficient PLE, or CHAPLE disease: • one of the following: • increase in current serum albumin concentration from baseline serum albumin concentration; **or** • serum albumin concentration stabilized above lower threshold for normal range (≥3.5 g/dL); **and** • one of the following: • increase in current serum IgG concentration from baseline serum IgG concentration; **or** • serum IgG concentration stabilized above lower threshold for age-adjusted normal range; **and** • improvement or no worsening of clinical symptoms (e.g., abdominal pain, bowel movements, facial and peripheral edema). • Documentation of all of the following is required for a diagnosis of generalized myasthenia gravis: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • member is AchR antibody positive; **and** • prescriber is a neurologist or consult notes from a specialist are provided; **and** • inadequate response, adverse reaction or contraindication to pyridostigmine; **and** • one of the following: • both of the following: • member has severe disease requiring faster onset medication; **and** • inadequate response, adverse reaction, or contraindication to IVIG or plasmapheresis with glucocorticoids; **or** • inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclosporine, glucocorticoids, mycophenolate, tacrolimus; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: • Rystiggo; **or** • Vyvgart or Vyvgart Hytrulo; **and** • inadequate response, adverse reaction, or

	Clinical Notes
	contraindication to both of the following: Ultomiris and Zilbrysq; **and** • appropriate dosing. • Documentation of all of the following is required for a diagnosis of NMOSD: • appropriate diagnosis; **and** • prescriber is a neurologist or consult notes from a specialist are provided; **and** • a positive serologic test for anti-aquaporin-4 (AQP4); **and** • member is ≥ 18 years of age; **and** • appropriate dosing; **and** • inadequate response, adverse reaction, or contraindication to Ultomiris. • Documentation of all of the following is required for a diagnosis of PNH:appropriate diagnosis; **and** • prescriber is a hematologist or consult notes from a specialist are provided; **and** • member is ≥ 18 years of age; **and** • inadequate response, adverse reaction, or contraindication to Ultomiris; **and** • appropriate dosing. Tavneos • Documentation of all of the following is required for a diagnosis of granulomatosis with polyangiitis or microscopic polyangiitis: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is a rheumatologist or nephrologist or consult notes from a rheumatologist or nephrologist are provided; **and** • requested quantity is ≤ six capsules/day; **and** • appropriate dosing; **and** • requested agent will be used as adjunctive therapy with both of the following: • a systemic glucocorticoid; **and** • one of the following: azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil, or rituximab. Ultomiris • Documentation of all of the following is required for a diagnosis of aHUS:

	Clinical Notes
	• appropriate diagnosis; **and** • prescriber is a specialist (e.g., hematologist or nephrologist) or consult notes are provided; **and** • appropriate dosing. • Documentation of all of the following is required for a diagnosis of generalized myasthenia gravis: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • member is AchR antibody positive; **and** • prescriber is a neurologist or consult notes from a specialist are provided; **and** • inadequate response, adverse reaction or contraindication to pyridostigmine; **and** • one of the following: • both of the following: • member has severe disease requiring faster onset medication; **and** • inadequate response, adverse reaction, or contraindication to IVIG or plasmapheresis with glucocorticoids; **or** • inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclosporine, glucocorticoids, mycophenolate, tacrolimus; **and** • inadequate response or adverse reaction to one or contraindication to all of the following: • Rystiggo; **or** • Vyvgart or Vyvgart Hytrulo; **and** • appropriate dosing. • Documentation of all of the following is required for a diagnosis of NMOSD: • appropriate diagnosis; **and** • prescriber is a neurologist or consult notes from a specialist are provided; **and** • a positive serologic test for anti-aquaporin-4 (AQP4); **and** • member is ≥ 18 years of age; **and** • appropriate dosing; **and** • Documentation of all of the following is required for a diagnosis of PNH: • appropriate diagnosis; **and** • prescriber is a hematologist or consult notes from a specialist are provided; **and** • appropriate dosing.

	Clinical Notes

	Veopoz
	• Documentation of all of the following is required for a diagnosis of CD55-deficient PLE, or CHAPLE disease:
	  • appropriate diagnosis; **and**
	  • member is ≥ one year of age; **and**
	  • prescriber is a specialist in rare genetic or hematologic diseases or consult notes from specialist are provided; **and**
	  • results from genetic testing confirming a CD55 loss-of-function mutation; **and**
	  • inadequate response, adverse reaction, or contraindication to Soliris; **and**
	  • appropriate dosing.
	• For recertification, medical records documenting all of the following is required for a diagnosis of CD55-deficient PLE, or CHAPLE disease:
	  • one of the following:
	  • increase in current serum albumin concentration from baseline serum albumin concentration; **or**
	  • serum albumin concentration stabilized above lower threshold for normal range (≥3.5 g/dL); **and**
	  • one of the following:
	  • increase in current serum IgG concentration from baseline serum IgG concentration; **or**
	  • serum IgG concentration stabilized above lower threshold for age-adjusted normal range; **and**
	  • improvement or no worsening of clinical symptoms (e.g., abdominal pain, bowel movements, facial and peripheral edema).
	
	Voydeya
	• Documentation of all of the following is required for a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH):
	  • appropriate diagnosis; **and**
	  • prescriber is a hematologist or consult notes from a specialist are provided; **and**
	  • member is ≥ 18 years of age; **and**
	  • appropriate dosing (150 to 200 mg three times daily); **and**
	  • member has clinically significant extravascular hemolysis; **and**
	  • inadequate response (defined as ≥ 6 months of therapy) to one of the following: Soliris, Ultomiris; **and**

	Clinical Notes
	• requested medication wil be used in combination with one of the following: Soliris, Ultomiris. **Vyvgart, Vyvgart Hytrulo, and Zilbrysq** • Documentation of all of the following is required for a diagnosis of generalized myasthenia gravis: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • member is AchR antibody positive; **and** • prescriber is a neurologist or consult notes from a specialist are provided; **and** • inadequate response, adverse reaction or contraindication to pyridostigmine; **and** • one of the following: • both of the following: • member has severe disease requiring faster onset medication; **and** • inadequate response, adverse reaction, or contraindication to IVIG or plasmapheresis with glucocorticoids; **or** • inadequate response or adverse reaction to two or contraindication to all of the following: azathioprine, cyclosporine, glucocorticoids, mycophenolate, tacrolimus; **and** • appropriate dosing; **and** • for Zilbrysq, inadequate response or adverse reaction to one or contraindication to all of the following: • Rystiggo; **or** • Vyvgart or Vyvgart Hytrulo.

Agents not Otherwise Classified – Amyotrophic Lateral Sclerosis (ALS) Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
edaravone injection	Radicava	PA		**Exservan, Tiglutik** • Documentation of all of the following is required: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • one of the following: • member has severe dysphagia and is currently utilizing only dosage formulations that can easily be swallowed; **or** • member utilizes tube feeding (J-tube, G-tube) and is unable to use crushed tablets; **or** • medical necessity for use instead of riluzole
edaravone suspension	Radicava ORS	PA		
riluzole film	Exservan	PA		
riluzole suspension	Tiglutik	PA		
riluzole tablet	Rilutek		# , A90	
tofersen	Qalsody	PA	MB	

	Clinical Notes
	tablets; **and** • appropriate dosing. • For recertification, documentation of all of the following is required: • one of the following: • member has severe dysphagia and is currently utilizing only dosage formulations that can easily be swallowed; **or** • member utilizes tube feeding (J-tube, G-tube) and is unable to use crushed tablets; **or** • continued medical necessity for use instead of riluzole tablets; **and** • appropriate dosing. **Radicava, Radicava ORS** • Documentation of all of the following is required: • medical records supporting the diagnosis of definite, probable, or probable-laboratory supported ALS per El Escorial criteria; **and** • prescriber is a neurologist, neuromuscular specialist, or other specialist in the treatment of ALS, or consult notes from a specialist are provided; **and** • pre-treatment ALSFRS-R questionnaire score (within the past 12 weeks); **and** • pre-treatment ALSFRS-R questionnaire score of ≥ two on each individual item; **and** • pre-treatment FVC ≥ 80%; **and** • member is not dependent on invasive mechanical ventilation by intubation or tracheostomy; **and** • appropriate dosing; **and** • one of the following: • requested agent will be used in combination with riluzole; **or** • adverse reaction or contraindication to riluzole. • For recertification, documentation of all of the following is required: • a current (within the last 12 weeks) copy of the ALSFRS-R questionnaire including scores on each individual domain; **and** • member is not dependent on invasive mechanical ventilation by intubation or tracheostomy. **Qalsody** • Documentation of all of the following is required:

	Clinical Notes

	• appropriate diagnosis; **and**
	• member is ≥ 18 years of age; **and**
	• prescriber is a neurologist, neuromuscular specialist, or other specialist in the treatment of ALS, or consult notes from a specialist are provided; **and**
	• genetic test confirming SOD1 mutation; **and**
	• pre-treatment ALSFRS-R questionnaire score (within the past 12 weeks); **and**
	• appropriate dosing; **and**
	• member is not depended on invasive mechanical ventilation by intubation or tracheostomy; **and**
	• one of the following:
	  • requested agent will be used in combination with riluzole; **or**
	  • adverse reaction or contraindication to riluzole.
	• For recertification, documentation of all of the following is required:
	  • a current (within the last 12 weeks) copy of the ALSFRS-R questionnaire including scores on each individual domain; **and**
	  • member is not dependent on invasive mechanical ventilation by intubation or tracheostomy.

Agents not Otherwise Classified – Wound Care

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

anacaulase-bcdb	Nexobrid	PA	MB	**Filsuvez**
				• Documentation of all of the following is required:
				  • diagnosis of dystrophic or junctional epidermolysis bullosa (DEB or JEB); **and**
				  • member is ≥ six months of age; **and**
				  • prescriber is a specialist (e.g., dermatologist, geneticist, histopathologist) or consult notes from a specialist are provided; **and**
				  • copy of a genetic test confirming diagnosis of DEB or JEB (e.g., mutation of COL7A1 gene or PLOD3 gene for DEB or mutation of LAMA3, LAMB3, LAMC2, COL17A1, ITGA3, ITGA6, or ITGB4 genes for JEB); **and**
				  • documentation of ≥ one partial thickness wound that is clean in appearance and does not appear infected; **and**
				  • for the diagnosis of DEB, requested agent will not be used in combination with Vyjuvek.
				• For recertification, documentation of all of the following

becaplermin	Regranex	PA		
beremagene geperpavec-svdt	Vyjuvek	PA		
birch triterpenes	Filsuvez	PA		
collagenase	Santyl	PA		

	Clinical Notes

	is required:
	• requested agent is not being applied on target wounds that have completely healed; **and**
	• positive response to therapy as indicated by one of the following:
	  • decrease in wound size; **or**
	  • decrease in pain or itch severity for target wound sites associated with dressing changes.
	Nexobrid
	• Documentation of all of the following is required:
	  • diagnosis of deep partial thickness and/or full thickness thermal burns; **and**
	  • prescriber is a specialist (e.g., dermatologist, burn specialist) or consult notes from a specialist are provided; **and**
	  • one of the following:
	  • requested quantity is one unit; **or**
	  • both of the following:
	  • requested quantity is two units; **and**
	  • BSA of wound area is > 15 % and ≤ 20 %.
	
	Regranex
	• Documentation of all of the following is required:
	  • diagnosis of diabetic neuropathic ulcers in the lower extremities; **and**
	  • number and size of the ulcers intended for treatment; **and**
	  • requested duration of treatment; **and**
	  • ulcer extends to subcutaneous tissue or beyond; **and**
	  • lower extremities have adequate blood supply; **and**
	  • ulcer is clear of infection; **and**
	  • member has ≥ two months of good wound care (sharp debridement, saline dressing, and pressure relief) without adequate ulcer healing.
	
	Santyl
	• Documentation of all of the following is required:
	  • diagnosis of chronic dermal ulcers or severely burned areas; **and**
	  • number and size of the ulcers and/or size of lesion intended for treatment; **and**
	  • requested duration of treatment; **and**
	  • one of the following:
	  • member is not a candidate for surgical intervention

	Clinical Notes
	alone; **or** • member is not a candidate for autolytic debridement; **or** • the requested agent is being used in combination with surgery. **Vyjuvek** • Documentation of all of the following is required: • diagnosis of DEB; **and** • copy of a genetic test confirming diagnosis of dystrophic epidermolysis bullosa (e.g., mutation of COL7A1 gene); **and** • member is ≥ six months of age; **and** • prescriber is a specialist (i.e., dermatologist, geneticist, histopathologist, etc.) or consult notes from a specialist are provided; **and** • member has ≥ one cutaneous wound that is clean in appearance with adequate granulation tissue, has excellent vascularization, and dose not appear infected; **and** • appropriate dosing. • For recertification, documentation of all of the following is required: • one of the following: • complete wound healing of ≥ one wound after six months of treatment; **or** • clinical rationale for continued treatment despite lack of efficacy; **and** • member has ≥ one cutaneous wound that is clean in appearance with adequate granulation tissue, has excellent vascularization, and dose not appear infected.

Agents not Otherwise Classified – Neuromuscular Potassium Channel Blockers

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
amifampridine	Firdapse	PA		**Firdapse** • Documentation of all of the following is required: • diagnosis of symptomatic Lambert-Eaton myasthenic syndrome (LEMS); **and** • member is ≥ six years of age; **and** • prescriber is a neurologist or consult notes from a neurologist are provided; **and** • one of the following laboratory results confirming the

	Clinical Notes
	diagnosis: • neurophysiology study tests; **or** • positive anti-P/Q type voltage-gated calcium channel antibody test; **and** • appropriate dosing.

Agents not Otherwise Classified – Interferon Gamma Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
emapalumab-lzsg	Gamifant	PA		**Gamifant** • Documentation of all of the following is required: • appropriate diagnosis; **and** • prescriber is a specialist (e.g., hematologist or oncologist) or consult notes from a specialist are provided; **and** • one of the following: • molecular tests confirming diagnosis of primary hemophagocytic lymphohistiocytosis (HLH); **or** • at least five of the following suggesting primary HLH: fever, splenomegaly, cytopenia (defined by two of the following: hemoglobin < 9 g/dL, platelets < 100 x 10^9/L, neutrophils < 1 x 10^9/L), hypertriglyceridemia (defined by fasting triglycerides > 3 mmol/L or ≥ 265 mg/dL) and/or hypofibrinogenemia (≤ 1.5 g/L), hemophagocytosis in bone marrow, spleen, or lymph nodes, low or absent NK-cell activity based on laboratory reference, ferritin ≥ 500 mcg/L, soluble CD25 ≥ 2400 U/mL; **and** • member has active disease; **and** • member does not have active infections caused by specific pathogens favored by interferon gamma neutralization (e.g., mycobacteria, Histoplasma Capsulatum, Shigella, salmonella, campylobacter, leishmanial infections); **and** • inadequate response, adverse reaction, or contraindication to conventional HLH therapy (chemotherapy, systemic corticosteroids, immunosuppressive therapy); **and** • requested agent will be administered in combination with dexamethasone, or clinical rationale for not using dexamethasone; **and** • anticipated hematopoietic stem cell transplantation (HSCT) date is provided, or member is not a candidate

	Clinical Notes
	for HSCT; **and** • appropriate dosing. • For recertification, documentation of the following is required: • positive response to therapy as evidenced by one of the following: • complete response (normalization of all HLH abnormalities); **or** • partial response (normalization of ≥ 3 HLH abnormalities); **or** • HLH improvement (≥ 3 HLH abnormalities improved by at least 50% from baseline); **and** • requested agent will be administered in combination with dexamethasone, or clinical rationale for not using dexamethasone; **and** • anticipated HSCT date is provided, or member is not a candidate for HSCT.

Agents not Otherwise Classified – Small Interfering RNA Therapies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
givosiran	Givlaari PD	PA	MB	**Givlaari** • Documentation of all of the following is required for acute hepatic porphyria (AHP): • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • member's current weight; **and** • appropriate dosing. **Oxlumo** • Documentation of all of the following is required for primary hyperoxaluria type 1: • appropriate diagnosis; **and** • prescriber is a specialist (e.g., nephrologist) or consult notes from a specialist are provided; **and** • results from genetic testing showing mutations in the AGXT gene; **and** • member's current weight; **and** • appropriate dosing. • For recertification, documentation of all of the following is required: • positive response to therapy; **and** • updated member weight; **and** • appropriate dosing.
lumasiran	Oxlumo PD	PA	MB	

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

gabapentin capsule, solution, tablet	Neurontin	PA - < 6 years and PA > 3600 mg/day	#	**gabapentin capsule, solution, tablet > 3,600 mg/day and pregabalin > 600 mg/day**
				• Documentation of all of the following is required:
				  • appropraite diagnosis; and
				  • clinical rationale for exceeding the maximum daily dose limit.
				
				gabapentin extended-release
				• Documentation of all of the following is required for a diagnosis of postherpetic neuralgia:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • inadequate response, adverse reaction, or contraindication to a tricyclic antidepressant; **and**
				  • inadequate response (defined as ≥ 14 days of therapy at a dose of ≥ 1,200 mg/day) or adverse reaction to gabapentin immediate-release; **and**
				  • inadequate response or adverse reaction to Horizant.
				• Documentation of all of the following is required for a diagnosis of fibromyalgia:
				  • appropriate diagnosis; **and**
				  • inadequate response (defined as ≥ 14 days of therapy at a dose of ≥ 1,200 mg/day) or adverse reaction to gabapentin immediate-release; **and**
				  • inadequate response (defined as ≥ 4 weeks of therapy) or adverse reaction to one or contraindication to all of the following: cyclobenzaprine, SSRI/SNRI, tricyclic antidepressant; **and**
				  • inadequate response or adverse reaction to Horizant.
				• Documentation of all of the following is required for a diagnosis of diabetic peripheral neuropathy:
				  • appropriate diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • inadequate response (defined by ≥ 14 days of therapy at a dose of ≥ 1,200 mg/day), or adverse reaction to gabapentin immediate-release; **and**
				  • inadequate response, adverse reaction, or contraindication to a tricyclic antidepressant; **and**
				  • inadequate response or adverse reaction to Horizant.
				
				Horizant > 1200 mg/day
				• Documentation of all of the following is required:

gabapentin enacarbil	Horizant	PA - < 6 years and PA > 1200 mg/day	BP	
gabapentin extended-release	Gralise	PA		
pregabalin	Lyrica	PA - < 6 years and PA > 600 mg/day	#	
pregabalin extended-release	Lyrica CR	PA	BP	

	Clinical Notes

	• appropriate diagnosis; **and**
	• clinical rationale for exceeding the maximum daily dose limit.
	
	pregabalin extended-release
	• Documentation of all of the following is required:
	  • appropriate diagnosis; **and**
	  • inadequate response or adverse reaction to one or contraindication to all of the following: duloxetine, lidocaine patch, a tricyclic antidepressant, venlafaxine; **and**
	  • inadequate response (defined as ≥ 14 days of therapy at a dose of ≥ 1,200 mg/day), adverse reaction or contraindication to gabapentin; **and**
	  • inadequate response (defined as ≥ 14 days of therapy) or adverse reaction to pregabalin immediate-release; **and**
	  • one of the following:
	  • for diabetic peripheral neuropathy, requested quantity is ≤ one unit/day; **or**
	  • for postherpetic neuralgia, requested quantity is ≤ two units/day.
	
	Concomitant gabapentin and pregabalin Polypharmacy (a history of at least one paid MassHealth pharmacy claim for the other agent within the last 30 days)
	• For all requests, individual drug PA criteria must be met first where applicable.
	• Documentation of the following is required:
	  • appropriate diagnosis for gabapentin; **and**
	  • appropriate diagnosis for pregabalin; **and**
	  • complete treatment plan; **and**
	  • clinical rationale for the concomitant use of gabapentin and pregabalin; **and**
	  • one of the following:
	  • inadequate response to the maximum daily dose of each agent as monotherapy; **or**
	  • inadequate response to the maximum tolerated dose of each agent as monotherapy and requested doses are less than the doses at which the adverse drug reaction or side effect occurred; **and**
	  • inadequate response or adverse reaction to two or contraindication to all other alternatives for the requested indication.

	Clinical Notes
	In addition to individual drug PA criteria where applicable, the above behavioral health medications are subject to additional polypharmacy and age limit restrictions as per the Pediatric Behavioral Health Initiative. See Table 71 for additional information.

Agents not Otherwise Classified – Oral Immunotherapy Agent

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
grass pollen allergen extract	Oralair	PA		Grastek • Documentation of all of the following is required: • diagnosis of allergic rhinoconjunctivitis; **and** • prescriber is an allergist or immunologist, or consult notes from an allergist or immunologist are provided; **and** • member is ≥ five years of age; **and** • medical records of the skin test confirming pollen-specific immunoglobulin E (IgE) antibodies for the specific antigen; **and** • member is not currently a candidate for subcutaneous immunotherapy; **and** • inadequate response (defined as at least two weeks of therapy), adverse reaction, or contraindication to one agent from all of the following classes of symptomatic therapy: intranasal antihistamine, intranasal corticosteroid, second generation antihistamine; **and** • inadequate response, adverse reaction, or contraindication to Oralair; **and** • requested quantity is ≤ one unit/day. Odactra • Documentation of all of the following is required: • diagnosis of allergic rhinoconjunctivitis; **and** • prescriber is an allergist or immunologist, or consult notes from an allergist or immunologist are provided; **and** • member is ≥ 12 years of age; **and** • medical records of the skin test confirming pollen-specific immunoglobulin E (IgE) antibodies for the specific antigen; **and** • member is not currently a candidate for subcutaneous immunotherapy; **and**
house dust mite allergen extract	Odactra	PA		
peanut allergen powder-dnfp	Palforzia	PA		
short ragweed pollen allergen extract	Ragwitek	PA		
timothy grass pollen allergen extract	Grastek	PA		

	Clinical Notes
	• inadequate response (defined as at least two weeks of therapy), adverse reaction, or contraindication to one agent from all of the following classes of symptomatic therapy: intranasal antihistamine, intranasal corticosteroid, second generation antihistamine; **and** • requested quantity is ≤ one unit/day. **Oralair** • Documentation of all of the following is required: • diagnosis of allergic rhinoconjunctivitis; **and** • prescriber is an allergist or immunologist, or consult notes from an allergist or immunologist are provided; **and** • member is ≥ five years of age; **and** • medical records of the skin test confirming pollen-specific immunoglobulin E (IgE) antibodies for the specific antigen; **and** • member is not currently a candidate for subcutaneous immunotherapy; **and** • inadequate response (defined as at least two weeks of therapy), adverse reaction, or contraindication to one agent from all of the following classes of symptomatic therapy: intranasal antihistamine, intranasal corticosteroid, second generation antihistamine; **and** • for Oralair 300 mg immediate-release tablet, requested quantity is ≤ one unit/day. **Palforzia** • Documentation of all of the following is required: • diagnosis of peanut allergy; **and** • prescriber is an allergist or immunologist, or consult notes from an allergist or immunologist are provided; **and** • one of the following: • member is ≥ four to 18 years of age; **or** • documentation that member started Palforzia at four to 18 years of age; **and** • confirmation of diagnosis with one of the following: • serum peanut-specific immunoglobulin (IgE); **or** • skin test confirmation of immunoglobulin (IgE) antibodies for the specific antigen; **and** • appropriate dosing. • For recertification of Palforzia, documentation of

	Clinical Notes

	tolerance to therapy during the initial dose escalation and up-dosing phases.
	
	Ragwitek
	• Documentation of all of the following is required:
	  • diagnosis of allergic rhinoconjunctivitis; **and**
	  • prescriber is an allergist or immunologist, or consult notes from an allergist or immunologist are provided; **and**
	  • member is ≥ five years of age; **and**
	  • medical records of the skin test confirming pollen-specific immunoglobulin E (IgE) antibodies for the specific antigen; **and**
	  • member is not currently a candidate for subcutaneous immunotherapy; **and**
	  • inadequate response (defined as at least two weeks of therapy), adverse reaction, or contraindication to one agent from all of the following classes of symptomatic therapy: intranasal antihistamine, intranasal corticosteroid, second generation antihistamine; **and**
	• requested quantity is ≤ one unit/day.

Agents not Otherwise Classified – Melanocortin Receptor Agonists

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

afamelanotide	Scenesse	PA	MB	**Imcivree**
				• Documentation of the following is required for a diagnosis of obesity due to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency:
				  • diagnosis of obesity is due to to a homozygous or presumed homozygous variant in at least one of the following genes (genetic test must be provided): POMC, PCSK1, LEPR; **and**
				  • one of the following:
				  • for adult members, baseline height and weight supporting body mass index (BMI) ≥ 30 kg/m^2; **or**
				  • for pediatric members, baseline BMI supporting ≥ 95th percentile using growth chart assessment; **and**
				  • genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS); **and**
				• prescriber is an endocrinologist; **and**

setmelanotide	Imcivree	PA		

	Clinical Notes
	• appropriate dosing; **and** • member is ≥ six years of age. • Documentation of all of the following is required for a diagnosis of obesity due to Bardet-Biedl syndrome (BBS): • appropriate diagnosis; **and** • member is ≥ six years of age; **and** • one of the following: • for adult members, baseline height and weight supporting BMI of ≥ 30 kg/m2; **or** • for pediatric members, baseline BMI supporting ≥ 95th percentile using growth chart assessment; and • prescriber is an endocrinologist; **and** • requested dose is ≤ three mg/day. • For recertification, documentation of the following is required: • one of the following: • for adult members, at least a 5% reduction in baseline body weight or maintenance in reduction of at least 5% in baseline body weight; **or** • for pediatric members, at least a 5% reduction in baseline BMI or maintenance in reduction of at least 5% in baseline BMI in members with continued growth potential; **and** • requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to the requested agent. Scenesse • Documentation of the following is required for a diagnosis of erythropoietic protoporphyria: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is a dermatologist or consultation notes from a dermatologist are provided; **and** • implant procedure will be performed at a specialized treatment center; **and** • appropriate dosing.

Agents not Otherwise Classified – Vasopressin Antagonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

tolvaptan-Jynarque	Jynarque	PA		**Jynarque**
				• Documentation of all of the following is required:
				  • diagnosis of autosomal dominant polycystic kidney disease (ADPKD); **and**
				  • member is ≥ 18 and < 56 years of age; **and**
				  • prescriber is a nephrologist or consultation notes from a nephrologist are provided; **and**
				  • estimated glomerular filtration rate (eGFR) ≥ 25 mL/min (e.g., within the last 6 months).
				• For recertification, documentation of positive response to therapy and that eGFR continues to be ≥ 25 mL/min (e.g., within the last 6 months) is required.

Agents not Otherwise Classified – Oral Carbonic Anhydrase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

acetazolamide			A90	**dichlorphenamide**
				• Documentation of all of the following is required for a diagnosis of primary hyperkalemic periodic paralysis:
				  • appropriate diagnosis; **and**
				  • prescriber is a specialist (e.g., genetic disease specialist, neurologist) or consult notes from a specialist are provided; **and**
				  • inadequate response, adverse reaction, or contraindication to both of the following: acetazolamide, hydrochlorothiazide.
				• Documentation of all of the following is required for a diagnosis of primary hypokalemic periodic paralysis:
				  • appropriate diagnosis; **and**
				  • prescriber is a specialist (e.g., genetic disease specialist, neurologist) or consult notes from a specialist are provided; **and**
				  • inadequate response, adverse reaction, or contraindication to both of the following:
				  • acetazolamide; **and**
				  • one of the following:
				  • spironolactone; **or**
				  • triamterene.

dichlorphenamide	Keveyis	PA		

Agents not Otherwise Classified – Metachromatic Leukodystrophy (MLD) Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
atidarsagene autotemcel	Lenmeldy	PA	CO, MB	**Lenmeldy** • Documentation of all of the following is required:

	Clinical Notes

	• diagnosis of one of the following:
	  • presymptomatic late infantile metachromatic leukodystrophy (MLD); **or**
	  • presymptomatic early juvenile MLD; **or**
	  • early symptomatic early juvenile MLD; **and**
	• prescriber is a specialist in the treatment of MLD (e.g., neurologist, geneticist); **and**
	• deficient ARSA enzyme activity in leukocytes; **and**
	• elevated sulfatides on 24-hour urine collection; **and**
	• for presymptomatic late infantile MLD, all of the following:
	  • two null (0) mutant ARSA alleles; **and**
	  • member is ≤ 30 months of age; **and**
	  • absence of neurological signs and symptoms of MLD with the exception of abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia); **and**
	  • peripheral neuropathy as determined by electroneurographic study; **or**
	• for presymptomatic early juvenile MLD, all of the following:
	  • one null (0) and 1 R mutant ARSA allele(s); **and**
	  • member is < seven years of age; **and**
	  • absence of neurological signs and symptoms of MLD or physical exam findings limited to abnormal reflexes and/or clonus with the exception of abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia); **and**
	  • peripheral neuropathy as determined by electroneurographic study; **or**
	• for early symptomatic early juvenile MLD, all of the following:
	  • one null (0) and 1 R mutant ARSA allele(s); **and**
	  • disease onset > 30 months and < seven years of age; **and**
	  • member is <18 years of age; **and**
	  • Intelligence quotient ≥ 85 on age-appropriate neurodevelopmental testing; **and**
	  • Gross Motor Function Classification in metachromatic leukodystrophy (GMFC-MLD) level

	Clinical Notes

	0 with ataxia OR GMFC-MLD level 1; **and**
	• appropriate dosing; **and**
	• infusion will take place in a qualified treatment facility; **and**
	• member has negative serology tests for all of the following:
	  • human immunodeficiency virus (HIV)-1/2; **and**
	  • human T-lymphotrophic virus (HTLV)-1/2; **and**
	  • hepatitis B virus (HBV); **and**
	  • hepatitis C virus (HCV); **and**
	  • mycoplasma; **and**
	• member has NOT had previous gene therapy for MLD.

Agents not Otherwise Classified – Potassium Binding Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

patiromer	Veltassa	PA - > 1 unit/day		**Lokelma and Veltassa > one unit/day**
				• Documentation of all of the following is required:
				  • diagnosis of hyperkalemia; **and**
				  • medical necessity for exceeding the quantity limit.

sodium polystyrene sulfonate				
sodium zirconium cyclosilicate	Lokelma	PA - > 1 unit/day		

Agents not Otherwise Classified – Gene Therapy

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

voretigene neparvovec-rzyl	Luxturna	PA	CO, MB	**Luxturna**
				• Documentation of all of the following is required:
				  • diagnosis of biallelic RPE65 mutation-associated retinal dystrophy; **and**
				  • prescriber is a specialist (e.g., ophthalmologist or retinal specialist) or consult notes from a specialist are provided; **and**
				  • the treatment procedure will be performed at a specialized treatment center; **and**
				  • medical records documenting the results from genetic testing showing mutations in the RPE65 gene; **and**
				  • viable retinal cells (e.g., retinal thickness > 100 microns); **and**
				  • baseline full-field light sensitivity threshold (FST) scores; **and**
				  • member is ≥ one year of age on treatment date; **and**
				  • member has not undergone recent ocular surgery in the last six months; **and**
				  • member has discontinued retinoid compounds for at

	Clinical Notes
	least 18 months; **and** • appropriate dosing and treatment schedule; **and** • member has not received any prior gene therapy for biallelic RPE65 mutation-associated retinal dystrophy. • MassHealth Drug Utilization Review will be reaching out to prescribers after PA approval to verify administration date and at ongoing intervals for long-term monitoring of response.

Agents not Otherwise Classified – Acetylcholinesterase Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
pyridostigmine bromide 30 mg tablet		PA	A90	**pyridostigmine bromide 30 mg tablet** • Documentation of the following is required: • diagnosis of myasthenia gravis; **and** • medical necessity for the 30 mg tablet instead of the 60 mg tablet. • For recertification, documentation of continued medical necessity for the requested dosage formulation is required.
pyridostigmine bromide 60 mg tablet, 180 mg extended-release tablet	Mestinon		# , A90	
pyridostigmine bromide solution	Mestinon		BP, A90	

Agents not Otherwise Classified – Progestin Antagonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
mifepristone 200 mg	Mifeprex		#	

Agents not Otherwise Classified – Leptin Analog

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
metreleptin	Myalept	PA		**Myalept** • Documentation of all of the following is required: • diagnosis of one of the following: • Congenital Generalized Lipodystrophy (CGL) or Berardinelli-Seip syndrome; **or** • Acquired Generalized Lipodystrophy (AGL) or Lawrence syndrome; **and** • member has at least one of the following metabolic abnormalities: • diabetes mellitus; **or** • fasting insulin levels > 30 microU/mL; **or** • fasting serum triglycerides > 200 mg/dL; **and** • member will be using as an adjunct to dietary

	Clinical Notes

	restrictions; **and**
	• one of the following:
	  • if the member has diabetes mellitus or fasting insulin levels > 30 microU/mL, medical records documenting an inadequate response to 90 days of therapy or adverse reaction to three different classes of antidiabetic therapies; **or**
	  • if the member has fasting serum triglycerides > 200 mg/dL, medical records documenting an inadequate response to at least 90 days of therapy, adverse reaction or contraindication to both of the following: a fibrate, a high-potency statin (rosuvastatin 20 mg or 40 mg or atorvastatin 40 mg or 80 mg).
	• For recertification, medical records documenting positive response to therapy (e.g., improvements in HbA1c, fasting plasma glucose, and/or triglyceride levels by month four of metreleptin therapy) are required.

Agents not Otherwise Classified – Pseudobulbar Affect Agent

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

dextromethorphan / quinidine	Nuedexta	PA		Nuedexta
				• Documentation of all of the following is required:
				  • diagnosis of pseudobulbar affect; **and**
				  • requested quantity is ≤ two units/day.

Agents not Otherwise Classified – Stem Cell Therapies

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

omidubicel-onlv	Omisirge	PA	CO, MB	Omisirge
				• Documentation of all of the following is required:
				  • diagnosis of hematologic malignancy; **and**
				  • prescriber is a hematologist or oncologist; **and**
				  • member is ≥ 12 years of age on treatment date; **and**
				  • member is planned for umbilical cord blood transplantation following myeloablative conditioning; **and**
				  • appropriate dosing of one-time treatment.
				• MassHealth Drug Utilization Review will be reaching out to prescribers after PA approval to verify administration date and at ongoing intervals for long-term monitoring of response.

Agents not Otherwise Classified – Human Nerve Growth Factor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

cenegermin-bkbj	Oxervate	PA		**Oxervate**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • member is ≥ two years of age; **and**
				  • prescriber is a specialist (e.g., ophthalmologist) or consult notes from a specialist are provided.

Agents not Otherwise Classified – Retinoic Acid Derivative

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

alitretinoin	Panretin	PA		**Panretin**
				• Documentation of all of the following is required for the diagnosis of AIDS-related Kaposi's sarcoma:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to all of the following: chemotherapy (e.g., pegylated liposomal doxorubicin, vinblastine or vincristine [with or without bleomycin], paclitaxel, oral etoposide, vinorelbine, gemcitabine, sirolimus) , local radiation therapy, systemic antiretoviral therapy.
				• Documentation of all of the following is required for the diagnosis of Non-AIDS-related Kaposi's sarcoma:
				  • appropriate diagnosis; **and**
				  • inadequate response, adverse reaction, or contraindication to all of the following: two first line systemic therapies (e.g., pegylated liposomal doxorubicin, vinblastine or vincristine [with or without bleomycin], paclitaxel, oral etoposide, vinorelbine, gemcitabine, sirolimus), intralesional therapy, local radiation therapy.

Agents not Otherwise Classified – Antioxidant

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

coenzyme Q10		PA - ≥ 21 years		**coenzyme Q10 for members ≥ 21 years of age**
				• Documentation of all of the following is required:
				  • appropriate diagnosis; **and**
				  • one of the following:
				  • muscle biopsy positive for mitochondrial disease; **or**
				  • pathogenic mtDNA abnormality.
				SmartPA: Claims for coenzyme Q10 and coenzyme Q10

sodium thiosulfate	Pedmark	PA	MB	

	Clinical Notes

	with vitamin E combination products will usually process at the pharmacy without a PA request if the member is ≥ 21 years of age and has a history of paid MassHealth pharmacy claims of the requested agent for at least 90 out of the last 120 days of the requested agent.†
	
	Pedmark
	• Documentation of all of the following is required:
	  • diagnosis of localized, non-metastatic solid tumor; **and**
	  • prescriber is an oncologist; **and**
	  • member is ≥ one month and < 18 years of age; **and**
	  • member is receiving cisplatin with an infusion duration ≤ six hours; **and**
	  • appropriate dosing.

Agents not Otherwise Classified – Thyroid Hormone Receptor-Beta Agonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

resmetirom	Rezdiffra	PA		**Rezdiffra**
				• Documentation of all of the following is required:
				  • diagnosis of nonalcoholic steatohepatitis (NASH) or metabolic dysfunction-associated steatohepatitis (MASH), with moderate to advanced liver fibrosis (consistent with stages F2 and F3 fibrosis); **and**
				  • results from liver biopsy or noninvasive testing supporting the diagnosis; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a gastroenterologist or hepatologist or consult notes from a gastroenterologist or hepatologist are provided; **and**
				  • member has been counseled to continue a reduced-calorie diet and increased physical activity; **and**
				  • member has been counseled to abstain from alcohol use; **and**
				  • member's current weight; **and**
				  • requested quantity is ≤ one unit/day

Agents not Otherwise Classified – Urinary Tract Anti-Inflammatory Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
dimethyl sulfoxide solution	Rimso-50			

Agents not Otherwise Classified – Friedreich's Ataxia Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

omaveloxolone	Skyclarys	PA		Skyclarys
				• Documentation of all of the following is required:
				  • diagnosis of Friedreich's Ataxia (FA); **and**
				  • member is ≥ 16 years of age; **and**
				  • prescriber is a neurologist or consult notes from a neurologist are provided; **and**
				  • genetic testing confirming the diagnosis of FA; **and**
				  • requested quantity is ≤ three units/day.
				• For recertification, documentation of both of the following is required:
				  • positive response to therapy; **and**
				  • requested quantity is ≤ three units/day.

Agents not Otherwise Classified – Cerebral Adrenoleukodystrophy [CALD] Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

elivaldogene autotemcel	Skysona	PA	CO, MB	Skysona
				• Documentation of all of the following is required:
				  • diagnosis of cerebral adrenoleukodystrophy (CALD); **and**
				  • member is ≥ four years and < 18 years of age at the time of treatment; **and**
				  • elevated very long chain fatty acids (VLCFAs); **and**
				  • genetic testing showing mutation in the ABCD1; **and**
				  • prescriber is a specialist in the treatment of CALD (e.g., neurologist); **and**
				  • member has all of the following:
				  • neurologic Function Score (NFS) score ≤1; **and**
				  • Loes score between 0.5 and 9 (inclusive); **and**
				  • gadolinium enhancement on brain magnetic resonance imaging (MRI); **and**
				  • member has not had previous allogeneic transplant or gene therapy.
				• MassHealth Drug Utilization Review will be reaching out to prescribers after PA approval to verify administration date and at ongoing intervals for long-term monitoring of response.

Agents not Otherwise Classified – Retinoic Acid Receptor Agonist

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

palovarotene	Sohonos	PA		Sohonos
				• Documentation of all of the following is required:
				  • diagnosis of Fibrodysplasia Ossificans Progressiva (FOP) with ACVR1 R206H mutation; **and**
				  • results from genetic testing to confirm diagnosis; **and**
				  • one of the following:
				  • for members assigned female at birth/biologic female, member is ≥ eight years of age; **or**
				  • for members assigned male at birth/biologic male, member is ≥ ten years of age; **and**
				  • prescriber is a specialist in rare connective tissue disorders or consult notes from a specialist are provided; **and**
				  • for members < 14 years of age, current weight; **and**
				  • appropriate dosing; **and**
				  • for members of reproductive potential, both of the following:
				  • attestation that the member is not pregnant; **and**
				  • appropriate contraception methods will be used at least one month before treatment, during treatment, and one month after the last dose.

Agents not Otherwise Classified – Sclerosing Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

tetradecyl sulfate injection	Sotradecol	PA	MB	Sotradecol
				• Documentation of all of the following is required:
				  • diagnosis of varicose veins; **and**
				  • symptoms due to varicose veins are non-cosmetic.
				• For recertification, documentation that significant symptoms persist following previously approved invasive treatment is required.

Agents not Otherwise Classified – Thyroid Eye Disease Agent

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

teprotumumab-trbw	Tepezza	PA	MB	Tepezza
				• Documentation of all of the following is required:
				  • diagnosis of thyroid eye disease; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is an endocrinologist or ophthalmologist, or consult notes from an endocrinologist or

	Clinical Notes
	ophthalmologist are provided; **and** • inadequate response, adverse reaction, or contraindication to glucocorticoids; **and** • appropriate dosing.

Agents not Otherwise Classified – Nonhormonal Agents for Menopausal Symptoms

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
fezolinetant	Veozah	PA		**paroxetine mesylate capsule** • Documentation of all of the following is required: • appropriate diagnosis; **and** • medical records documenting an inadequate response or adverse reaction to paroxetine hydrochloride; **and** • medical records documenting an inadequate response or adverse reaction to three or contraindication to all of the following: clonidine, desvenlafaxine or venlafaxine, gabapentin, menopausal hormone therapy, oxybutynin, an SSRI other than paroxetine. **Veozah** • Documentation of all of the following is required: • appropriate diagnosis; **and** • inadequate response or adverse reaction to one or contraindication to all menopausal hormonal agents; **and** • inadequate response or adverse reaction to two or contraindication to all of the following: clonidine, gabapentin, oxybutynin, SNRI, SSRI; **and** • requested quantity is ≤ one unit/day.
paroxetine mesylate capsule		PA	A90	

Agents not Otherwise Classified – C-Type Natriuretic Peptide

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
vosoritide	Voxzogo	PA		**Voxzogo** • Documentation of the following is required: • medical records documenting diagnosis of achondroplasia based on symptoms and radiographic findings or genetic testing; **and** • member is ≥ five years of age; **and** • prescriber is an endocrinologist or geneticist or consult notes from an endocrinologist or geneticist are

	Clinical Notes
	provided; **and** • requested dose is 15 mcg/kg once daily; **and** • requested quantity is ≤ one unit/day; **and** • member has open epiphyses. • For recertification, documentation of the following is required: • member continues to have open epiphyses; **and** • growth velocity is at least 2.5 cm/year.

Agents not Otherwise Classified – Presbyopia Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
pilocarpine 1.25% ophthalmic solution	Vuity	PA		**Vuity** • Documentation of all of the following is required: • diagnosis of presbyopia; **and** • prescriber is an optometrist or ophthalmologist or consult notes from an optometrist or ophthalmologist are provided; **and** • member is ≥ 40 years of age; **and** • member has a contraindication to the use of corrective lenses; **and** • appropriate dosing.

Agents not Otherwise Classified – Transthyretin Stabilizer

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
tafamidis	Vyndamax	PA		**Vyndamax, Vyndaqel** • Documentation of all of the following is required for wild-type transthyretin-mediated or hereditary transthyretin-mediated amyloidosis: • appropriate diagnosis; **and** • member is ≥ 18 years of age; **and** • prescriber is a cardiologist or consult notes from a specialist are provided; **and** • one of the following: • results from genetic testing showing mutations in the TTR gene; **or** • presence of amyloid deposits in biopsy tissue with confirmed TTR; **or** • TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry; **and** • appropriate dosing; **and** • one of the following:
tafamidis	Vyndaqel	PA		

	Clinical Notes
	• for Vyndamax, requested quantity is ≤ one unit/day; **or** • for Vyndaqel, requested quantity is ≤ four units/day.

Agents not Otherwise Classified – Purified Collagenase

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

collagenase clostridium histolyticum	Xiaflex	PA		**Xiaflex**
				• Documentation of all of the following is required for a diagnosis of Dupuytren's contracture:
				  • appropriate diagnosis; **and**
				  • number of cords being treated.
				• Documentation of all of the following is required for a diagnosis of Peyronie's disease:
				  • appropriate diagnosis; **and**
				  • prescriber is a urologist or consult notes from a urologist are provided; **and**
				  • member is ≥ 18 years of age; **and**
				  • appropriate dosing; **and**
				  • member is not a candidate for surgery at this time; **and**
				  • one of the following:
				  • both of the following:
				  • member has active disease; **and**
				  • inadequate response, adverse reaction, or contraindication to pentoxifylline; **or**
				  • both of the following:
				  • member has stable disease; **and**
				  • member's penile curvature is > 30 degrees.
				SmartPA: Claims for Xiaflex will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for Dupuytren's contracture and the current claim plus all history is ≤ one vial.†

Agents not Otherwise Classified – Phosphate Binders and Phosphate Absorption Inhibitors

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

tenapanor 20 mg, 30 mg tablet	Xphozah	PA		**Xphozah**
				• Documentation of all of the following is required:
				  • diagnosis of hyperphosphatemia in chronic kidney disease on dialysis for ≥ three months; **and**
				  • member is ≥ 18 years of age; **and**
				  • prescriber is a nephrologist or consult notes from a nephrologist are provided; **and**

	Clinical Notes
	• inadequate response or adverse reaction to two or contraindication to all of the following: Auryxia, calcium acetate, lanthanum, sevelamer hydrochloride or sevelamer carbonate, Velphoro; **and** • appropriate dosing; **and** • requested quantity is ≤ two units/day.

Agents not Otherwise Classified – Farnesyltransferase Inhibitor

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
lonafarnib	Zokinvy	PA		**Zokinvy** • Documentation of all of the following is required: • one of the following: • diagnosis of processing deficient Progeroid Laminopathy with one of the following: • heterozygous LMNA mutation with progerin-like protein accumulation; **or** • homozygous or compound heterozygous ZMPSTE24 mutations; **or** • diagnosis of Hutchinson-Gilford progeria syndrome; **and** • results from genetic testing or molecular analysis to confirm diagnosis; **and** • prescriber is a specialist in genetic diseases or consult notes from a specialist are provided; **and** • member is ≥ one year of age; **and** • member's BSA is ≥ 0.39 m^2; **and** • appropriate dosing; **and** • requested dose cannot be consolidated; **and** • requested quantity is ≤ four units/day.

Agents not Otherwise Classified – Decongestant

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
pseudoephedrine		PA - > 240 mg/day	*	**pseudoephedrine > 240 mg/day** • Documentation of all of the following is required: • appropriate diagnosis; **and** • member is ≥ 12 years of age; **and** • medical necessity for exceeding the dose limit. • For recertification, documentation of positive response to therapy is required.

Agents not Otherwise Classified – Medical Foods

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

levomethylfolate tablet		PA - > 1 unit/day		**Deplin FC and levomethylfolate/algal oil capsule**
				• Documentation of all of the following is required:
				  • diagnosis of one of the following:
				  • depression; **or**
				  • schizophrenia; **or**
				  • other clinically appropriate diagnosis; **and**
				  • medical necessity for use instead of levomethylfolate tablets; **and**
				  • one of the following:
				  • requested quantity is ≤ one unit/day; **or**
				  • medical necessity for exceeding the quantity limits.
				
				levomethylfolate tablet > one unit/day
				• Documentation of all of the following is required:
				  • diagnosis of one of the following:
				  • depression; **or**
				  • schizophrenia; **or**
				  • other clinically appropriate diagnosis; **and**
				  • medical necessity for exceeding the quantity limit.

Agents not Otherwise Classified – Melatonin Agents

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes
melatonin gummy, solution, tablet			*, A90	

Agents not Otherwise Classified – Potassium Iodide

Drug Generic Name	Drug Brand Name	PA Status	Drug Notes	Clinical Notes

potassium iodide		PA - > 1 mL/day		**potassium iodide > one mL/day**
				• Documentation of the following is required for the indication for the use of thyroid protection prior to MIBG scan or prior to thyroidectomy surgery:
				  • appropriate indication; **and**
				  • requested dose and frequency; **and**
				  • requested duration of therapy.
				• Documentation of the following is required for all other indications:
				  • appropriate indication; **and**
				  • requested dose and frequency; **and**
				  • requested duration of therapy.

This designates a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for

example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.

BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
CO	Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements.
PD	Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Various

Non-FDA-approved, for example:

- Various

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Please see clinical criteria for agents requiring PA in the table above under the Clinical Notes section.

† Note: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 73 - Iron Agents and Chelators

Drug Category: Iron supplementation and management

Medication Class/Individual Agents: Nutrients and antidotes

I. Prior-Authorization Requirements

Iron Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
ferric carboxymaltose injection	Injectafer	PA	MB
ferric citrate	Auryxia	PA	
ferric derisomaltose	Monoferric	PA	
ferric maltol	Accrufer	PA	
ferric pyrophosphate citrate	Triferic		MB
ferrous fumarate			*, M90
ferrous gluconate			*, M90
ferrous sulfate			*, M90
ferumoxytol	Feraheme	PA	
iron polysaccharide complex			*, M90
iron sucrose	Venofer		MB
low molecular weight iron dextran	Infed		
sodium ferric gluconate complex	Ferrlecit		#

Iron Chelators			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
deferasirox 125 mg, 250 mg, 500 mg	Exjade		BP, A90
deferasirox 90 mg, 180 mg, 360 mg	Jadenu		# , A90
deferiprone	Ferriprox	PA	A90
deferoxamine	Desferal		#

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Intravenous iron replacement therapies[1]

- Injectable iron replacement products are iron-carbohydrate complexes consisting of a core made of an iron-oxyhydroxy gel surrounded by a shell of carbohydrate that stabilizes the gel, slows the release of iron, and maintains the resulting particles in colloidal suspension.
- Current injectable iron replacement formulations differ from each other by chemical structure, adverse event profile, cost and dosing schedule.

Parenteral Iron Chelators:

- Deferoxamine
  - Food and Drug Administration (FDA)-approved for the treatment of acute iron intoxication and chronic iron overload due to transfusion-dependent anemias.
  - Available in vials for intramuscular, subcutaneous, and intravenous administration.
  - Generally requires infusion on at least 5 days per week for at least 8 hours per day.

Oral Iron Chelators:

	Clinical Notes

	• Deferasirox
	  • Once-daily formulation that was FDA-approved for the treatment of chronic iron overload due to blood transfusions in patients two years of age and older.
	• Deferiprone
	  • Approved by the FDA for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate, sickle cell disease, or other anemias.
	  • Administered three times daily.
	
	[1] Auerbach M, Ballard H. Clinical Use of Intravenous Iron: Administration, Efficacy, and Safety. Hematology. 2010 Dec; 1: 338-347.

#	This designates a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP	Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
*	The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.
MB	This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.
A90	Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.
M90	Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- hyperphosphatemia in chronic kidney disease on dialysis (Auryxia)
- iron deficiency (Accrufer)
- iron deficiency anemia (Auryxia, ferumoxytol, Injectafer, Monoferric)
- iron deficiency in adults with heart failure categorized as NYHA class II/III (Injectafer)
- transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias (deferiprone)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Accrufer

- Documentation of all of the following is required:
  - diagnosis of iron deficiency; **and**
  - inadequate response or adverse reaction to two of the following oral iron products: ferrous fumarate, ferrous gluconate, ferrous sulfate or polysaccharide iron complex; **and**
  - member has attempted strategies to improve tolerability of other iron products if gastrointestinal adverse events occurred.

Auryxia

- Documentation of all of the following is required for a diagnosis of iron deficiency anemia:
  - appropriate diagnosis; **and**
  - inadequate response or adverse reaction two of the following oral iron products: ferrous fumarate, ferrous gluconate, ferrous sulfate or polysaccharide iron complex; **and**
  - member has attempted strategies to improve tolerability of other iron products if gastrointestinal adverse events occurred.
- Documentation of all of the following is required for a diagnosis of hyperphosphatemia in chronic kidney disease on dialysis:
  - appropriate diagnosis; **and**
  - member is ≥18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: calcium acetate, lanthanum, sevelamer hydrochloride or sevelamer carbonate, Velphoro; **and**
  - appropriate dosing.

SmartPA: Claims for Auryxia will usually process at the pharmacy without a PA request if the member has a history of medical claims for hyperphosphatemia, is greater than or equal to 18 years of age, and has a history of paid claims for at least two lower-cost phosphate binders [calcium acetate, sevelamer hydrochloride or sevelamer carbonate, lanthanum, Velphoro (sucroferric oxyhydroxide)] in all claims history. †

deferiprone

- Documentation of all of the following is required:
  - one of the following:
    - diagnosis of transfusional iron overload due to thalassemia syndromes; **or**

    - diagnosis of transfusional iron overload due to sickle cell disease or other anemia; **and**
  - member is under the care of an appropriate specialist (hematologist, oncologist); **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: deferoxamine, deferasirox; **and**
  - for the tablet formulation, the member is ≥ eight years of age; **and**
  - for the oral solution formulation, one of the following:
    - member is ≥ three years to ≤ 13 years of age; **or**
    - medical necessity for the use of an oral solution formulation.

Injectafer

- Documentation of all of the following is required for a diagnosis of iron deficiency anemia:
  - diagnosis of iron deficiency anemia; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Infed (low molecular weight iron dextran), sodium ferric gluconate complex, Venofer (iron sucrose).
- Documentation of all of the following is required for a diagnosis of iron deficiency in adults with heart failure categorized as NYHA class II/III:
  - diagnosis of iron deficiency in adults with heart failure categorized as NYHA class II/III; **and**
  - member is ≥18 years of age; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Infed (low molecular weight iron dextran), sodium ferric gluconate complex, Venofer (iron sucrose); **and**
  - appropriate dosing.

ferumoxytol and Monoferric

- Documentation of all of the following is required:
  - diagnosis of iron deficiency anemia; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: Infed (low molecular weight iron dextran), sodium ferric gluconate complex, Venofer (iron sucrose).

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 74 - Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors

Drug Category: VMAT2 Inhibitors

Medication Class/Individual Agents: VMAT2 Inhibitors

I. Prior-Authorization Requirements

Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.
deutetrabenazine	Austedo	PA		
deutetrabenazine extended-release	Austedo XR	PA		
tetrabenazine	Xenazine	PA	M90	
valbenazine	Ingrezza	PA		

M90 Mandatory 90-day supply. After dispensing up to a 30-day supply initial fill, dispensing in a 90-day supply is required. May not include all strengths or formulations. Quantity limits and other restrictions may also apply.

II. Therapeutic Uses

FDA-approved, for example:

- chorea associated with Huntington's disease
- tardive dyskinesia

Non-FDA-approved, for example:

- tardive dyskinesia (tetrabenazine)
- Tourette's syndrome/tics (Austedo, Austedo XR, Ingrezza, tetrabenazine)
- unspecified hyperkinetic movement disorder (Austedo, Austedo XR, Ingrezza, tetrabenazine)

Note: The above lists may not include all FDA-approved and non-FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.

- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Austedo and Austedo XR

- Documentation of all of the following is required for a diagnosis of Huntington's disease:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to tetrabenazine; **and**
  - one of the following:
    - requested dose is ≤ 36 mg/day; **or**
    - requested dose is > 36 mg/day and ≤ 48 mg/day, and member has been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer; **and**
  - one of the following:
    - for Austedo, requested quantity is ≤ four units/day; **or**
    - for Austedo XR 6 mg or 12 mg, requested quantity is ≤ three units/day; **or**
    - for Austedo XR 24 mg, requested quantity is ≤ two units/day.
- Documentation of all of the following is required for a diagnosis of tardive dyskinesia:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - persistent, disabling, or intrusive tardive dyskinesia; **and**
  - one of the following:
    - requested dose is ≤ 36 mg/day; **or**
    - requested dose is > 36 mg/day and ≤ 48 mg/day, and member has been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer; **and**
    - one of the following:
    - for Austedo, requested quantity is ≤ four units/day; **or**
    - for Austedo XR 6 mg or 12 mg, requested quantity is ≤ three units/day; **or**
    - for Austedo XR 24 mg, requested quantity is ≤ two units/day.
- Documentation of all of the following is required for a diagnosis of Tourette's syndrome/tics:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, botulinum toxin, clonidine or guanfacine, first or second generation antipsychotic, topiramate or levetiracetam; **and**
  - inadequate response or adverse reaction to tetrabenazine; **and**
  - one of the following:
    - requested dose is < 36 mg/day; **or**
    - requested dose is > 36 mg/day and < 48 mg/day and member has been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer; **and**
    - one of the following:

    - for Austedo, requested quantity is ≤ four units/day; **or**
    - for Austedo XR 6 mg or 12 mg, requested quantity is ≤ three units/day; **or**
    - for Austedo XR 24 mg, requested quantity is ≤ two units/day.
- Documentation of all of the following is required for a diagnosis of unspecified hyperkinetic movement disorder:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, benzodiazepine, botulinum toxin, clonidine, levodopa/carbidopa, trihexyphenidyl; **and**
    - inadequate response or adverse reaction to tetrabenazine; **and**
    - one of the following:
        - requested dose is < 36 mg/day; **or**
        - requested dose is > 36 mg/day and < 48 mg/day and member has been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer; **and**
    - one of the following:
        - for Austedo, requested quantity is ≤ four units/day; **or**
        - for Austedo XR 6 mg or 12 mg, requested quantity is ≤ three units/day; **or**
        - for Austedo XR 24 mg, requested quantity is ≤ two units/day.

Ingrezza
- Documentation of all of the following is required for a diagnosis of Huntington's Disease:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - inadequate response or adverse reaction to tetrabenazine; **and**
    - requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for a diagnosis of tardive dyskinesia:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - persistent, disabling, or intrusive tardive dyskinesia; **and**
    - requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for a diagnosis of unspecified Tourette’s syndrome/tics:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, botulinum toxin, clonidine or guanfacine, first or second generation antipsychotic, topiramate or levetiracetam, **and**
    - inadequate response or adverse reaction to tetrabenazine; **and**
    - requested quantity is ≤ one unit/day.
- Documentation of all of the following is required for a diagnosis of unspecified hyperkinetic movement disorder:
    - appropriate diagnosis; **and**
    - member is ≥ 18 years of age; **and**
    - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, benzodiazepine, botulinum toxin, clonidine, levodopa/carbidopa, trihexyphenidyl, **and**
    - inadequate response or adverse reaction to tetrabenazine; **and**
    - requested quantity is ≤ one unit/day.

tetrabenazine
- Documentation of all of the following is required for a diagnosis of Huntington’s disease:
    - appropriate diagnosis; **and**
    - one of the following:

    - requested dose is ≤ 50 mg/day; **or**
    - requested dose is > 50 mg/day and ≤ 100 mg/day, and member has been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer.
  - member is ≥ 18 years of age.
- Documentation of all of the following is required for a diagnosis of tardive dyskinesia:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - persistent, disabling, or intrusive tardive dyskinesia; **and**
  - requested dose is ≤ 200 mg/day.
- Documentation of all of the following is required for a diagnosis of Tourette's syndrome/tics:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, botulinum toxin, clonidine or guanfacine, first or second generation antipsychotic, topiramate or levetiracetam; **and**
  - requested dose is ≤ 75 mg/day.
- Documentation of all of the following is required for a diagnosis of unspecified hyperkinetic movement disorder:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - inadequate response or adverse reaction to two or contraindication to all of the following: baclofen, benzodiazepine, botulinum toxin, clonidine, levodopa/carbidopa, trihexyphenidyl; **and**
  - requested dose is ≤ 200 mg/day.

SmartPA: Claims for tetrabenazine at a dose of ≤ 100 mg/day will usually process at the pharmacy without a PA request if the member is ≥ 18 years of age, has a history of MassHealth medical claims for Huntington's disease with chorea, and has a history of paid MassHealth pharmacy claims for tetrabenazine for at least 90 out of the last 120 days.†

† **Note:** The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 75 - T-Cell Immunotherapies

Drug Category: Immunotherapies

Medication Class/Individual Agents: T-Cell Immunotherapies

I. Prior-Authorization Requirements

T-Cell Immunotherapies - Chimeric Antigen Receptor (CAR)-T Immunotherapies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
axicabtagene ciloleucel	Yescarta	PA	CO, MB
brexucabtagene autoleucel	Tecartus	PA	CO, MB
ciltacabtagene autoleucel	Carvykti	PA	CO, MB
idecabtagene vicleucel	Abecma	PA	CO, MB
lisocabtagene maraleucel	Breyanzi	PA	CO, MB
tisagenlecleucel	Kymriah	PA	CO, MB

T-Cell Immunotherapies - Autologous T-cell Immunotherapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
lifileucel	Amtagvi	PA	CO, MB

T-Cell Immunotherapies - Bispecific Antibodies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
elranatamab-bcmm	Elrexfio	PA	MB
epcoritamab-bysp	Epkinly	PA	MB
glofitamab-gxbm	Columvi	PA	MB
mosunetuzumab-axgb	Lunsumio	PA	MB
talquetamab-tgvs	Talvey	PA	MB
teclistamab-cqyv	Tecvayli	PA	MB

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

CAR-T immunotherapy is unique; a patient's own T cells are genetically modified ex vivo to activate the patient's immune response and then reinfused back into the patient. These therapies have produced promising results in clinical trials, and thus far, the long-term durability of response is not known.

Given the risk of serious adverse reactions such as cytokine release syndrome (CRS) and neurological toxicities, these agents are administered by certified treatment centers. MassHealth Drug Utilization Review will be reaching out to prescribers after infusion date to verify clinical effectiveness and for long-term monitoring of sustained response. For additional information regarding CAR-T immunotherapies, please see the Acute Hospital Carve-Out Drugs List found at www.mass.gov/druglist .

Epcoritamab-bysp is a T-cell engaging bispecific antibody indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise

	Clinical Notes
	specified (DLBCL, NOS), including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy. This agent also has a black box warning for potential CRS and immune effector cell-associated neurotoxicity syndrome (ICANS). It should only be administered by a healthcare professional with immediate access to appropriate medical support, including supportive medications to manage these possible side effects. Glofitamab-gxbm is a bispecific antibody that binds to CD20 expressed on the surface of B-cells, and to CD3 receptor expressed on the surface of T-cells. It is indicated for the treatment of adult patients with relapsed or refractory DLBCL, NOS or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy. Glofitamab-gxbm has a black box warning for potential CRS and thus should only be administered by a healthcare professional with immediate access to appropriate medical support, including supportive medications to manage severe CRS. Teclistamab-cqyv is a subcutaneous “off-the-shelf” T-cell-redirecting, bispecific antibody that targets both B-cell maturation antigen (BCMA) and CD3. It is indicated for the treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory (IMiD) agent, and an anti-CD38 monoclonal antibody. It is approved with a REMS requiring that healthcare facilities that dispense the therapy must be specially certified to recognize and manage CRS and neurologic toxicities.

CO Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse (Kymriah)
- Relapsed or refractory B-cell precursor ALL (Tecartus)
- Relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (Kymriah, Lunsumio, Yescarta)
- Relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from FL, after two or more lines of systemic therapy (Columvi)
- Relapsed or refractory LBCL after two or more lines of systemic therapy, including DLBCL, NOS, high grade B-cell lymphoma, and DLBCL arising from FL (Kymriah)
- Relapsed or refractory LBCL after two or more lines of systemic therapy, including DLBCL, NOS, primary mediastinal LBCL, high grade B-cell lymphoma, and DLBCL arising from FL (Yescarta)
- LBCL refractory to first line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy (Yescarta)
- LBCL refractory to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy, or refractory to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age (Breyanzi)
- Relapsed or refractory LBCL after two or more lines of systemic therapy, including DLBCL, NOS (including DLBCL arising from indolent lymphoma), and high grade B-cell lymphoma (Epkinly)
- Relapsed or refractory LBCL after two or more lines of systemic therapy, including DLBCL, NOS (including DLBCL arising from indolent lymphoma), high grade B-cell lymphoma, primary mediastinal LBCL, and FL grade 3B (Breyanzi)
- Relapsed or refractory mantle cell lymphoma (Tecartus)
- Relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody (Abecma, Carvykti, Elrexfio, Talvey, Tecvayli)
- Unresectable or metastatic melanoma (Amtagvi)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate

and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Abecma, Carvykti, Elrexfio, Talvey, and Tecvayli

- Documentation of the following is required:
  - diagnosis of relapsed or refractory multiple myeloma; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to four lines of systemic therapies or contraindication to all other lines of systemic therapies; **and**
  - member's disease is refractory to at least one proteasome inhibitor or has a contraindication to all proteasome inhibitors; **and**
  - member's disease is refractory to at least one immunomodulatory agent or has a contraindication to all immunomodulatory agents; **and**
  - member's disease is refractory to at least one anti-CD38 monoclonal antibody or has a contraindication to all anti-CD38 monoclonal antibodies; **and**
  - administration will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.

Amtagvi

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - prescriber is an oncologist; **and**
  - inadequate response or adverse reaction to one or contraindication to all appropriate PD-1 blocking antibodies; **and**
  - for BRAF V600 mutation positive, inadequate response or adverse reaction to one or contraindication to all BRAF inhibitors; **and**
  - appropriate dosing and treatment dates; **and**
  - infusion will take place in a qualified treatment facility.

Breyanzi

- Documentation of the following is required for large B-cell lymphoma refractory to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy, or refractory to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to one line of systemic therapy; **and**
  - one of the following:
    - member has refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; **or**
    - member has refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and is not eligible for HSCT (e.g., due to comorbidities or age); **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.
- Documentation of the following is required for a diagnosis of relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL, NOS (including DLBCL arising from indolent lymphoma), high grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and FL grade 3B:
  - appropriate diagnosis; **and**

- prescriber is a hematologist or oncologist; **and**
- appropriate dosing (member's weight must be provided); **and**
- member is ≥ 18 years of age on treatment date; **and**
- inadequate response or adverse reaction to two lines of systemic therapies; **and**
- infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.

Columvi
- Documentation of the following is required:
  - diagnosis of relapsed or refractory DLBCL, NOS or LBCL arising from FL; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing; **and**
  - member is ≥ 18 years of age; **and**
  - member has received at least two lines of systemic therapies, including at least one anti-CD20 monoclonal antibody.

Epkinly
- Documentation of the following is required:
  - diagnosis of one of the following:
    - relapsed or refractory DLBCL, NOS; **or**
    - relapsed or refractory DLBCL arising from indolent lymphoma; **or**
    - relapsed or refractory DLBCL arising from high-grade B-cell lymphoma; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing; **and**
  - member is ≥ 18 years of age; **and**
  - member has received at least two lines of systemic therapies, including at least one anti-CD20 monoclonal antibody.

Kymriah
- Documentation of the following is required for a diagnosis of relapsed or refractory FL after two or more lines of systemic therapy, or diagnosis of relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), high grade B-cell lymphoma and DLBCL arising from FL:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to two lines of systemic therapies; **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.
- Documentation of the following is required for a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is < 26 years of age on treatment date; **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided; **and**
  - one of the following:
    - all of the following:
      - member has Philadelphia chromosome positive ALL; **and**

- member has refractory disease or ≥ two relapses; **and**
- inadequate response or adverse reaction to two tyrosine kinase inhibitors or contraindication to all tyrosine kinase inhibitors; **or**

- both of the following:
  - member has Philadelphia chromosome negative ALL; **and**
  - member has refractory disease or ≥ two relapses.

Lunsumio

- Documentation of the following is required for relapsed or refractory FL:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing; **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to two lines of systemic therapies including at least one anti-CD20 monoclonal antibody.

Tecartus

- Documentation of the following is required for relapsed or refractory MCL:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to one or contraindication to both of the following: anthracycline-containing chemotherapy, bendamustine-containing chemotherapy; **and**
  - inadequate response or adverse reaction to one or contraindication to all of the following: ibrutinib, acalabrutinib, zanubrutinib; **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.
- Documentation of the following is required for relapsed or refractory B-cell precursor ALL:
  - appropriate diagnosis; **and**
  - prescriber is hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - one of the following:
    - member has primary refractory ALL; **or**
    - member experienced a first relapse following a remission lasting ≤ 12 months; **or**
    - member has relapsed or refractory ALL after second-line or higher therapy; **or**
    - member has relapsed or refractory ALL at least 100 days after allogenic stem cell transplant; **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided; **and**
  - if the member has Philadelphia positive ALL, inadequate response, adverse reaction, or contraindication to one tyrosine kinase inhibitor.

Yescarta

- Documentation of the following is required for a diagnosis of relapsed or refractory FL after two or more lines of systemic therapy, or a diagnosis of relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL, NOS, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from FL:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**

- appropriate dosing (member's weight must be provided); **and**
- member is ≥ 18 years of age on treatment date; **and**
- inadequate response or adverse reaction to two lines of systemic therapies; **and**
- infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.

- Documentation of the following is required for a diagnosis of large B-cell lymphoma refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy:
  - appropriate diagnosis; **and**
  - prescriber is a hematologist or oncologist; **and**
  - appropriate dosing (member's weight must be provided); **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - inadequate response or adverse reaction to one line of systemic therapy; **and**
  - one of the following:
    - member has primary refractory disease; **or**
    - member relapsed within 12 months of a completed first line chemoimmunotherapy regimen; **and**
  - infusion will take place in a health care facility that has been certified pursuant to the REMS program specific to the treatment being provided.

MassHealth Evaluation Criteria

Table 76 - Neuromuscular Agents – Duchenne Muscular Dystrophy and Spinal Muscular Atrophy

Drug Category: Genetic/Developmental Disorder

Medication Class/Individual Agents: Neuromuscular

I. Prior-Authorization Requirements

Neuromuscular Agents - Duchenne Muscular Dystrophy Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
casimersen	Amondys 45	PA	
delandistrogene moxeparvovec-rokl	Elevidys	PA	CO, MB
eteplirsen	Exondys 51	PA	
golodirsen	Vyondys 53	PA	
viltolarsen	Viltepso	PA	

Neuromuscular Agents - Spinal Muscular Atrophy Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
nusinersen	Spinraza	PA	MB
onasemnogene abeparvovec-xioi	Zolgensma [PD]	PA	CO, MB
risdiplam	Evrysdi	PA	

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Casimersen, eteplirsen, golodirsen, and viltolarsen

- Casimersen, eteplirsen, golodirsen, and viltolarsen are intravenously (IV) administered antisense oligonucleotides directed at dystrophin pre-messenger ribonucleic acid (mRNA) with amenable mutations
- FDA-approved dosing:
  - Casimersen, eteplirsen, golodirsen: 30 mg/kg weekly
  - Viltolarsen: 80 mg/kg weekly
- The same motor function measures must be used for both the pre-treatment baseline and current test
- Quarterly objective testing is required for recertification

Nusinersen and risdiplam

- Nusinersen and risdiplam target survival motor neuron-2 (SMN2)
- Use of nusinersen in combination with risdiplam has not been evaluated
- Examples of baseline motor function tests to include: Hammersmith Functional Motor Scale [HFMSE], Hammersmith Infant Neurological Examination [HINE], Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], World Health Organization [WHO] Motor Milestones, etc.

	Clinical Notes
	Onasemnogene abeparvovec-xioi • MassHealth Drug Utilization Review will be reaching out to prescribers after PA approval to verify administration date and at ongoing intervals for long-term monitoring of response.

CO Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Duchenne muscular dystrophy (Amondys 45, Elevidys, Exondys 51, Viltepso, Vyondys 53)
- Spinal muscular atrophy (Evrysdi, Spinraza, Zolgensma)

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Amondys 45

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - confirmed out-of-frame deletion in the DMD gene that is amenable to exon 45 skipping; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - member is ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - appropriate dosing (30 mg/kg intravenously every week); **and**
  - one of the following:
    - member has received a corticosteroid for at least six months prior and member will continue to use a corticosteroid in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has at least a baseline measurement for each of the following timed function tests as shown in medical records (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds); **and**
  - member has not previously received treatment with a gene therapy for DMD.

- For recertification requests, documentation of all of the following is required:
  - member remains ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all interim results (all previous 6MWTs results must be included); **and**
  - dosing remains appropriate; **and**
  - one of the following:
    - member continues to utilize corticosteroids in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has a stable or improving pattern of observed performance on at least two of the following five timed function tests as shown in medical records (all results for all tests must be included with the date of performance; tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds); **and**
  - member has not previously received treatment with a gene therapy for DMD.

Elevidys

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ four years of age and < six years of age at the time of administration; **and**
  - prescriber is a neuromuscular specialist; **and**

- copy of genetic test with a confirmed mutation in the DMD gene; **and**
- member does not have any deletion in exon 8 or exon 9 of the DMD gene; **and**
- copy of baseline anti-AAVrh74 total binding antibody titers < 1:400; **and**
- member has a baseline measurement for both of the following:
  - North Star Ambulatory Assessment, including scores and times on individual items (within the past three months); **and**
  - Six-minute walk test (within the past three months); **and**
- member is ambulatory as defined by a current six-minute walk test (6MWT – distance walked in six minutes in meters) ≥ 200 meters; **and**
- one of the following:
  - member is on a stable dose of corticosteroid; **or**
  - attestation that the member will continue to utilize chronic corticosteroids after Elevidys infusion; **or**
  - demonstrated contraindication to corticosteroids; **and**
- member has not previously received treatment with a gene therapy for DMD; **and**
- infusion will take place in a qualified treatment facility; **and**
- member is not currently utilizing antisense oligonucleotides; **and**
- appropriate dosing.

Evrysdi

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - copy of genetic test confirming member has 4 copies of SMN2 and one of the following:
      - member is symptomatic; **or**
      - member is a pre-symptomatic infant diagnosed via newborn screening; **or**
    - copy of genetic test confirming member has 2 or 3 copies of SMN2; **and**
  - genetic test confirming diagnosis of SMA; **and**
  - prescriber is a neurologist or consult notes from a neurologist are provided; **and**
  - current motor function test; **and**
  - if the member has previously received Zolgensma, all of the following:
    - attestation that the member has had an inadequate response to Zolgensma; **and**
    - pre-treatment baseline motor function test (prior to treatment with any SMA agent); **and**
    - pre-Zolgensma baseline motor function test (if different than pre-treatment baseline); **and**
    - post-Zolgensma motor function tests; **and**
  - appropriate dosing for age and weight; **and**
  - requested quantity is ≤ 5 mg (6.67 mL) per day; **and**
  - member does not have evidence of permanent ventilator dependence (defined as any of the following: member has an endotracheal tube, member has a tracheotomy tube, member had at least 14 days of continuous respiratory assistance for at least 16 hours per day); **and**
  - requested agent will not be used in combination with Spinraza.

- For recertification requests, documentation of both of the following is required:
  - one of the following:
    - current motor function test documenting positive response to therapy; **or**
    - medical necessity for continuing therapy; **and**
  - member does not have evidence of permanent ventilator dependence (defined as any of the following: member has an endotracheal tube, member has a tracheotomy tube, member had at least 14 days of continuous respiratory assistance for at least 16 hours per day).

Exondys 51

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - confirmed out-of-frame deletion in the DMD gene that is amenable to exon 51 skipping; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - member is ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - appropriate dosing (30 mg/kg intravenously every week); **and**
  - one of the following:
    - member has received a corticosteroid for at least six months prior and member will continue to use a corticosteroid in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has at least a baseline measurement for each of the following timed function tests as shown in medical records (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds; **and**
  - member has not previously received treatment with a gene therapy for DMD.

- For recertification requests, documentation of all of the following is required:
  - member remains ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all interim results (all previous 6MWTs results must be included); **and**
  - dosing remains appropriate; **and**
  - one of the following:
    - member continues to utilize corticosteroids in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has a stable or improving pattern of observed performance on at least two of the following five timed function tests as shown in medical records (all results for all tests must be included with the date of performance; tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds); **and**
  - member has not previously received treatment with a gene therapy for DMD.

Spinraza

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - one of the following:
    - copy of genetic test confirming member has 4 copies of SMN2 and one of the following:

        - member is symptomatic; **or**
        - member is a pre-symptomatic infant diagnosed via newborn screening; **or**
      - copy of genetic test confirming member has 2 or 3 copies of SMN2; **and**
    - genetic test confirming diagnosis of SMA; **and**
    - prescriber is a neurologist or consult notes from a neurologist are provided; **and**
    - current motor function test; **and**
    - if the member has previously received Zolgensma, all of the following:
      - attestation that the member has had an inadequate response to Zolgensma; **and**
      - pre-treatment baseline motor function test (prior to treatment with any SMA agent); **and**
      - pre-Zolgensma baseline motor function test (if different than pre-treatment baseline); **and**
      - post-Zolgensma motor function tests; **and**
    - member does not have evidence of permanent ventilator dependence (defined as any of the following: member has an endotracheal tube, member has a tracheotomy tube, member had at least 14 days of continuous respiratory assistance for at least 16 hours per day); **and**
    - requested agent will not be used in combination with Evrysdi; **and**
    - appropriate dosing.

- For recertification requests, documentation of both of the following is required:
  - one of the following:
    - current motor function test documenting positive response to therapy; **or**
    - medical necessity for continuing therapy; **and**
  - member does not have evidence of permanent ventilator dependence (defined as any of the following: member has an endotracheal tube, member has a tracheotomy tube, member had at least 14 days of continuous respiratory assistance for at least 16 hours per day).

Viltepso

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - confirmed out-of-frame deletion in the DMD gene that is amenable to exon 53 skipping; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - member is ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - appropriate dosing (80 mg/kg intravenously every week); **and**
  - one of the following:
    - member has received a corticosteroid for at least three months prior and member will continue to use a corticosteroid in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has at least a baseline measurement for each of the following timed function tests as shown in medical records (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds); **and**
  - member has not previously received treatment with a gene therapy for DMD.

- For recertification requests, documentation of all of the following is required:
  - member remains ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all interim results (all previous 6MWTs results must be included); **and**
  - dosing remains appropriate; **and**
  - one of the following:
    - member continues to utilize corticosteroids in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has a stable or improving pattern of observed performance on at least two of the following five timed function tests as shown in medical records (all results for all tests must be included with the date of performance; tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds); **and**
  - member has not previously received treatment with a gene therapy for DMD.

Vyondys 53

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - confirmed out-of-frame deletion in the DMD gene that is amenable to exon 53 skipping; **and**
  - prescriber is a neuromuscular neurologist or consult notes from a neuromuscular neurology office are provided; **and**
  - member is ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - appropriate dosing (30 mg/kg intravenously every week); **and**
  - one of the following:
    - member has received a corticosteroid for at least six months prior and member will continue to use a corticosteroid in combination with the requested agent; **or**
    - contraindication to corticosteroids; **and**
  - member has at least a baseline measurement for each of the following timed function tests as shown in medical records (tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
    - timed ten-meter walk/run (time in seconds); **and**
    - timed floor (supine) to stand (time in seconds); **and**
    - timed four-step descend (time in seconds); **and**
    - timed four-step climb (time in seconds); **and**
    - timed sit to stand (time in seconds); **and**
  - member has not previously received treatment with a gene therapy for DMD.

- For recertification requests, documentation of all of the following is required:
  - member remains ambulatory as defined by a current six-minute walk test (6MWT - distance walked in six minutes in meters) of ≥ 200 meters (test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner); **and**
  - member has a stable or improving pattern of 6MWTs as shown in medical records with results of a pretreatment baseline and all

interim results (all previous 6MWTs results must be included); **and**

- dosing remains appropriate; **and**
- one of the following:
  - member continues to utilize corticosteroids in combination with the requested agent; **or**
  - contraindication to corticosteroids; **and**
- member has a stable or improving pattern of observed performance on at least two of the following five timed function tests as shown in medical records (all results for all tests must be included with the date of performance; tests must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner):
  - timed ten-meter walk/run (time in seconds); **and**
  - timed floor (supine) to stand (time in seconds); **and**
  - timed four-step descend (time in seconds); **and**
  - timed four-step climb (time in seconds); **and**
  - timed sit to stand (time in seconds); **and**
- member has not previously received treatment with a gene therapy for DMD.

Zolgensma

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - prescriber is a neuromuscular specialist; **and**
  - member is < two years of age; **and**
  - genetic test confirming diagnosis of bi-allelic mutation in the SMN1 gene; **and**
  - genetic test confirming the member has two, three, or four copies of the SMN2 gene; **and**
  - baseline AAV9 antibody test confirming titers < 1:50; **and**
  - pre-treatment baseline Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) score; **and**
  - member does not have evidence of complete paralysis of limbs; **and**
  - member does not have evidence of permanent ventilator dependence (defined as any of the following: member has an endotracheal tube, member has a tracheotomy tube, member had at least 14 days of continuous respiratory assistance for at least 16 hours per day) at the time the requested agent is to be administered; **and**
  - member does not have active viral infection, including human immunodeficiency virus [HIV] or positive serology for hepatitis B or C, or Zika virus; **and**
  - member has not previously received treatment with a gene therapy for spinal muscular atrophy.

MassHealth Evaluation Criteria
Table 77 - Hyaluronan Injections

Drug Category: Hyaluronan Injections

Medication Class/Individual Agents: Hyaluronan Injections

I. Prior-Authorization Requirements

Hyaluronan Injections			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
hyaluronan, high molecular weight	Orthovisc	PA	MB
hyaluronate, crossed-linked	Gel-One	PA	MB
hyaluronate, modified	Hymovis	PA	MB
hyaluronate, stabilized	Durolane	PA	MB
hyaluronate-Euflexxa	Euflexxa	PA	MB
hyaluronate-Gelsyn	Gelsyn	PA	MB
hyaluronate-Genvisc	Genvisc	PA	MB
hyaluronate-Hyalgan	Hyalgan	PA	MB
hyaluronate-Monovisc	Monovisc	PA	MB
hyaluronate-Supartz	Supartz	PA	MB
hyaluronate-Synojoynt	Synojoynt	PA	MB
hyaluronate-Triluron	Triluron	PA	MB
hyaluronate-Trivisc	Trivisc	PA	MB
hyaluronate-Visco-3	Visco-3	PA	MB
hylan G-F20-Synvisc	Synvisc	PA	MB
hylan G-F20-Synvisc-One	Synvisc-One	PA	MB

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

Hyaluronic acid (HA) is a constitutive component of matrix cartilage, which plays a key role in the maintenance of joint homeostasis. HA is also a biologically active component, secreted by chondrocytes, that protects the cartilage from degradation by interacting with matrix metalloproteinase (MMPs) and pain mediators.[1]

In patients with osteoarthritis (OA), the concentration and molecular weight of HA are reduced, diminishing elastoviscosity of the synovial fluid, joint lubrication and shock absorbency, and possible anti-inflammatory, analgesic, and chondroprotective effects.[2, 3]

The aim of HA treatment is to reduce pain and improve physical function by supplementing the viscosity and elasticity of synovial fluid which are reduced in OA.[2]

References:

1. Iannitti T, Lodi D, Palmieri B. Intra-articular injections for the treatment of osteoarthritis. Drugs R D 2011; 11(1):13-27.

2. Gigante A, Callegari L. The role of intra-articular hyaluronan in the treatment of osteoarthritis. Rheumatol Int 2011; 31:427-44.

	Clinical Notes
	3. Strauss EJ, Hart JA, Miller MD, Altman RD, Rosen JE. Hyaluronic acid viscosupplementation and osteoarthritis. Am J Sports Med 2009; 37(8):1636-44.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- treatment of pain associated with osteoarthritis (OA) or degenerative joint disease (DJD) of the knee

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All prior-authorization requests must include clinical diagnosis, product name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

All Hyaluronan Injections

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to acetaminophen; **and**
  - inadequate response or adverse reaction to one or contraindication to all intra-articular corticosteroid injections; **and**
  - inadequate response (defined as ≥ 30 days of therapy) or adverse reaction to one or contraindication to all nonsteroidal anti-inflammatory drug (NSAIDs).

MassHealth Evaluation Criteria
Table 78 - Diabetes Medical Supplies and Emergency Treatments

Drug Category: Various

Medication Class/Individual Agents: Various

I. Prior-Authorization Requirements

Diabetes Emergency Treatments			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
dasiglucagon	Zegalogue		
glucagon auto-injection, prefilled syringe, vial-Gvoke	Gvoke		
glucagon nasal powder	Baqsimi PD		
glucagon vial			
glucagon vial-Glucagen	Glucagen		

Diabetes Medical Supplies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
continuous glucose monitoring system	Dexcom G6	PA	PND
continuous glucose monitoring system	Dexcom G7	PA	PND
continuous glucose monitoring system	Freestyle Libre 14 day	PA	PND
continuous glucose monitoring system	Freestyle Libre 2	PA	PND
continuous glucose monitoring system	Freestyle Libre 3	PA	PND
insulin bolus delivery patch	Cequr Simplicity	PA	PND
insulin continuous subcutaneous infusion patch	V-Go	PA	PND
insulin continuous subcutaneous infusion pump	Omnipod 5	PA	PND

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

In addition to the products listed in Table 78: Diabetes Medical Supplies and Emergency Treatments, the following non-drug diabetes medical supplies are covered through the Pharmacy Online Processing System (POPS):

Medical Supplies

- Alcohol swabs
- Disposable syringe and needle units
- Lancets
- Urine glucose testing reagent strips used for the management of diabetes

Devices

- Insulin cartridge delivery devices and needles or other devices for injection of medication (for example, epinephrine auto-injectors)

Please see the following link to find out more information regarding the Non-Drug Product List: https://masshealthdruglist.ehs.state.ma.us/MHDL/pubdownloadpdfwelcome.do?docId=8&fileType=PDF .

Diabetes Medical Supplies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
insulin continuous subcutaneous infusion pump	Omnipod Classic	PA	PND
insulin continuous subcutaneous infusion pump	Omnipod Dash	PA	PND
insulin continuous subcutaneous infusion pump	Omnipod Go	PA	PND
test strips, blood glucose, all other non-preferred		PA	
test strips, blood glucose, preferred	Freestyle	PA - > 100 units/30 days	PND
test strips, blood glucose, preferred	Freestyle Insulinx	PA - > 100 units/30 days	PND
test strips, blood glucose, preferred	Freestyle Lite	PA - > 100 units/30 days	PND
test strips, blood glucose, preferred	Freestyle Neo	PA	PND
test strips, blood glucose, preferred	Precision Xtra	PA - > 100 units/30 days	PND

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

PND Preferred Non-Drug Product. This product is a preferred non-drug product for which MassHealth has entered into a rebate agreement with product manufacturer.

II. Therapeutic Uses

FDA-approved, for example:

- Diabetes mellitus

non-FDA-approved, for example:

- Hypoglycemia due to a diagnosis other than diabetes mellitus

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.

- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

All requests for blood glucose testing reagent strips at quantities above established quantity limits

- Documentation of one of the following is required:
  - for members utilizing a continuous glucose monitoring device, both of the following:
    - medical necessity for increased testing; **and**
    - treatment plan describing self-testing frequency.
  - for members not utilizing a continuous glucose monitoring device, one of the following:
    - medical necessity for increased testing; **or**
    - treatment plan describing self-testing frequency.

SmartPA: Claims for Freestyle, Freestyle Lite, Freestyle Insulinx, or Precision Xtra brand blood glucose testing reagent strips for > 100 strips/30 days but ≤ 200 strips/30 days will usually process at the pharmacy without a PA request if the member has a paid MassHealth pharmacy claim for injectable insulin or a prenatal vitamin within the last 90 days.†

Cequr Simplicity

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 21 years of age; **and**
  - one of the following:
    - member's current treatment plan involves testing blood glucose at least four times per day; **or**
    - use of continuous glucose monitoring; **and**
  - member is currently receiving at least three daily insulin injections or an insulin pump; **and**
  - one of the following:
    - member's A1c > 7.0% or does not meet documented target treatment; **or**
    - frequent hypoglycemia; **or**
    - fluctuations of more than 100 mg/dL in blood glucose before mealtime; **or**
    - dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; **or**
    - history of severe glycemic excursions; **and**
  - for Cequr Simplicity 4 day patch, one of the following:
    - both of the following:
      - requested quantity is ≥ one patch/four days; **and**
      - medical necessity for the Cequr Simplicity 4 day patch instead of the Cequr Simplicity 3 day patch; **and**
    - requested quantity is ≤ one patch/four days; **or**
  - for Cequr Simplicity 3 day patch, one of the following:
    - requested quantity is ≤ one patch/three days; **or**
    - both of the following:
      - requested quantity is ≥ one patch/one day; **and**

- medical necessity for > one patch/two days as noted as daily insulin requirement > 100 units; **or**
- both of the following:
  - requested quantity is one patch/two days; **and**
  - medical necessity for > one patch/three days as noted as one of the following:
    - daily insulin requirement is > 66 units; **or**
    - injection site irritation and inadequate response to at least one mitigation strategy; **or**
    - history of adhesion failure and inadequate response to at least one mitigation strategy; **or**
    - member has lipoatrophy or lipohypertrophy at the injection site; **or**
    - pooling of insulin at the injection site.

Dexcom G6, Dexcom G7, Freestyle Libre 2, Freestyle Libre 3, Freestyle Libre 14 Day

- Documentation of all of the following is required for a diagnosis of diabetes mellitus:
  - appropriate diagnosis; **and**
  - member's treatment regimen includes insulin; **and**
  - one of the following:
    - A1c ≥ 7% or that does not meet documented target treatment goal; **or**
    - frequent hypoglycemia (or nocturnal hypoglycemia); **or**
    - history of hypoglycemic unawareness; **or**
    - dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; **or**
    - history of emergency room visit or hospitalization related to ketoacidosis or hypoglycemia; **or**
    - use with compatible insulin pump to achieve glycemic control; **or**
    - pregnancy; **and**
  - for Dexcom G6 or Dexcom G7, one of the following:
    - for receiver, requested quantity is ≤ one unit/365 days; **or**
    - for sensor, requested quantity is ≤ one unit/ten days; **or**
    - for Dexcom G6 transmitter, requested quantity is ≤ one unit/90 days; **and**
  - for Freestyle Libre 14 day, Libre 2, or Libre 3, one of the following:
    - for receiver, requested quantity is ≤ one unit/365 days; **or**
    - for sensor, requested quantity is ≤ one unit/14 days.
- Documentation of all of the following is required for a diagnosis of hypoglycemia due to a diagnosis other than diabetes mellitus:
  - appropriate diagnosis; **and**
  - clinical rationale for use of continuous glucose monitoring instead of capillary blood glucose monitoring using test strips and a blood glucose meter.

Freestyle Neo

- Documentation of all of the following is required:
  - documentation that member is using compatible continuous glucose monitoring device; **and**
  - requested quantity is ≤ 100 strips/30 days.

SmartPA: Claims for Freestyle Neo test strips at less than or equal to 100 strips/30 days will usually process and pay at the pharmacy without a PA request if the member has a paid MassHealth pharmacy claim for Freestyle Libre 2, Freestyle Libre 3, or Freestyle Libre 14 Day sensors within the last 90 days.†

Non-preferred blood glucose testing reagent strips

- Documentation of all of the following is required:
  - medical necessity for a non-preferred product; **and**
  - requested quantity is ≤ 100 strips/30 days.

SmartPA: Claims for Prodigy brand blood glucose testing reagent strips for ≤ 100 strips/30 days will usually process at the pharmacy without a PA request if the member has a history of MassHealth medical claims for visual impairment. Claims for Prodigy brand

blood glucose testing reagent strips for > 100 strips/30 days but ≤ 200 strips/30 days will also usually process at the pharmacy without a PA request if the member has a history of a paid MassHealth pharmacy claim for injectable insulin or a prenatal vitamin within the last 90 days in addition to a history of MassHealth medical claims for visual impairment.†

Omnipod 5, Omnipod Classic, Omnipod Dash, V-Go

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - for V-Go, both of the following:
    - member is ≥ 18 years of age; **and**
    - requested quantity is ≤ one unit/one day; **and**
  - one of the following:
    - member's current treatment plan involves testing blood glucose at least four times per day; **or**
    - use of continuous glucose monitoring; **and**
  - member is currently receiving at least three daily insulin injections or an insulin pump; **and**
  - one of the following:
    - member's A1c > 7.0% or does not meet documented target treatment; **or**
    - frequent hypoglycemia; **or**
    - fluctuations of more than 100 mg/dL in blood glucose before mealtime; **or**
    - dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; **or**
    - history of severe glycemic excursions; **and**
  - for Omnipod 5, Omnipod Classic, or Omnipod Dash, one of the following:
    - requested quantity is ≤ one pod/three days; **or**
    - both of the following:
      - requested quantity is ≥ one pod/one day; **and**
      - medical necessity for > one pod/two days as noted as daily insulin requirement > 100 units; **or**
    - both of the following:
      - requested quantity is one pod/two days; **and**
      - medical necessity for > one pod/three days as noted as one of the following:
        - member is < 19 years of age; **or**
        - daily insulin requirement is > 66 units; **or**
        - injection site irritation and inadequate response to at least one mitigation strategy; **or**
        - history of adhesion failure and inadequate response to at least one mitigation strategy; **or**
        - member has lipoatrophy or lipohypertrophy at the injection site; **or**
        - pooling of insulin at the injection site.

Omnipod Go

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 18 years of age; **and**
  - one of the following:
    - member's current treatment plan involves testing blood glucose at least four times per day; **or**
    - use of continuous glucose monitoring; **and**
  - member is currently receiving long-acting insulin or NPH insulin; **and**
  - one of the following:
    - member's A1c > 7.0% or does not meet documented target treatment; **or**
    - frequent hypoglycemia; **or**
    - fluctuations of more than 100 mg/dL in blood glucose before mealtime; **or**
    - dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; **or**

    - history of severe glycemic excursions; **and**
- one of the following:
    - requested quantity is ≤ 1 pod/3 days; **or**
    - medical necessity for one pod/two days as noted by one of the following:
        - injection site irritation and inadequate response to at least one mitigation strategy; **or**
        - history of adhesion failure and inadequate response to at least one mitigation strategy; **or**
        - member has lipoatrophy or lipohypertrophy at the injection site; **or**
        - pooling of insulin at the injection site.

†**Note**: The decision on whether PA is required is based upon information available in the MassHealth medical claim and pharmacy claim databases. The MassHealth database contains member information exclusive to MassHealth, and no other health plans.

MassHealth Evaluation Criteria
Table 79 - Pharmaceutical Compounds

Drug Category: Compounding Agents

Medication Class/Individual Agents: Various

I. Prior-Authorization Requirements

Pharmaceutical Compounds				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	
cherry syrup			*	**Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.** This Table does not represent the complete list of drugs that can be used for pharmaceutical compounding. For information regarding the management of other drugs that could be used in pharmaceutical compounding, please see the appropriate Therapeutic Class Table. Compounded pharmaceutical products utilizing covered ingredients with a total allowed ingredient cost < $100 and non-intradermal/topical/transdermal route of administration are covered without PA. Please note, the following compounding ingredients are not covered. This list is subject to change at any time: • benzodiazepine powders (alprazolam, clonazepam, diazepam, lorazepam, midazolam powders) • chorionic gonadotropin, human, powder • clomiphene powder • cocaine crystals, powder • diethylpropion powder • flibanserin powder • ketamine powder • methylphenidate powder • opioid powders (apomorphine, buprenorphine, cocaine, codeine, fentanyl, hydrocodone, hydromorphone,
compounded pharmaceutical product with a total allowed ingredient cost ≥ $100		PA	CP	
compounded pharmaceutical product with a total allowed ingredient cost <$100 and non-intradermal/topical/transdermal ROA			CP	
compounded pharmaceutical product with intradermal, topical or transdermal ROA		PA	CP	
gelatin capsule, empty			*	
glycerin			*	
hydrophilic ointment			*, A90	
lanolin			*	
Ora-Plus suspending vehicle			*	
Ora-Sweet oral syrup			*	
Ora-Sweet-SF oral syrup			*	
petrolatum			*, A90	
simple syrup			*	
zinc oxide			*	

	Clinical Notes
	levorphanol, methadone, morphine sulfate, oxycodone, sufentanil powders) • papaverine • PCCA compounding inactive ingredients • phentolamine • tadalafil powder

* The generic OTC and, if any, generic prescription versions of the drug are payable under MassHealth without PA.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

CP Compounded pharmaceutical products with a total allowed ingredient cost greater than or equal to $100 require PA. In addition, compounded pharmaceutical products with intradermal, topical, or transdermal route of administration (ROA) require PA. The following ROAs are excluded from the PA requirement for products with a total allowed ingredient cost greater than or equal to $100: infusion, intramuscular, intravenous, intravenous piggyback, intravenous push, subcutaneous. Compounded pharmaceutical products utilizing any PA-requiring agent or not covered ingredient as part of the compound require PA.

II. Therapeutic Uses

FDA-approved, for example:

- Various

Non-FDA-approved, for example:

- Various

Note: The above lists may not include all FDA-approved and non-FDA approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.

- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

compounded pharmaceutical products with allowed ingredient cost ≥ $100, compounded pharmaceutical products with intradermal, topical, or transdermal route of administration, and compounded pharmaceutical products with PA-requiring or not covered ingredients

- Documentation of all of the following is required:
  - individual drug PA criteria must be met first where applicable; **and**
  - one of the following:
    - treatment of an FDA-approved indication; **or**
    - treatment of a clinically-appropriate indication supported by medical literature; **and**
  - requested indication is not excluded from coverage by MassHealth regulations; **and**
  - medical necessity for use of the requested compounded product for the requested route of administration; **and**
  - inadequate response or adverse reaction to two or contraindication to all other commercially available alternatives; **and**
  - one of the following:
    - requested compounded product is not commercially available; **or**
    - commercial product has been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness; **or**
    - member has a medical necessity for a dosage form or dosage strength that is not commercially available; **and**
  - medical necessity for the use of inactive ingredients in the requested compounded product.

Please note: The MassHealth agency does not pay for any drug when used for excluded purposes as described in 130 CMR 406.413(B) “Limitations on Coverage of Drugs – Drug Exclusions” (see link below). https://www.mass.gov/regulations/130-CMR-406000-pharmacy-services

MassHealth Evaluation Criteria
Table 80 - Anti-Hemophilia Agents

Drug Category: Anti-Hemophilia Agents

Medication Class/Individual Agents: Anti-Hemophilia Agents

I. Prior-Authorization Requirements

Anti-Hemophilia Agents – Factor VIII Replacement Therapies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
antihemophilic factor, recombinant pegylated-Adynovate	Adynovate		
antihemophilic factor, recombinant pegylated-aucl-Jivi	Jivi PD		
antihemophilic factor, recombinant, fc-vwf-xten fusion protein-ehtl	Altuviiio		
antihemophilic factor, recombinant, single chain-Afstyla	Afstyla		
antihemophilic factor, recombinant-Advate	Advate		
antihemophilic factor, recombinant-Helixate	Helixate		
antihemophilic factor, recombinant-Hemofil-M	Hemofil-M		
antihemophilic factor, recombinant-Kogenate	Kogenate PD		
antihemophilic factor, recombinant-Kovaltry	Kovaltry PD		
antihemophilic factor, recombinant-Novoeight	Novoeight		
antihemophilic factor,	Nuwiq		

Clinical Notes

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

etranacogene dezaparvovec-drlb and valoctocogene roxaparvovec-rvox

- MassHealth Drug Utilization Review will be reaching out to prescribers after PA approval to verify administration date and at ongoing intervals for long-term monitoring of response.

Anti-Hemophilia Agents – Factor VIII Replacement Therapies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
recombinant-Nuwiq			
antihemophilic factor, recombinant-Recombinate	Recombinate		
antihemophilic factor, recombinant-Xyntha	Xyntha PD		
factor VIII recombinant, Fc fusion protein	Eloctate		
factor VIII recombinant, glycopegylated-exei	Esperoct		

Anti-Hemophilia Agents – Human Plasma-Derived Factor VIII and Von Willebrand Factor Concentrates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
antihemophilic factor / von willebrand factor complex, human	Alphanate		
antihemophilic factor, human-Humate-P	Humate-P		
antihemophilic factor, human-Koate-DVI	Koate-DVI		
von willebrand factor / coagulation factor VIII complex	Wilate		

Anti-Hemophilia Agents – Plasma-Derived Factor IX Concentrates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
factor IX	Mononine		
factor IX, human	Alphanine SD		

Anti-Hemophilia Agents – Recombinant Factor IX Concentrates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
coagulation factor IX recombinant, glycopegylated-Rebinyn	Rebinyn		
coagulation factor IX, recombinant	Rixubis		
factor IX human recombinant-Benefix	Benefix PD		
factor IX human recombinant-Ixinity	Ixinity		
factor IX recombinant, albumin fusion protein	Idelvion		
factor IX recombinant, Fc fusion protein	Alprolix		

Anti-Hemophilia Agents – Human Plasma-Derived Factor X Concentrate			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
coagulation factor X, human	Coagadex		

Anti-Hemophilia Agents – Human Plasma-Derived Factor XIII Concentrate			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
factor XIII concentrate, human	Corifact		

Anti-Hemophilia Agents – Bypassing Agents			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
anti-inhibitor coagulant complex-Feiba NF	Feiba NF		
coagulation factor VIIa, recombinant	Novoseven		
coagulation factor VIIa, recombinant	Sevenfact		

Anti-Hemophilia Agents – Human Plasma-Derived Fibrinogen Concentrate			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
fibrinogen	Fibryga		
fibrinogen concentrate	Riastap		

Anti-Hemophilia Agents – Hemophilia B Gene Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
etranacogene dezaparvovec-drlb	Hemgenix	PA	CO, MB

Anti-Hemophilia Agents – Monoclonal Antibodies			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
emicizumab-kxwh	Hemlibra PD		

Anti-Hemophilia Agents – Recombinant Factor VIII Concentrates for Patients with Inhibitors			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
antihemophilic factor, recombinant, porcine sequence -Obizur	Obizur		

Anti-Hemophilia Agents – Human Plasma-Derived Prothrombin Complex Concentrates			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
factor IX complex human-Profilnine SD	Profilnine SD		

Anti-Hemophilia Agents – Hemophilia A Gene Therapy			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
valoctocogene roxaparvovec-rvox	Roctavian	PA	CO, MB

Anti-Hemophilia Agents – Recombinant Factor XIII-A Subunit			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
factor XIII A-subunit recombinant	Tretten		

Anti-Hemophilia Agents – Recombinant Von Willebrand Factor			
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**
von willebrand factor, recombinant	Vonvendi		

CO Carve-Out. This agent is listed on the Acute Hospital Carve-Out Drugs List and is subject to additional monitoring and billing requirements.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

II. Therapeutic Uses

FDA-approved, for example:

- Hemophilia A
- Hemophilia B
- Factor deficiencies

Note: The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.

- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

Hemgenix

- Documentation of the following is required:
  - diagnosis of moderately severe to severe hemophilia B (FIX activity level ≤ 2% of normal); **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - appropriate dosing; **and**
  - member's current weight; **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - member is a biologic male/male assigned at birth; **and**
  - member will be screened for acute infection prior to administration; **and**
  - member is not currently receiving immunosuppressive therapy; **and**
  - one of the following:
    - member currently uses FIX prophylaxis therapy; **or**
    - has current life-threatening hemorrhage; **or**
    - member has history of life-threatening hemorrhage; **or**
    - member has repeated, serious spontaneous bleeding episodes; **and**
  - all of the following:
    - baseline annualized bleeding rate (ABR); **and**
    - NAb titer (AAV5); **and**
    - FIX activity level.

Roctavian

- Documentation of the following is required:
  - diagnosis of severe hemophilia A (FVIII activity level ≤ 1% of normal); **and**
  - prescriber is a hematologist or consult notes from a hematologist are provided; **and**
  - appropriate dosing; **and**
  - member's current weight; **and**
  - member is ≥ 18 years of age on treatment date; **and**
  - member is a biologic male/male assigned at birth; **and**
  - member will be screened for acute infection prior to administration; **and**
  - member has been assessed for their ability to receive corticosteroids and/or immunosuppressive therapy; **and**
  - member currently uses FVIII prophylaxis therapy or Hemlibra; **and**
  - baseline annualized bleeding rate (ABR); **and**
  - FVIII activity level; **and**
  - member does not have any of the following: detectable pre-existing immunity to adeno-associated virus serotype 5 (AAV5), history of factor VIII inhibitor, hepatic fibrosis (stage 3 or 4 on the Batts Ludwig scale), cirrhosis, history of thrombosis or thrombophilia, active malignancy.

MassHealth Evaluation Criteria
Table 81 - Anti-Obesity Agents

Drug Category: Anti-Obesity Agents

Medication Class/Individual Agents: Anti-Obesity Agents

I. Prior-Authorization Requirements

Anti-Obesity Agents				Clinical Notes
Drug Generic Name	**Drug Brand Name**	**PA Status**	**Drug Notes**	Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.
benzphetamine		PA		
diethylpropion		PA		
diethylpropion extended-release		PA		
liraglutide-Saxenda	Saxenda PD	PA		
orlistat	Xenical	PA	BP, A90	
phendimetrazine		PA		
phendimetrazine extended-release		PA		
phentermine 15 mg, 30 mg capsule		PA		
phentermine 37.5 mg capsule, tablet	Adipex-P	PA		
phentermine 8 mg tablet	Lomaira	PA		
semaglutide injection-Wegovy	Wegovy PD	PA		
tirzepatide-Zepbound	Zepbound PD	PA		

BP Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

A90 Allowable 90-day supply. Dispensing in up to a 90-day supply is allowed. May not include all strengths or formulations. Quantity limits and other restrictions may apply.

II. Therapeutic Uses

FDA-approved, for example:

- Obesity
- Overweight
- **Note:** The above list may not include all FDA-approved indications.

III. Evaluation Criteria for Approval

Please note: In the case where the prior authorization (PA) status column indicates PA, both the brand and generic (if available) require PA. Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- All PA requests must include clinical diagnosis, drug name, dose, and frequency.
- Dispensing in a 90-day supply of medication may be mandated or allowable for agents in this therapeutic class (designated by M90 or A90, respectively, in the Drug Notes section above). Applicable quantity limits are described below as units per day, per month, per 28 days, or as clinically appropriate, and may be extrapolated for fills of longer day supply.
- A preferred drug may be designated for this therapeutic class. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at www.mass.gov/druglist.
- For recertification requests, approval may require submission of additional documentation including, but not limited to, documentation of: some or all criteria for the original approval; response to therapy; clinical rationale for continuation of use; status of member's condition; appropriate diagnosis; appropriate age; appropriate dose, frequency, and duration of use for requested medication; complete treatment plan; current laboratory values; and member's current weight.
- Additional criteria may apply depending upon diagnosis and/or requested medication (see below). Other factors, including rebate and FDA-approval status, may change independently of scheduled MassHealth updates, which may result in additional restrictions.

orlistat, Saxenda, and Wegovy

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 12 years of age; **and**
  - appropriate dosing; **and**
  - member weight (dated within the 90 days prior to treatment initiation); **and**
  - member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
  - for Saxenda and Wegovy, the requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
  - one of the following:
    - for orlistat, requested quantity is ≤ three units/day; **or**
    - for Saxenda, requested quantity is ≤ five pens/30 days; **or**
    - for Wegovy (semaglutide), requested quantity is ≤ four pens/28 days; **and**
  - one of the following:
    - member BMI is ≥30 kg/m2 (dated within the 90 days prior to treatment initiation); **or**
    - both of the following:
      - member is ≥ 12 years and ≤ 17 years of age; **and**
      - member BMI is in the 95th percentile or greater (dated within the 90 days prior to treatment initiation); **or**
    - both of the following:
      - member BMI is ≥27 kg/m2 (dated within the 90 days prior to treatment initiation); **and**
      - one of the following weight-related comorbid conditions:
        - coronary heart disease or other atherosclerotic disease; **or**
        - dyslipidemia; **or**
        - hypertension; **or**
        - non-alcoholic steatohepatitis (NASH); **or**
        - obstructive sleep apnea; **or**
        - systemic osteoarthritis; **or**

        - type 2 diabetes mellitus.
- For recertification of orlistat, Saxenda, or Wegovy for obesity/overweight, documentation of the following is required:
  - member weight (dated within the last 90 days); **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - clinical rationale for continuation of therapy.
- For recertification of Wegovy for cardiovascular disease and obesity/overweight, documentation of the following is required:
  - member requires semaglutide for cardiovascular protection and the benefit of cardiovascular protection outweighs the risk associated with the use of GLP-1 agents.

phentermine 37.5 mg capsule, tablet, benzphetamine, diethylpropion, diethylpropion ER, Lomaira, phentermine 15 mg, 30 mg capsule, phendimetrazine ER, phendimetrazine

- Documentation of the following is required:
  - appropriate diagnosis; **and**
  - member is ≥ 17 years of age; **and**
  - member weight (dated within the 90 days prior to treatment initiation); **and**
  - member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
  - one of the following:
    - for diethylpropion ER, phendimetrazine ER, phentermine 15mg, 30mg capsule, or phentermine 37.5 mg capsule or tablet, requested quantity is ≤ one unit/day; **or**
    - for benzphetamine, diethylpropion, Lomaira, or phendimetrazine, requested quantity is ≤ three units/day; **and**
  - for benzphetamine, diethylpropion, diethylpropion ER, phendimetrazine, and phendimetrazine ER, inadequate response or adverse reaction to one or contraindication to both of the following: Saxenda,Wegovy; **and**
  - one of the following:
    - member BMI is ≥ 30 kg/m2 (dated within the 90 days prior to treatment initiation); **or**
    - both of the following:
      - member BMI is ≥27 kg/m2 (dated within the 90 days prior to treatment initiation); **and**
      - one of the following weight-related comorbid conditions:
        - coronary heart disease or other atherosclerotic disease; **or**
        - dyslipidemia; **or**
        - hypertension; **or**
        - non-alcoholic steatohepatitis (NASH); **or**
        - obstructive sleep apnea; **or**
        - systemic osteoarthritis; **or**
        - type 2 diabetes mellitus.
- For recertification of phentermine in combination with topiramate for obesity/overweight, documentation of the following is required:
  - member weight (dated within the last 90 days); **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - clinical rationale for continuation of therapy.

Zepbound

- Documentation of the following is required:

- appropriate diagnosis; **and**
- member is ≥ 18 years of age; **and**
- appropriate dosing; **and**
- member weight (dated within the 90 days prior to treatment initiation); **and**
- member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
- requested quantity is ≤ four pens/28 days; **and**
- requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
- one of the following:
  - both of the following:
    - one of the following weight-related comorbid conditions:
      - coronary heart disease or other atherosclerotic disease; **or**
      - dyslipidemia; **or**
      - hypertension; **or**
      - non-alcoholic steatohepatitis (NASH); **or**
      - obstructive sleep apnea; **or**
      - systemic osteoarthritis; **or**
      - type 2 diabetes mellitus; **and**
    - member BMI is ≥27 kg/m2 (dated within the 90 days prior to treatment initiation); **or**
  - member BMI is ≥30 kg/m2 (dated within the 90 days prior to treatment initiation).
- For recertification for obesity/overweight, documentation of the following is required:
  - member weight (dated within the last 90 days); **and**
  - one of the following:
    - weight loss of ≥ 5% from baseline body weight; **or**
    - both of the following:
      - improvement in secondary measures; **and**
      - clinical rationale for continuation of therapy.

*Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to these agents.

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Androgen Therapy
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Androderm (testosterone patch)
- ☐ Androgel (testosterone 1% packet)
- ☐ Androgel (testosterone 1.62% packet)
- ☐ Androgel (testosterone 1.62% pump)
- ☐ Aveed (testosterone undecanoate injection)[MB]
- ☐ Jatenzo (testosterone undecanoate capsule)
- ☐ methyltestosterone
- ☐ Natesto (testosterone nasal gel)
- ☐ Testopel (testosterone intramuscular pellet)
- ☐ testosterone 1% gel tube
- ☐ testosterone 2% pump
- ☐ testosterone cypionate
- ☐ testosterone enanthate
- ☐ testosterone topical solution
- ☐ Tlando (testosterone undecanoate capsule)
- ☐ Vogelxo (testosterone 1% packet)
- ☐ Vogelxo (testosterone 1% pump)
- ☐ Xyosted (testosterone enanthate)
- ☐ Other* _____

Dose, frequency, and duration of medication requested _____

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

[MB] This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above,this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Delayed puberty
- ☐ Hypogonadism
- ☐ Gender Identity Disorder
- ☐ Metastatic mammary cancer
- ☐ Other (if none of the above apply) _____

Please note: MassHealth does not pay for any drug when used for the treatment of sexual dysfunction as described in 130 CMR 406.413(B): Drug Exclusions. For additional information go to: www.mass.gov/regulations/130-CMR-406000-pharmacy-services.

Is the member stabilized on the requested medication? ☐ Yes. Please provide start date. _____ ☐ No

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Section I. Please provide any lab test results that confirm the diagnosis as indicated above.

1. Test _____ Lab value _____

   Reference range _____ Date obtained _____

2. Test Lab value

   Reference range Date obtained

3. Test Lab value

   Reference range Date obtained

Section II. Please complete for Aveed and Xyosted requests.

1. Has the member tried testosterone cypionate intramuscular injection?
   ☐ Yes. Please describe the dates/duration of use and outcome.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe the details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No
2. Has the member tried testosterone enanthate intramuscular injection?
   ☐ Yes. Please describe the dates/duration of use and outcome.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe the details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No
3. For Xyosted requests, is there a contraindication to testosterone cypionate intramuscular injection and testosterone enanthate intramuscular injection?
   ☐ Yes. Please describe.

   ☐ No
4. For Xyosted requests, does the member have needle phobia? ☐ Yes ☐ No

   If yes, has the member had a trial of two non-injectable formulations of testosterone?

   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.

   ☐ No. Please describe if there is a contraindication to all non-injectable formulations of testosterone.

   Please provide details for the previous trials.

   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Section III. Please complete for Jatenzo, methyltestosterone, and Tlando requests.

1. Has the member tried two non-injectable formulations of testosterone?
   ☐ Yes. Please describe the drug names, dates/duration of use, and outcomes.

   Drug Name Dates/duration of use

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe the details of adverse reaction, inadequate response, contraindication, or other.

Drug Name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe the details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe if there is a contraindication to all non-injectable formulations of testosterone.

2. For methyltestosterone requests, has the member also tried testosterone undecanoate capsules?

☐ Yes. Please describe the dates/duration of use, and outcomes. Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe the details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe if there is a contraindication to testosterone undecanoate capsules.

3. For methyltestosterone capsule requests, please provide medical necessity for use instead of tablet formulation.

Section IV. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit.

Section V. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

over

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details. _____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Anti-Amyloid Monoclonal Antibodies
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Aduhelm (aducanumab-avwa)
☐ Leqembi (lecanemab-irmb)

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Alzheimer's Disease (Specify stage of disease.)

☐ Mild cognitive impairment ☐ Mild dementia ☐ Other

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Is the prescriber a specialist in the treatment of dementia or Alzheimer's Disease?
☐ Yes
☐ No. Please attach consultation notes from a specialist in the treatment of dementia or Alzheimer's Disease (e.g., neurologist, geriatric psychiatrist, geriatrician who specializes in treating dementia).

Section I. Please complete for all requests.

For Leqembi requests, please note testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing amyloid related imaging abnormalities (ARIA). ApoE ε4 genotyping is covered with prior authorization obtained through the Provider Online Service Center (POSC).

1. Please provide baseline (within the past three months) score of one of the following tests and attach supporting documentation.

   Mini Mental State Exam (MMSE) (Please attach a copy.) Date

   Montreal Cognitive Assessment (MoCA) (Please attach a copy.) Date

   Saint Louis University Mental Status Examination (SLUMS) (Please attach a copy.) Date

2. Does the member have confirmed evidence of clinically significant Alzheimer's Disease (AD) neuropathology based on one of the following? If yes, please attach supporting documentation.
   ☐ Yes, based on Cerebral Spinal Fluid (CSF) biomarkers. Please attach supporting documentation.
   ☐ Yes, based on Amyloid positron emission tomography (PET). Please attach supporting documentation.
   ☐ No

3. Has the member had a brain magnetic resonance imaging (MRI) in the previous 12 months?

   ☐ Yes. Date ☐ No

Section II. Please also complete for Aduhelm requests.

1. Has the member and/or authorized representative been informed of the known and potential risks and lack of established clinical benefit associated with treatment?
   ☐ Yes (Member) ☐ Yes (Authorized Representative) ☐ No
2. Has the member had a trial with Leqembi?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.*
   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please describe why Leqembi is not appropriate for this member.
3. Does the member have any of the following non-AD neurodegenerative disorders?

Probable dementia with Lewy bodies by consensus criteria	☐ Yes	☐ No
Suspected frontotemporal degeneration	☐ Yes	☐ No
Dementia in Down syndrome	☐ Yes	☐ No

4. Does the member have significant cerebrovascular disease as established by brain MRI showing any of the following? (Check all that apply.)
   ☐ Yes
   - ☐ Acute or sub-acute hemorrhage
   - ☐ Prior macro-hemorrhage or prior subarachnoid hemorrhage (unless finding is not due to an underlying structural or vascular hemorrhage)
   - ☐ Microhemorrhages
     Please provide number.
   - ☐ Cortical infarct
   - ☐ Lacunar infarct
     Please provide number.
   - ☐ Superficial siderosis
   - ☐ History of diffuse white matter disease

   ☐ No
5. Does the member have any of the following cardiovascular conditions?

Uncontrolled hypertension	☐ Yes	☐ No
Coronary artery disease (including unstable angina and myocardial infarction)	☐ Yes	☐ No
Heart failure	☐ Yes	☐ No
Arrhythmia	☐ Yes	☐ No
Clinically significant carotid atherosclerosis and/or peripheral arterial disease	☐ Yes	☐ No
History of stroke (within the past year)	☐ Yes. Date	☐ No
History of transient ischemic attack (within the past year)	☐ Yes. Date	☐ No
History of unexplained loss of consciousness (within the past year)	☐ Yes. Date	☐ No
Coagulopathy	☐ Yes	☐ No
Requirement for therapeutic anticoagulation and/or dual antiplatelet therapy (not including aspirin ≤ 325 mg/day as monotherapy)	☐ Yes	☐ No

over

6. Please indicate if the member has any of the following chronic medical conditions (Check all that apply and please describe.)

☐ Active chronic infection (HIV, HCV)

☐ Anxiety disorder

☐ Autoimmune disease requiring chronic immunosuppression

☐ Diabetes mellitus

☐ Pulmonary disease

☐ Liver disease

☐ Malignant neoplasm

☐ Mood disorder

☐ Psychosis

☐ Seizure disorder

☐ Other clinically significant condition

If the member has any of the above, is the condition(s) controlled?

☐ Yes. Please explain*.

☐ No. Please explain*.

Section III. Please complete for recertification requests. For Aduhelm requests, please complete questions 1 through 6. For Leqembi requests, please complete questions 1 and 2.

1. Has the member had follow-up MRIs completed in accordance with the FDA-approved label?

   ☐ Yes. Please describe.

   ☐ No

2. Please provide most recent score and date administered for one of the following tests, and attach supporting documentation.

   MMSE (Please attach a copy.) Date

   MoCA (Please attach a copy.) Date

   SLUMS (Please attach a copy.) Date

3. Does the member have new incident ARIA-hemosiderin deposition (ARIA-H) microhemorrhages?

   ☐ Yes. Please provide the following information below.

   Please indicate number of new incident microhemorrhage(s).

   Please describe symptoms: ☐ Asymptomatic (no clinical symptoms) ☐ Mild ☐ Moderate ☐ Severe

   Have the member's microhemorrhages been stabilized? ☐ Yes ☐ No

   ☐ No

4. Does the member have new incident ARIA-H areas of superficial siderosis?

   ☐ Yes. Please provide the following information below.

   Please indicate number of new incident areas of superficial siderosis.

   Please describe symptoms: ☐ Asymptomatic (no clinical symptoms) ☐ Mild ☐ Moderate ☐ Severe

   Has the member's superficial siderosis been stabilized? ☐ Yes ☐ No

   ☐ No

over

5. Does the member have ARIA-edema (ARIA-E)?
   ☐ Yes. Please provide the following information below.
   Does the member have new ARIA-E? ☐ Yes ☐ No
   Please describe symptoms: ☐ Asymptomatic (no clinical symptoms) ☐ Mild ☐ Moderate ☐ Severe
   What is the severity of ARIA-E on MRI? ☐ Mild ☐ Moderate ☐ Severe
   Has the member's ARIA-E been stabilized? ☐ Yes ☐ No
   ☐ No
6. Did the member initiate or develop any of the following? (Check all that apply.)
   ☐ Yes
   ☐ Initiation of anticoagulation
   ☐ Development of active immune-mediated/autoimmune conditions (e.g., Crohn's disease, systemic lupus erythematosus, aplastic anemia, myasthenia gravis, meningitis/encephalitis)
   ☐ Initiation of immunomodulatory medications (e.g., cancer immunotherapies, rituximab, azathioprine)
   ☐ Development of other neurologic conditions (e.g., intracerebral bleeds, traumatic brain injury, stroke)
   If yes, please describe clinical rationale for continued treatment*.
   ☐ No

* Please attach a letter documenting additional information as applicable.

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Anti-Obesity Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication Requested

- ☐ benzphetamine
- ☐ diethylpropion
- ☐ diethylpropion ER
- ☐ Lomaira (phentermine 8 mg tablet)
- ☐ orlistat
- ☐ phendimetrazine
- ☐ phendimetrazine ER
- ☐ phentermine 15 mg, 30 mg capsule
- ☐ phentermine 37.5 mg capsule, tablet
- ☐ Saxenda (liraglutide)
- ☐ Wegovy (semaglutide injection)
- ☐ Zepbound (tirzepatide)
- ☐ Other

Dose and frequency of medication requested

Is the member stabilized on the requested medication? ☐ Yes. Please provide start date. ☐ No

Indication or ICD-10 code, if applicable

- ☐ Obesity
- ☐ Overweight
- ☐ Other

Section I. Please complete for all requests.

1. Member's baseline weight ____ kg Date ____
2. Member's current weight ____ kg Date ____
3. Member's current height ____ cm Date ____
4. Member's baseline BMI ____ kg/m^2 Date ____
5. Member's current BMI ____ kg/m^2 Date ____
6. Has the member been counseled to continue reduced-calorie diet and increased physical activity?
   ☐ Yes ☐ No
7. Does the member have any of the following weight-related comorbid conditions?

Coronary heart disease or other atherosclerotic disease	☐ Yes ☐ No
Dyslipidemia	☐ Yes ☐ No
Hypertension	☐ Yes ☐ No
Non-alcoholic steatohepatitis (NASH)	☐ Yes ☐ No
Obstructive sleep apnea	☐ Yes ☐ No
Systemic osteoarthritis	☐ Yes ☐ No
Type 2 diabetes mellitus	☐ Yes ☐ No
Other comorbidity	☐ Yes ☐ No

8. For Saxenda, Wegovy and Zepbound requests, will the requested agent be used in combination with another GLP-1 receptor agonist? ☐ Yes ☐ No
9. For phentermine requests, will the requested agent be used in combination with topiramate? ☐ Yes ☐ No
10. For benzphetamine, diethylpropion, diethylpropion ER, phendimetrazine, and phendimetrazine ER requests, has the member had a trial with Saxenda or Wegovy?

☐ Yes. Please list the dates/duration of trials and outcomes below.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe why Saxenda and Wegovy are not appropriate for this member.

Section II. Please complete for recertification requests.

1. Member's current weight Date
2. Does the member have improvement in measures of comorbid conditions? ☐ Yes ☐ No

   If yes, please describe.
3. Please provide clinical rationale for continuation of therapy.
4. For Wegovy recertification requests, does the member require use of Wegovy for cardiovascular protection and the benefit of cardiovascular protection outweighs the risk associated with use of GLP-1 agents?

   ☐ Yes, please provide cardiovascular indication or ICD-10 code.

   ☐ No

Section III. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

over

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Anticoagulant and Antiplatelet Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Anticoagulants

- ☐ Pradaxa (dabigatran oral pellet)
- ☐ Savaysa (edoxaban)
- ☐ Xarelto (rivaroxaban 2.5 mg tablet) > 2 units/day
- ☐ Xarelto (rivaroxaban suspension) ≥ 18 years

Antiplatelet

- ☐ Zontivity (vorapaxar)

Dose and frequency of medication requested _____ **Duration requested** _____

Indication for Anticoagulant (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Nonvalvular atrial fibrillation
- ☐ Reduce the risk of major cardiovascular (CV) events in coronary artery disease (CAD)/peripheral artery disease (PAD)
- ☐ Reduce the risk of recurrence of DVT and PE
- ☐ Thromboprophylaxis in pediatric member with congenital heart disease after Fontan procedure
- ☐ Treatment of DVT
- ☐ Treatment of PE
- ☐ Other _____

Indication for Antiplatelet (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Non-ST elevation myocardial infarction (MI)
- ☐ PAD
- ☐ ST elevation MI
- ☐ Other _____

Section I. Please complete for Pradaxa oral pellet requests.

1. Member's current weight _____ Date _____
2. Has the member received or will the member receive ≥ five days of injectable or intravenous anticoagulation prior to starting the requested agent? ☐ Yes ☐ No
3. Has the member had a trial with Xarelto oral suspension or tablets?
   - ☐ Yes. Please list the drug name, dose and frequency, dates/duration of trials, and outcomes below.

     Drug name _____ Dose and frequency _____ Dates/duration of use _____

     Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

     Briefly describe details of adverse reaction, inadequate response, or other.

     _____
   - ☐ No. Please describe why Xarelto oral suspension or tablets are not appropriate for this member.

     _____

4. For members ≥ eight years of age, has the member had a trial with dabigatran capsule?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why dabigatran capsule is not appropriate for this member, or describe if there is medical necessity for the oral pellet formulation.

Section II. Please complete for Savaysa requests.

1. Has the member had a trial with dabigatran capsule?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why dabigatran capsule is not appropriate for this member.

2. Has the member had a trial with Eliquis?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why Eliquis is not appropriate for this member.

3. Has the member had a trial with Xarelto?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why Xarelto is not appropriate for this member.

Section III. Please complete for Xarelto 2.5 mg tablet requests > 2 units/day.

Please describe the medical necessity for use above the established quantity limit.

over

Section IV. Please complete for Xarelto suspension requests for members ≥ 18 years of age.

Please describe the medical necessity for the suspension formulation of Xarelto.

Section V. Please complete for Zontivity requests.

1. Does the member have a history of stroke, transient ischemic attack, or intracranial hemorrhage?
   ☐ Yes ☐ No
2. Is the member receiving concurrent aspirin and/or clopidogrel therapy?
   ☐ Yes. Drug Dose Frequency
   ☐ No

Section VI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Anticonvulsant
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about anticonvulsants and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form**.

Medication information

Medication requested (Check one or all that apply.)

- ☐ Aptiom (eslicarbazepine)
- ☐ Briviact (brivaracetam solution, tablet)
- ☐ Diacomit (stiripentol)
- ☐ diazepam rectal gel > 5 kits (10 syringes)/30 days
- ☐ Elepsia XR (levetiracetam extended-release)
- ☐ Epidiolex (cannabidiol)
- ☐ Eprontia (topiramate solution)
- ☐ everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg
- ☐ everolimus tablets for oral suspension
- ☐ Fintepla (fenfluramine)
- ☐ Fycompa (perampanel)
- ☐ gabapentin >3600 mg/day
- ☐ Lamictal XR starter kit, lamotrigine extended-release
- ☐ lamotrigine orally disintegrating tablet (ODT), ODT starter kit
- ☐ lamotrigine tablet starter kit
- ☐ Libervant (diazepam buccal film) > 10 units/30 days or ≥ 6 years of age
- ☐ Motpoly XR (lacosamide extended-release capsule)
- ☐ Nayzilam (midazolam nasal spray) >10 units/30 days
- ☐ Oxtellar XR (oxcarbazepine extended-release)
- ☐ pregabalin > 600 mg/day
- ☐ rufinamide
- ☐ Spritam (levetiracetam tablet for oral suspension)
- ☐ Sympazan (clobazam film)
- ☐ tiagabine
- ☐ topiramate extended-release capsule [Trokendi XR]
- ☐ Valtoco (diazepam nasal spray) >10 units/30 days
- ☐ vigabatrin
- ☐ Xcopri (cenobamate)
- ☐ Zonisade (zonisamide suspension)
- ☐ Ztalmy (ganaxolone)
- ☐ Other* _____

Dose, frequency, and duration of medication requested _____

Drug NDC (if known) or service code _____

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Bipolar disorder
- ☐ Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) (provide documentation of genetic testing)
- ☐ Diabetic peripheral neuropathy
- ☐ Dravet syndrome
- ☐ Epilepsy or seizure disorder
  Type _____
- ☐ Epilepsy associated with tuberous sclerosis complex
- ☐ Fibromyalgia
- ☐ Infantile spasms
- ☐ Lennox-Gastaut syndrome
- ☐ Migraine prophylaxis
- ☐ Pain associated with trigeminal neuralgia
- ☐ Postherpetic neuralgia
- ☐ Other _____

Please list all other medications currently prescribed for the member for this indication.

Please indicate prescriber specialty below.

☐ Neurology ☐ Psychiatry ☐ Other

If prescriber is not a specialist, please attach consult notes from specialist.

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

1. Drug Dates of Use Outcome
2. Drug Dates of Use Outcome
3. Drug Dates of Use Outcome
4. Drug Dates of Use Outcome

**Attach a letter with additional information regarding medication trials as applicable.*

Section II. Please also complete for requests for Elepsia XR, Eprontia, Lamictal XR starter kit, lamotrigine extended-release, lamotrigine tablet starter kit, Motpoly XR, Oxtellar XR, Spritam, topiramate extended-release capsule [Trokendi XR], and Zonisade.

Please provide medical necessity for the use of the requested formulation instead of the respective formulation(s) that is available without prior authorization. For Motpoly XR, please also provide the member's current weight.

Section III. Please complete for requests for gabapentin > 3600 mg/day and pregabalin > 600 mg/day.

Please provide clinical rationale for exceeding the maximum daily dose limit.

Section IV. Please complete for requests for Diacomit.

1. Has the member experienced an inadequate response or adverse reaction to other anticonvulsants?
   ☐ Yes. Please complete Section I above.

over

☐ No. Explain why other anticonvulsants have not been tried.

2. Will the requested agent be used in combination with clobazam? ☐ Yes ☐ No

Section V. For requests for Epidiolex, please attach medical records supporting the diagnosis.

Section VI. Please complete for requests for lamotrigine ODT.

1. Does the member have a medical condition in which they are not able to swallow pills?

   ☐ Yes. Please describe. ☐ No

2. Has the member experienced an inadequate response or adverse reaction to lamotrigine dispersible tablets?

   ☐ Yes. Please describe trial below.

   Dose and frequency Dates of Use Outcome

   ☐ No. Explain why lamotrigine dispersible tablets have not been tried.

Section VII. Please complete for requests for diazepam rectal gel (> 5 kits/month), Libervant (> 10 units/30 days), Nayzilam (> 10 units/30 days), and Valtoco (> 10 units/30 days).

1. Is the diagnosis for as needed (intermittent) treatment of acute seizure clusters that are distinct from a member's usual seizure pattern? ☐ Yes ☐ No
2. Please describe the medical necessity for use over quantity limits.

Section VIII. Please complete for requests for Libervant for members ≥ six years of age.

1. Is the diagnosis for as needed (intermittent) treatment of acute seizure clusters that are distinct from a member's usual seizure pattern? ☐ Yes ☐ No
2. Has the member experienced an inadequate response or adverse reaction to Valtoco?

   ☐ Yes. Please describe trial below.

   Dose and frequency Dates of Use Outcome

   ☐ No. Explain why Valtoco has not been tried.

Section IX. Concomitant gabapentin and pregabalin. Complete this section for all members, if request will result in prescription of concomitant gabapentin and pregabalin.

Please document complete treatment plan.

1. gabapentin dose/frequency Indication
2. pregabalin dose/frequency Indication
3. Other(s)

Please document clinical rationale for concomitant use of gabapentin and pregabalin for this member.

over

Please document monotherapy trials (include dose/frequency, dates/duration of use, and outcome) with gabapentin and pregabalin.*

Has the member experienced an inadequate response or adverse reaction to at least two other alternative agents for the requested indication(s)?

☐ Yes. Please complete Section I above.

☐ No. Explain why other alternative agents have not been tried.

Section X. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details.

   ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

over

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name _____ Dose/frequency _____ Indication _____
2. Medication name _____ Dose/frequency _____ Indication _____
3. Medication name _____ Dose/frequency _____ Indication _____
4. Medication name _____ Dose/frequency _____ Indication _____
5. Medication name _____ Dose/frequency _____ Indication _____
6. Medication name _____ Dose/frequency _____ Indication _____
7. Other(s) _____

Is the member currently in an acute care setting?

☐ Yes (Inpatient) ☐ Yes (Community Based Acute Treatment)
☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name _____ Contact information _____

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months. _____
☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?

☐ Yes. Please provide details. _____ ☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g., weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain. _____

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other _____
☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

_____

Name(s) of the specialist(s) _____ Date(s) of last visit or consult _____

Contact information _____

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

_____

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

over

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility

☐ Uncertain ☐ Other

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH) ☐ Department of Developmental Services (DDS)

☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

* *Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to:* *https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information*

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation.

☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

Section II. Mood Stabilizer Polypharmacy. Complete this section for all members < 18 years of age, if request will result in prescription of three or more mood stabilizers for ≥ 60 days within a 90-day period (agents considered to be used only for seizure diagnoses are not included).

Please document if monotherapy trials (include drug name, dates/duration of use, and outcome) with mood stabilizers were tried before prescribing polypharmacy with three or more mood stabilizers in this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on a mood stabilizer polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?

☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

over

Section III. Mood Stabilizer Request for Members < six years of age (agents considered to be used only for seizure diagnoses are not included).

Please document any previous medication trial(s). Include the drug name, dates/duration of use, and outcome.*

Please document clinical rationale for use of a mood stabilizer for this member < six years of age.

Has the member been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Section IV. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Antidepressant
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about antidepressants and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form**.

Medication information

Medication requested

- ☐ amoxapine
- ☐ Aplenzin (bupropion hydrobromide extended-release)
- ☐ Auvelity (dextromethorphan/bupropion)
- ☐ bupropion XL > 1 unit/day
- ☐ bupropion hydrochloride extended-release 450 mg tablet
- ☐ citalopram capsule
- ☐ clomipramine
- ☐ desipramine
- ☐ desvenlafaxine extended-release
- ☐ desvenlafaxine succinate extended-release > 1 unit/day
- ☐ Drizalma (duloxetine sprinkle capsule)
- ☐ duloxetine 40 mg capsule
- ☐ Emsam (selegiline)
- ☐ Fetzima (levomilnacipran)
- ☐ fluoxetine 60 mg tablet
- ☐ fluoxetine 90 mg delayed-release capsule
- ☐ fluvoxamine extended-release
- ☐ imipramine pamoate tablet
- ☐ Ketalar (ketamine injection)[MB]
- ☐ Marplan (isocarboxazid)
- ☐ mirtazapine orally disintegrating tablet
- ☐ olanzapine/fluoxetine
- ☐ paroxetine controlled-release
- ☐ protriptyline
- ☐ sertraline capsule
- ☐ Spravato (esketamine)
- ☐ trazodone 300 mg tablet
- ☐ trimipramine
- ☐ Trintellix (vortioxetine)
- ☐ venlafaxine besylate extended-release tablet
- ☐ venlafaxine hydrochloride extended-release tablet
- ☐ vilazodone
- ☐ Zulresso (brexanolone)[MB]
- ☐ Zurzuvae (zuranolone)
- ☐ Other*

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

[MB] This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

Dose, frequency, and duration of medication requested

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Major depressive disorder
- ☐ Obsessive-compulsive disorder
- ☐ Premenstrual dysphoric disorder
- ☐ Panic disorder
- ☐ Postpartum depression
- ☐ Other (describe)

Please list all other psychotropic medications currently prescribed for the member.

Has member been hospitalized for this condition?

☐ Yes. Dates of most recent hospitalization ☐ No

Is the member under the care of psychiatrist? ☐ Yes ☐ No

Name of psychiatrist

Telephone no. Date of last visit or consult with psychiatrist

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for Aplenzin, bupropion hydrochloride extended-release 450 mg tablet, citalopram capsule, desvenlafaxine extended-release, duloxetine 40 mg capsule, fluoxetine 60 mg tablet, fluoxetine 90 mg delayed-release capsule, fluvoxamine extended-release, imipramine pamoate, paroxetine controlled-release, sertraline capsule, trazodone 300 mg tablet, venlafaxine besylate extended-release tablet, and venlafaxine hydrochloride extended-release tablet.

Please attach medical records documenting an inadequate response (defined as at least four weeks of therapy) or adverse reaction to the respective formulation of the agent requested at an equivalent dose that is available without prior authorization.

Section II. Please complete for requests for amoxapine, Auvelity, clomipramine, desipramine, Fetzima, Marplan, protriptyline, trimipramine, Trintellix, and vilazodone.

Please describe applicable antidepressant trials and outcomes (attach a letter with additional information regarding trials as applicable).

Drug name Dates/duration of use Dose and frequency

Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use Dose and frequency

Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Section III. Please complete for requests for Emsam.

1. Has the member had a trial with one SSRI and one non-SSRI antidepressant?

☐ Yes. Please list the drug name, dose and frequency, dates/duration of trials, and outcomes below.

Drug name Dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

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Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not.

2. Is there a medical necessity for the transdermal formulation? ☐ Yes ☐ No

   If yes, please explain.

Section IV. Please complete for requests for Drizalma

Please document medical necessity for the requested formulation instead of the solid oral formulation.

Section V. Please complete for requests for mirtazapine orally disintegrating tablet.

Is there a medical necessity for the specific dosage formulation?

☐ Yes. Please explain.

☐ No. Please attach medical records documenting an inadequate response (defined as at least four weeks of therapy) or adverse reaction to mirtazapine tablet.

Section VI. Please complete for requests for olanzapine/fluoxetine.

Please describe the medical necessity for use of the combination product instead of the commercially available separate agents.

Section VII. Please complete for requests for Ketalar and Spravato.

For requests for Ketalar and Spravato for treatment resistant depression, please complete questions 1, 2, and 4. Initial requests for Spravato for major depressive disorder with acute suicidal ideation or behavior, please complete questions 3 and 4. Subsequent requests for Spravato for major depressive disorder with acute suicidal ideation or behavior should complete the questions for treatment resistant depression.

1. Please attach medical records documenting a trial with one SSRI and one non-SSRI antidepressant.
2. Please attach medical records documenting a trial with one of the following antidepressant augmentation strategies: second-generation antipsychotic, lithium, a second antidepressant from a different class, thyroid hormone. If there is a contraindication to all antidepressant augmentation strategies, attach medical records documenting the contraindication.
3. Please attach medical records documenting either current acute suicidal ideation or behavior related to depressive symptoms of major depressive disorder, or that the member was stabilized on esketamine during a psychiatric hospitalization.
4. Will the requested agent be used in combination with an oral antidepressant? ☐ Yes ☐ No

over

Section VIII. Please complete for requests for bupropion XL > 1 unit/day, or desvenlafaxine succinate extended-release > 1 unit/day.

Has dose consolidation been attempted? ☐ Yes ☐ No. Please describe medical necessity for quantities above 1 unit/day.

Section IX. Please complete for requests for Zulresso.

1. Is the member pregnant? ☐ Yes ☐ No. Please document date of delivery.
2. Please document date of onset of major depressive episode(s).
3. Member's current weight Date

Section X. Please complete for requests for Zurzuvae.

1. Is the member ≤ 12 months postpartum? ☐ Yes. Please document date of delivery. ☐ No
2. Is the member currently pregnant? ☐ Yes ☐ No
3. Has the member had a trial with one of the following: bupropion, citalopram, duloxetine, escitalopram, fluoxetine, mirtazapine, sertraline, venlafaxine?
   ☐ Yes. Please list the drug name, dose and frequency, dates/duration of trials, and outcomes below.
   Drug name Dose and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please explain why not.
4. Does the member have a requirement for rapid symptom reduction? ☐ Yes ☐ No
5. For requests for 30 mg capsule, does the member have severe hepatic impairment (Child-Pugh Class C) or moderate to severe renal impairment (eGFR < 60 mL/min/1.73m^2)?
   ☐ Yes. Please describe.
   ☐ No
6. For recertification requests, please provide the last day of treatment with the requested agent and the total number of treatments including the current request.
   Last day of treatment with requested agent
   Total number of treatments including the current request

Section XI. Antidepressant Polypharmacy for members ≥ 18 years of age. Please complete information for medications requested and select the reason for polypharmacy with antidepressants (two or more SSRI, SNRI, or Serotonin Modulator antidepressants for ≥ 60 days within a 90-day period).

1. Antidepressant name/dose/frequency Indication
2. Antidepressant name/dose/frequency Indication
3. Antidepressant name/dose/frequency Indication

over

Is member under the care of a psychiatrist?

☐ Yes. Please attach specialist consult details (if the prescriber submitting the request is not a specialist). ☐ No

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

☐ Member was recently discharged from an inpatient setting on requested medications and is currently stable.

☐ Member experienced an inadequate response or adverse reaction to two monotherapy trials with antidepressants.

Drug name 1 Dates/Duration of use (if available)

Drug name 2 Dates/Duration of use (if available)

☐ Member is transitioning from one antidepressant to the other.

☐ Other, please explain.

Section XII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details.

   ☐ No

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MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name _____ Dose/frequency _____ Indication _____
2. Medication name _____ Dose/frequency _____ Indication _____
3. Medication name _____ Dose/frequency _____ Indication _____
4. Medication name _____ Dose/frequency _____ Indication _____
5. Medication name _____ Dose/frequency _____ Indication _____
6. Medication name _____ Dose/frequency _____ Indication _____
7. Other(s) _____

Is the member currently in an acute care setting?

☐ Yes (Inpatient) ☐ Yes (Community Based Acute treatment)
☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name _____ Contact information _____

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months. _____
☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?

☐ Yes. Please provide details. _____
☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g., weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain. _____

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty: ☐ Psychiatry ☐ Neurology ☐ Other _____

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

_____

Name(s) of the specialist(s) _____ Date(s) of last visit or consult _____

Contact information _____

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For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility ☐ Uncertain

☐ Other

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH) ☐ Department of Developmental Services (DDS)

☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

** Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to: https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information*

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation.

☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

Section II. Antidepressant Polypharmacy. Complete this section for all members < 18 years of age, if request will result in prescription of two or more antidepressants ≥ 60 days within a 90-day period.

Please document if monotherapy trials (include drug name, dates/duration of use, and outcome) with antidepressants were tried before prescribing polypharmacy with two or more antidepressants in this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

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Has the member been on an antidepressant polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?
☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Section III. Antidepressant Request for Members < six years of age.

Please document any previous medication trial(s). Include the drug name, dates/duration of use, and outcome.*

Please document clinical rationale for use of an antidepressant for this member < six years of age.

Has the member been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Section IV. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Antidiabetic Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested (Check one or all that apply. Where applicable, the brand name is provided in brackets for reference.)

Single Injectable Agents

- ☐ Bydureon Bcise (exenatide extended-release auto-injection)
- ☐ Byetta (exenatide 5 mcg) > 1.2 mL/30 days
- ☐ Byetta (exenatide 10 mcg) > 2.4 mL/30 days
- ☐ liraglutide [Victoza] > 9 mL/30 days
- ☐ Mounjaro (tirzepatide)
- ☐ Ozempic (semaglutide injection)
- ☐ Trulicity (dulaglutide) > 2 mL/28 days
- ☐ Tzield (teplizumab-mzwv)

Single Oral Agents

- ☐ alogliptin
- ☐ Inpefa (sotagliflozin)
- ☐ metformin extended-release, gastric tablet [Glumetza]
- ☐ metformin extended-release, osmotic tablet
- ☐ metformin immediate-release 625 mg tablet
- ☐ metformin immediate-release solution ≥ 13 years of age
- ☐ miglitol
- ☐ Riomet ER (metformin extended-release suspension)
- ☐ Rybelsus (semaglutide tablet)
- ☐ Steglatro (ertugliflozin)
- ☐ Zituvio (sitagliptin)

Combination Injectable Agents

- ☐ Soliqua (insulin glargine/lixisenatide)
- ☐ Xultophy (insulin degludec/liraglutide)

Insulin Agents

- ☐ Admelog (insulin lispro)
- ☐ Afrezza (insulin human inhalation powder)
- ☐ Basaglar (insulin glargine)
- ☐ Basaglar Tempo (insulin glargine)
- ☐ Fiasp (insulin aspart)
- ☐ Humalog Tempo (insulin lispro)
- ☐ Humulin N (insulin NPH)
- ☐ insulin glargine-yfgn
- ☐ Lyumjev (insulin lispro-aabc)
- ☐ Lyumjev Tempo (insulin lispro-aabc)
- ☐ Rezvoglar (insulin glargine-aglr)

Combination Oral Agents

- ☐ alogliptin/metformin
- ☐ alogliptin/pioglitazone
- ☐ Glyxambi (empagliflozin/linagliptin)
- ☐ pioglitazone/glimepiride
- ☐ Qtern (dapagliflozin/saxagliptin)
- ☐ repaglinide/metformin
- ☐ Segluromet (ertugliflozin/metformin)
- ☐ Steglujan (ertugliflozin/sitagliptin)
- ☐ Trijardy XR (empagliflozin/linagliptin/metformin extended-release)

Other Medication

☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose and frequency of medication requested _____

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Type 1 Diabetes Mellitus ☐ Type 2 Diabetes Mellitus

☐ Stage _____ What is the member's most recent hemoglobin A1C? _____ Date _____

☐ Reduction of risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit

☐ Cardiovascular risk factors _____

☐ Chronic kidney disease

☐ Other _____

Please list all other antidiabetic medications currently prescribed for the member for this indication.

Drug _____ Dose and Frequency _____ Dates of use _____

Drug _____ Dose and Frequency _____ Dates of use _____

Drug _____ Dose and Frequency _____ Dates of use _____

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial.

_____

Section I. Please complete for combination oral agents.

1. Has the member tried metformin used in combination with at least one of the non-metformin agents in the requested combination?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. If the answer to question 1 is no, has the member tried metformin?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the answer to question 1 is no, has the member tried at least one of the non-metformin agents in the requested combination?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
4. For Trijardy XR, please provide medical necessity for use instead of the commercially-available separate agents. _____

Section II. Please complete for single and combination injectable agents (excluding Byetta, liraglutide [generic Victoza], Trulicity, and Tzield) and Rybelsus.

1. Has the member tried metformin used in combination with Byetta, liraglutide (generic Victoza), or Trulicity?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. If the answer to question 1 is no, has the member tried metformin?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the answer to question 1 is no, has the member tried Byetta, liraglutide (generic Victoza), or Trulicity?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.*
   ☐ No. Please describe if there is a contraindication to Byetta, liraglutide (generic Victoza), and Trulicity.
   _____
4. If the request is for quantities exceeding the quantity limit, please complete Section XVII below.

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5. For Mounjaro, will the requested agent be used in combination with a GLP-1 receptor agonist?
   ☐ Yes ☐ No
   If yes, please provide clinical rationale for concurrent use with a GLP-1 receptor agonist.

Section III. Please complete for alogliptin.

1. Has the member tried metformin used in combination with Januvia, saxagliptin, or Tradjenta?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. If the answer to question 1 is no, has the member tried metformin?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the answer to question 1 is no, has the member tried Januvia, saxagliptin, or Tradjenta?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.*
   ☐ No. Please describe if there is a contraindication to Januvia, saxagliptin, and Tradjenta.
4. If the request is for greater than one tablet per day, please complete Section XVII below.

Section IV. Please complete for Zituvio.

1. Has the member tried metformin used in combination with alogliptin, saxagliptin, or Tradjenta?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. If the answer to question 1 is no, has the member tried metformin?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the answer to question 1 is no, has the member tried alogliptin, saxagliptin, or Tradjenta?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.*
   ☐ No. Please describe if there is a contraindication to alogliptin, saxagliptin, and Tradjenta.
4. Please provide clinical rationale for the requested agent instead of Januvia.
5. If the request is for greater than one tablet per day, please complete Section XVII below.

Section V. Please complete for Steglatro.

1. Has the member tried metformin used in combination with dapagliflozin, Invokana, or Jardiance?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. If the answer to question 1 is no, has the member tried metformin?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the answer to question 1 is no, has the member tried dapagliflozin, Invokana, or Jardiance?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.*
   ☐ No. Please describe if there is a contraindication to dapagliflozin, Invokana, and Jardiance.
4. If the request is for greater than one tablet per day, please complete Section XVII below.

Section VI. Please complete for Tzield.

1. Is the prescriber an endocrinologist? ☐ Yes ☐ No. Please attach consultation notes from an endocrinologist addressing the use of the requested agent.
2. Please attach lab results documenting ≥ two islet autoantibodies.

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3. Please complete the below lab test results as applicable.

   Fasting Plasma Glucose (FPG) _____ Date obtained _____

   2-hour Plasma Glucose (2-h PG) _____ Date obtained _____

   A1C: please document lab values from previous 12 months below.

   Lab value _____ Date obtained _____

   Lab value _____ Date obtained _____
4. Has the member been treated with Tzield previously? ☐ Yes ☐ No

Section VII. Please complete for Basaglar, Basaglar Tempo, insulin glargine-vfgn or Rezvoglar.

1. Has the member had an inadequate response or adverse reaction to insulin glargine (generic Lantus) prefilled syringe or vial?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. For Basaglar and Basaglar Tempo, has the member had an inadequate response or adverse reaction to insulin glargine-vfgn prefilled syringe or vial or Rezvoglar?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
3. For Basaglar Tempo, please provide medical necessity for use of the Tempo Pen formulation instead of the KwikPen formulation.

Section VIII. Please complete for Admelog, Fiasp, Lyumjev, or Lyumjev Tempo.

1. Has the member had an inadequate response or adverse reaction to Apidra, insulin lispro, or insulin aspart (generic Novolog)?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. For Lyumjev Tempo, please provide medical necessity for use of the Tempo Pen formulation instead of the KwikPen formulation.

Section IX. Please complete for Afrezza.

Please provide medical necessity for the use of an inhaled insulin product instead of an injectable or prefilled insulin syringe.

Section X. Please complete for Humalog Tempo.

Please provide medical necessity for use of the Tempo Pen formulation instead of the KwikPen formulation.

Section XI. Please complete for Humulin N.

Has the member had an inadequate response or adverse reaction to Novolin N?

☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No

over

Section XII. Please complete for metformin extended-release, gastric tablet (generic Glumetza), and metformin extended-release, osmotic tablet.

1. Please attach medical records documenting an inadequate response (defined as ≥ 90 days of therapy) or adverse reaction, at the requested dose, to the metformin extended-release, XR tablet formulation available without prior authorization.
2. For metformin extended-release, gastric tablet (generic Glumetza), please provide medical necessity for the use of the requested product instead of other metformin formulations available without prior authorization.

Section XIII. Please complete for metformin immediate-release solution and Riomet ER.

1. Is there a medical necessity for the liquid formulation?
   - ☐ Yes. Please explain.
   - ☐ No. Please attach medical records documenting an inadequate response (defined as ≥ 90 days of therapy), allergic reaction, or adverse reaction to metformin tablets.
2. For Riomet ER, please attach medical records documenting an inadequate response (defined as ≥ 90 days of therapy) to metformin immediate-release solution formulation.

Section XIV. Please complete for metformin immediate-release 625 mg tablet.

Please provide medical necessity for the requested formulation instead of metformin tablets available without prior authorization.

Section XV. Please complete for miglitol.

1. Has the member tried metformin used in combination with acarbose?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. If the answer to question 1 is no, has the member tried metformin?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the answer to question 1 is no, has the member tried acarbose?
   - ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.*
   - ☐ No. Please describe if there is a contraindication to acarbose.
4. If the request is for greater than three tablets per day, please complete Section XVII below.

Section XVI. Please complete for Inpefa.

1. For an indication of reduction of risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit, has the member tried or does the member have a contraindication to both dapagliflozin and Jardiance?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XVIII below.* ☐ No
2. For an indication of reduction of risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in type 2 diabetes mellitus and chronic kidney disease with other cardiovascular risk factors, has the member tried two or does the member have a contraindication to all of the following: dapagliflozin, Invokana, Jardiance?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcome in Section XVIII below.* ☐ No
3. If the request is for greater than one tablet per day, please complete Section XVII below.

over

Section XVII. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit.

Section XVIII. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

** Please attach a letter documenting additional trials as necessary.*

Section XIX. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

over

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details. _____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Antiemetics
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Akynzeo (fosnetupitant/palonosetron injection) > 2 units/28 days
- ☐ Akynzeo (netupitant/palonosetron capsule) > 2 units/28 days
- ☐ Anzemet (dolasetron)
- ☐ aprepitant 40 mg, 125 mg capsule > 2 units/28 days
- ☐ aprepitant 80 mg > 4 units/28 days
- ☐ aprepitant trifold pack > 2 packs/28 days
- ☐ Bonjesta (doxylamine/pyridoxine extended-release)
- ☐ Cinvanti (aprepitant injectable emulsion)
- ☐ doxylamine/pyridoxine delayed-release
- ☐ Emend (aprepitant 125 mg powder for oral suspension) > 6 units/28 days
- ☐ fosaprepitant injection > 2 units/28 day
- ☐ granisetron tablet > 2 units/28 days
- ☐ ondansetron solution
- ☐ palonosetron 0.25 mg/2 mL injection > 2 units/28 days
- ☐ palonosetron 0.25 mg/5 mL injection > 2 units/28 days
- ☐ Sancuso (granisetron transdermal system)
- ☐ Sustol (granisetron extended-release injection) > 2 units/28 days

Dose, frequency and duration of requested medication

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Chemotherapy-induced nausea and vomiting (CINV)
- ☐ Hyperemesis gravidarum
- ☐ Postoperative nausea and vomiting (PONV)
- ☐ Radiation-induced nausea and vomiting (RINV)
- ☐ Other

Section I. Please complete for Cinvanti requests.

Has the member had a trial of oral aprepitant or fosaprepitant injection?

☐ Yes. Please list the dates/duration of trial and outcomes below.

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. (Please explain why.)

Section II. Please complete for Akynzeo, aprepitant, fosaprepitant injection, granisetron tablet, palonosetron, and Sustol requests exceeding the quantity limit.

Please describe the medical necessity for exceeding the quantity limit.

Section III. Please complete for ondansetron solution requests.

Does the member have a medical condition in which they are unable to swallow tablets/capsules?

☐ Yes. (Please list reason.)

☐ No. (Please provide clinical rationale why conventional dosage forms cannot be used.)

Section IV. Please complete for Sancuso requests.

Has the member had a trial of ondansetron ODT?

☐ Yes. Please list the dates/duration of trial and outcomes below.

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. (Please explain why.)

Section V. Please complete for Bonjesta and doxylamine/pyridoxine delayed-release requests.

1. Has the member had a trial of pyridoxine?

   ☐ Yes. Please list the dates/duration of trial and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. (Please explain why.)

2. Has the member had a trial of doxylamine?

   ☐ Yes. Please list the dates/duration of trial and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. (Please explain why.)

3. For Bonjesta requests, has the member had a trial of doxylamine/pyridoxine delayed-release?

   ☐ Yes. Please list the dates/duration of trial and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. (Please explain why.)

over

Section VI. Please complete for Anzemet requests.

1. Has the member had a trial of granisetron tablet?
   ☐ Yes. Please list the dates/duration of trial and outcomes below.
   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   ☐ No. (Please explain why.)
2. Has the member had a trial of ondansetron tablet or ondansetron ODT?
   ☐ Yes. Please list the dates/duration of trial and outcomes below.
   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   ☐ No. (Please explain why.)

Section VII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Antihistamine Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested (Check one or all that apply.)

Intranasal Antihistamines

- ☐ azelastine 0.15% nasal spray
- ☐ olopatadine nasal spray

Single Oral Antihistamines

- ☐ carbinoxamine 6 mg tablet
- ☐ desloratadine orally disintegrating tablet (ODT)
- ☐ desloratadine tablet
- ☐ dexchlorpheniramine solution
- ☐ carbinoxamine extended-release
- ☐ levocetirizine solution

Combination Oral Antihistamines

- ☐ Clarinex-D (desloratadine/pseudoephedrine)

Dose and frequency of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Allergic Rhinitis
- ☐ Urticaria
- ☐ Non-allergic Rhinitis
- ☐ Other

Please list all other medications currently prescribed for the member for this indication.

Section I. Please complete for desloratadine ODT and levocetirizine solution requests. Please also complete Section II for these medications.

Does the member have a swallowing disorder or condition affecting swallowing ability?

- ☐ Yes. Please describe.
- ☐ No. Please describe clinical rationale for not using oral tablet formulation.

Section II. Please complete for Clarinex-D, desloratadine ODT, and levocetirizine solution.

Has the member had a trial with an intranasal corticosteroid and two second-generation antihistamines (e.g., cetirizine, levocetirizine, loratadine)?

For requests for combination antihistamines, please include information about trials with second-generation antihistamines in combination with pseudoephedrine (e.g., cetirizine/pseudoephedrine, loratadine/pseudoephedrine).

- ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe why intranasal corticosteroids and second-generation antihistamines are not appropriate for this member.

Section III. Please complete for azelastine 0.15% nasal spray and olopatadine nasal spray requests.

1. Has the member had a trial with an intranasal corticosteroid?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why intranasal corticosteroids are not appropriate for this member.
2. Has the member had a trial with azelastine 137 mcg nasal spray?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.*

   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why azelastine 137 mcg nasal spray is not appropriate for this member.
3. For requests for any agent at a quantity > 1 inhaler/30 days, please document an inadequate response to the manufacturer's recommended dosing.

Section IV. Please complete for carbinoxamine 6 mg tablet and carbinoxamine extended-release requests.

1. Has the member had a trial with an intranasal corticosteroid and two non-selective antihistamines?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

   Drug name Dates/duration of use

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe why intranasal corticosteroids and non-selective antihistamines are not appropriate for this member.

2. For carbinoxamine 6 mg tablet requests, has the member had a trial with carbinoxamine 4 mg tablet?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.*

   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why carbinoxamine 4 mg tablet is not appropriate for this member.
3. For carbinoxamine extended-release requests, has the member had a trial with carbinoxamine immediate-release solution?
   ☐ Yes. Please list the dates/duration of trials and outcomes below.*

   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe why carbinoxamine immediate-release solution is not appropriate for this member.

**Please attach a letter documenting additional trials as necessary.*

Section V. Please complete for dexchlorpheniramine solution requests.

Has the member had a trial with two antihistamine solutions that do not require prior authorization?
☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not.

Section VI. Please complete for desloratadine tablet requests.

Has the member had a trial with cetirizine, fexofenadine, levocetirizine, or loratadine?
☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe why cetirizine, fexofenadine, levocetirizine, and loratadine are not appropriate for this member.

Section VII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Antipsychotic
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about antipsychotics and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form**.

Medication information

Medication(s) requested

- ☐ Abilify Asimtufii (aripiprazole extended-release injection)
- ☐ Abilify Maintena (aripiprazole extended-release injection)
- ☐ Abilify Mycite (aripiprazole tablet with sensor)
- ☐ aripiprazole orally disintegrating tablet (ODT)
- ☐ aripiprazole solution ≥ 18 years old and > 25 mL/day
- ☐ aripiprazole tablet > 2 units/day
- ☐ asenapine sublingual tablet
- ☐ Caplyta (lumateperone)
- ☐ clozapine ODT
- ☐ Fanapt (iloperidone)
- ☐ lurasidone > quantity limits
- ☐ Lybalvi (olanzapine/samidorphan)
- ☐ olanzapine ODT > quantity limits
- ☐ olanzapine tablet > quantity limits
- ☐ paliperidone tablet > quantity limits
- ☐ perphenazine/amitriptyline
- ☐ Perseris (risperidone 90 mg, 120 mg extended-release subcutaneous injection) > 1 injection/ 28 days
- ☐ quetiapine > 3 units/day
- ☐ quetiapine extended-release > 2 units/day
- ☐ Rexulti (brexpiprazole)
- ☐ risperidone 3 mg, 4 mg ODT
- ☐ risperidone 0.25 mg, 0.5 mg, 1 mg, 2 mg, ODT > 2 units/day
- ☐ risperidone 12.5 mg, 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection [Risperdal Consta] > 2 injections/28 days
- ☐ risperidone solution > 16 mL/day
- ☐ risperidone tablet > quantity limits
- ☐ Rykindo (risperidone 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection)
- ☐ Secuado (asenapine transdermal)
- ☐ Uzedy (risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection) > 1 injection/28 days
- ☐ Uzedy (risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection) > 1 injection/56 days
- ☐ Versacloz (clozapine suspension)
- ☐ Vraylar (cariprazine)
- ☐ ziprasidone > 2 units/day
- ☐ Other

Dose and frequency of medication requested

For long-acting injectable agents, please indicate billing preference:

☐ Pharmacy ☐ Prescriber in-office ☐ Inpatient Psychiatry Unit

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Agitation associated with dementia due to Alzheimer's Disease
- ☐ Bipolar disorder
  - ☐ Bipolar depression
- ☐ Irritability associated with autistic disorder
- ☐ Major depressive disorder
- ☐ Psychosis, unspecified
- ☐ Schizophrenia
- ☐ Treatment-resistant depression
- ☐ Other

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Monotherapy

Please select previous medication trial(s) as applicable.*

**For aripiprazole ODT or solution for irritability associated with autistic disorder, a trial with risperidone alone is sufficient. For Abilify Asimtufii and Abilify Maintena requests, please document a trial of Aristada, or provide clinical rationale for use of the requested agent instead of Aristada. For Rykindo requests, please document a trial of risperidone extended-release intramuscular injection (generic Risperdal Consta), Perseris, and Uzedy, or provide clinical rationale for use of the requested agent instead of risperidone extended-release intramuscular injection (generic Risperdal Consta), Perseris, and Uzedy.*

☐ Trial(s) of second-generation (atypical) antipsychotics (Check all that apply.)

☐ aripiprazole ☐ clozapine ☐ olanzapine ☐ quetiapine ☐ risperidone ☐ ziprasidone ☐ Other

☐ Trial of other antipsychotics (Please specify below.)

Drug name 1 Drug name 2

☐ If requesting for major depressive disorder or treatment-resistant depression, please document trial(s) of antidepressants.

Drug name 1 Dates/Duration of use

Drug name 2 Dates/Duration of use

☐ If requesting Caplyta or Vraylar for bipolar depression, in addition to trials with other second-generation (atypical) antipsychotics, please document trials with olanzapine monotherapy or combination therapy with fluoxetine and quetiapine immediate-release or extended-release, if applicable.

Drug name 1 Dates/Duration of use

Drug name 2 Dates/Duration of use

Please select reason(s) for medical necessity as applicable.

☐ Member is new to MassHealth and has been previously stabilized on requested medication.

☐ If request is for major depressive disorder or treatment-resistant depression, please note if the requested agent will be used as adjunctive therapy with current antidepressant treatment or provide clinical rationale why the member is not a candidate for antidepressant therapy.

☐ If requesting ODT, solution, or transdermal formulation, please also describe medical necessity for the specific dosage formulation.

☐ If requesting Abilify Mycite, please also describe the medical necessity for monitoring the member's ingestion of oral aripiprazole, and the member's training to use the Abilify Mycite system.

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☐ If requesting perphenazine/amitriptyline, please also describe the medical necessity for the use of the combination product instead of the commercially available separate agents.

☐ If requesting Lybalvi, please also complete the questions below.

1. Is the member being treated with an opioid? ☐ Yes ☐ No
2. Is the member being treated for acute opioid withdrawal? ☐ Yes ☐ No

☐ If requesting Caplyta 10.5 mg or 21 mg capsules, please also describe any drug-drug interactions resulting in the modified dosing regimen and document if the member has at least moderate or severe hepatic impairment (Child-Pugh Class B or C), if applicable.

☐ Other, please explain.

Section II. Antipsychotic Polypharmacy for members ≥ 18 years of age. Please complete information for medications requested and select the reason for polypharmacy with antipsychotics (two or more first-generation and/or second-generation antipsychotics for ≥ 60 days within a 90-day period).

1. Antipsychotic name/dose/frequency Indication
2. Antipsychotic name/dose/frequency Indication
3. Antipsychotic name/dose/frequency Indication

Is member under the care of a specialist (e.g., psychiatry, neurology, or developmental/behavioral health)?
☐ Yes. Please attach specialist consult details (if the prescriber submitting the request is not a specialist). ☐ No
For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

☐ Member was recently discharged from an inpatient setting on requested medications and is currently stable.
☐ Member experienced an inadequate response or adverse reaction to two monotherapy trials with antipsychotics.

Drug name 1 Dates/Duration of use (if available)
Drug name 2 Dates/Duration of use (if available)

☐ Member is transitioning from one antipsychotic to the other.
☐ Other, please explain.

Section III. Quantity Limits. Please complete information for medication requested and select the reason for exceeding established quantity limits.

Drug, dose, and frequency of requested antipsychotic
☐ Member is not a candidate for dose consolidation (e.g., lurasidone 20 mg two times daily can be consolidated to lurasidone 40 mg once daily, which is available without PA).

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☐ Other. Please describe medical necessity for exceeding quantity limits.

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name Dose/frequency Indication
2. Medication name Dose/frequency Indication

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3. Medication name Dose/frequency Indication
4. Medication name Dose/frequency Indication
5. Medication name Dose/frequency Indication
6. Medication name Dose/frequency Indication
7. Other(s)

Is the member currently in an acute care setting?

☐ Yes (Inpatient) ☐ Yes (Community Based Acute Treatment)
☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name Contact information

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months.

☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?

☐ Yes. Please provide details.
☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g., weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain.

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other
☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s) Date(s) of last visit or consult

Contact information

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility
☐ Uncertain ☐ Other

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH) ☐ Department of Developmental Services (DDS)
☐ Department of Youth Services (DYS)

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Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

* *Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to: https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information*

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation.

☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

Section II. Antipsychotic Polypharmacy. Complete this section for all members < 18 years of age if request will result in prescription of two or more antipsychotics for ≥ 60 days within a 90-day period.

Please select the stage of treatment and clinical rationale for antipsychotic polypharmacy.

☐ **Acute stage** (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects)

☐ Member experienced an inadequate response or adverse reaction to two monotherapy trials with antipsychotics.

Drug name 1 Dates/Duration of use

Drug name 2 Dates/Duration of use

☐ Member is transitioning from one antipsychotic to the other.

☐ Other, please explain.

☐ **Maintenance stage** (response to antipsychotic treatment with goal of remission or recovery)

1. Is the regimen effective, therapy benefits outweigh risks, and appropriate monitoring is in place?
   ☐ Yes ☐ No
2. Has the member been on an antipsychotic polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?
   ☐ Yes. Please complete the applicable question in Section I. ☐ No

☐ **Discontinuation stage** (clinically indicated that the antipsychotic regimen can likely be successfully tapered)

☐ Member is transitioning from one antipsychotic to the other.

☐ Member is tapering antipsychotic. Please describe taper plan including duration.

over

Section III. Antipsychotic Request for Members < ten years of age.

Please select the stage of treatment and clinical rationale for use of an antipsychotic for this member < ten years of age.

☐ **Acute stage** (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects)

☐ **Maintenance stage** (response to antipsychotic treatment with goal of remission or recovery)

1. Is the regimen effective, therapy benefits outweigh risks, and appropriate monitoring is in place?
   ☐ Yes ☐ No
2. Has the member been on an antipsychotic agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?
   ☐ Yes. Please complete the applicable question in Section I. ☐ No

☐ **Discontinuation stage** (clinically indicated that the antipsychotic regimen can likely be successfully tapered)

☐ Member is transitioning from one antipsychotic to the other.

☐ Member is tapering antipsychotic. Please describe taper plan including duration.

Section IV. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Antiretroviral Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Antiretroviral requested

- ☐ Cimduo (lamivudine/tenofovir disoproxil fumarate)
- ☐ efavirenz/lamivudine/tenofovir disoproxil fumarate (600 mg/300 mg/300 mg)
- ☐ efavirenz/lamivudine/tenofovir disoproxil fumarate (400 mg/300 mg/300 mg)
- ☐ fosamprenavir
- ☐ maraviroc
- ☐ nevirapine extended-release
- ☐ Rukobia (fostemsavir)
- ☐ Sunlenca (lenacapavir)
- ☐ tenofovir disoproxil fumarate tablet > 1 unit/day
- ☐ Tivicay (dolutegravir) > 1 unit/day
- ☐ Trogarzo (ibalizumab-uiyk)
- ☐ Viread (tenofovir disoproxil fumarate) powder ≥ 13 years of age

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ HIV-1 Current viral load and date

☐ pre-exposure prophylaxis (PreEP)

☐ Chronic Hepatitis B ☐ Other (specify)

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial.

Section I. Please complete for requests for tenofovir disoproxil fumarate tablet > 1 unit/day, and Viread powder ≥ 13 years of age.

Please describe the medical necessity for the agent selected. Please address need for the requested quantity (tenofovir disoproxil fumarate tablet), or use in the requested age group (Viread powder), as appropriate.

Section II. Please complete for Tivicay requests > 1 unit/day.

1. Will the member be taking the requested medication concurrently with carbamazepine, efavirenz, fosamprenavir/ritonavir, Aptivus (tipranavir)/ritonavir, or rifampin?
   ☐ Yes. Please document drug name with dose and frequency. ☐ No
   Drug _____ Dose and Frequency _____
2. Does the member have integrase strand transfer inhibitor (INSTI)-associated resistance substitutions or clinically suspected INSTI-resistance?
   ☐ Yes ☐ No

Section III. Please complete for fosamprenavir requests.

1. Has the member tried an antiretroviral regimen containing atazanavir, darunavir, or ritonavir?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   _____
   ☐ No. Explain why atazanavir, darunavir, and ritonavir are not appropriate for this member.
   _____
2. Will the member be taking the requested medication concurrently with at least one other antiretroviral?
   ☐ Yes. Please document drug name with dose and frequency. ☐ No
   Drug _____ Dose and Frequency _____

Section IV. Please complete for nevirapine extended-release requests.

Please attach medical records documenting an inadequate response or adverse reaction to nevirapine immediate-release formulation.

Section V. Please complete for Cimduo and efavirenz/lamivudine/tenofovir disoproxil fumarate requests.

1. Does the member experience any of the following? (Check all that apply.)
   ☐ Yes
   ☐ Significant psychiatric diagnosis leading to documented difficulty with adherence.
   Please document diagnosis. _____
   ☐ Homelessness and difficulty storing larger amounts of medications.
   ☐ Difficulty with adherence leading to complications.
   ☐ Developmental issues without adequate support to properly manage their own HIV regimen.
   ☐ No. Please provide medical necessity for use of the combination product instead of the commercially available separate agents.
   _____
   _____
2. For members < 18 years of age, please provide member's current weight. _____
3. For Cimduo, will the member be taking the requested medication concurrently with at least one other antiretroviral?
   ☐ Yes. Please document drug name with dose and frequency. ☐ No
   Drug _____ Dose and Frequency _____

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Section VI. Please complete for Rukobia and Sunlenca requests.

1. Is the member antiretroviral-experienced with documented historical or baseline resistance, intolerability, and/or contraindication to antiretroviral?

☐ Yes. Please document drug name and outcome.* ☐ No

Drug ☐ Intolerability ☐ Resistant ☐ Other

Briefly describe details of intolerability, resistance, or other.

2. Has the member failed current antiretroviral regimen due to resistance, intolerance, or safety considerations?

☐ Yes. Please document drug name and outcome.* ☐ No

Drug ☐ Intolerability ☐ Resistant ☐ Other

Briefly describe details of intolerability, resistance, or other.

3. Will the member be taking the requested medication concurrently with at least one other antiretroviral?

☐ Yes. Please document drug name with dose and frequency. ☐ No

Drug Dose and Frequency

Section VII. Please complete for Trogarzo requests.

1. Does the member have resistance to one agent from each of the three classes of antiretrovirals [nucleoside analog reverse transcriptase inhibitor (NRTI), non-nucleoside reverse transcriptase inhibitor (NNRTI), protease inhibitor (PI)]?

☐ Yes. Please document drug names and outcomes.* ☐ No

NRTI ☐ Resistant ☐ Other

NNRTI ☐ Resistant ☐ Other

PI ☐ Resistant ☐ Other

Briefly describe details of resistance or other.

2. Will the member be taking the requested medication concurrently with at least one other antiretroviral?

☐ Yes. Please document drug name with dose and frequency. ☐ No

Drug Dose and Frequency

3. Has the member tried Rukobia or Sunlenca?

☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe the details of adverse reaction, inadequate response, or other.

☐ No. Explain why Rukobia and Sunlenca are not appropriate for this member.

Section VIII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

If yes, briefly describe details of contraindication, adverse reaction, or harm.

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2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Asthma/Allergy Monoclonal Antibodies
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Cinqair (reslizumab) [MB] ☐ Dupixent (dupilumab) ☐ Fasenra (benralizumab)
☐ Nucala (mepolizumab) ☐ Xolair (omalizumab) ☐ Tezspire (tezepelumab-ekko)

Dose, frequency, and duration of medication requested

☐ Naïve to therapy ☐ Continuation of therapy

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Chronic idiopathic urticaria
☐ Eosinophilic granulomatosis with polyangiitis
☐ Hypereosinophilic syndrome
☐ IgE-mediated food allergy
☐ Moderate-to-severe allergy-related asthma
☐ Moderate-to-severe atopic dermatitis
☐ Moderate-to-severe eosinophilic asthma
☐ Nasal polyps
☐ Oral corticosteroid-dependent asthma
☐ Prurigo nodularis
☐ Severe asthma
☐ Other (Please indicate.)

Please complete the following for all requests.

1. Member's current weight ____ Date ____
2. Please indicate prescriber specialty. ☐ Allergy & immunology ☐ Dermatology ☐ Otolaryngology ☐ Pulmonology ☐ Other (Please specify.) ____
3. Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
4. Is this member a referral candidate for care coordination? ☐ Yes ☐ No
   If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial.

Section I. Please complete for Xolair for the diagnosis of moderate-to-severe allergy-related asthma, for Cinqair, Fasenra, and Nucala for the diagnosis of severe eosinophilic asthma, and for Tezspire for the diagnosis of severe asthma.

For Xolair, please complete questions 1 through 4. For Cinqair, Fasenra, and Nucala, complete questions 3 and 4. For Tezspire, complete question 4.

1. Pretreatment serum IgE level _____ Test date _____
   Does the member have a history of positive skin test or radioallergosorbent test (RAST) to an aeroallergen(s)?

   ☐ Yes. Please list the allergens. _____
   ☐ No
2. For requests for the 150 mg and 300 mg syringe or auto-injection, please provide medical necessity for the requested formulation instead of the vial formulation.

   _____
3. Does the member have evidence of an eosinophilic phenotype of asthma?

   ☐ Yes. Please explain. _____
   ☐ No
4. Has the member tried other medications to treat this condition [including beta agonists, inhaled and oral corticosteroids, leukotriene modifiers, or combination therapies (LABA/ICS)]?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____

   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____

   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____

   ☐ No. Please explain why not. _____

Section II. Please complete for Xolair requests for the diagnosis of chronic idiopathic urticaria.

1. Has the member tried two different histamine$_1$ antihistamines?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____

   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____

   ☐ No. Please describe why histamine$_1$ antihistamines are not appropriate for this member.
   _____

over

2. Has the member tried a histamine$_2$ antihistamine?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why histamine$_2$ antihistamines are not appropriate for this member.
   _____
3. For requests for the 150 mg and 300 mg syringe or auto-injection, please provide medical necessity for the requested formulation instead of the vial formulation.
   _____

Section III. Please complete for Xolair requests for the diagnosis of IgE-mediated food allergy.

1. Pretreatment serum IgE level _____ Test date _____
2. Does the member have a history of positive skin test or radioallergosorbent test (RAST) to food allergen(s)?
   ☐ Yes. Please list the allergens. _____
   ☐ No
3. For requests for the 150 mg and 300 mg syringe or auto-injection, please provide medical necessity for the requested formulation instead of the vial formulation.
   _____

Section IV. Please complete for Nucala requests for the diagnosis of eosinophilic granulomatosis with polyangiitis.

1. Has the member tried a systemic glucocorticoid?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why systemic glucocorticoids are not appropriate for this member.
   _____
2. Has the member tried azathioprine or methotrexate?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why azathioprine and methotrexate are not appropriate for this member.
   _____

over

Section V. Please complete for Nucala requests for hypereosinophilic syndrome.

1. Has a non-hematologic secondary cause been excluded? ☐ Yes ☐ No
2. Has the member tried a systemic glucocorticoid?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why systemic glucocorticoids are not appropriate for this member.
   _____
3. Has the member tried hydroxyurea, interferon alfa, or methotrexate?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why hydroxyurea, interferon alfa, and methotrexate are not appropriate for this member.
   _____

Section VI. Please complete for Dupixent requests for moderate-to-severe atopic dermatitis.

1. Has the member tried a superpotent or potent topical corticosteroid to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why a superpotent or potent topical corticosteroid is not appropriate for this member.
   _____
2. Has the member tried topical tacrolimus or Eucrisa to treat this condition?
   ☐ Yes. Please list the dates/duration of trial and outcome.*
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   _____
   ☐ No. Please describe why topical tacrolimus and Eucrisa are not appropriate for this member.
   _____

Section VII. Please complete for Dupixent requests for moderate-to-severe eosinophilic asthma and oral corticosteroid-dependent asthma.

For requests for oral corticosteroid-dependent asthma, only question 1 is required.

1. Has the member tried other medications to treat this condition (including combination inhaler, combination of an inhaled corticosteroid and a long-acting beta agonist inhaler or chronic oral corticosteroids)?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

over

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe why other medications are not appropriate for this member.

2. Does the member have evidence of an eosinophilic phenotype of asthma?

☐ Yes. Please explain.

☐ No

Section VIII. Please complete for Dupixent, Nucala, and Xolair requests for nasal polyps.

1. Has the member tried an oral corticosteroid to treat this condition?

☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe why oral corticosteroids are not appropriate for this member.

2. Has the member tried an intranasal corticosteroid to treat this condition?

☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe why intranasal corticosteroids are not appropriate for this member.

3. For requests for Dupixent, has the member failed a prior nasal surgery? ☐ Yes ☐ No
4. Will the requested agent be used as adjunctive therapy?

☐ Yes

☐ No. Please describe why not.

5. For requests for Xolair 150 mg and 300 mg syringe or auto-injection, please provide medical necessity for the requested formulation instead of the vial formulation.

Section IX. Please complete for Dupixent requests for eosinophilic esophagitis.

1. Has the member tried a proton pump inhibitor to treat this condition?

☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

Drug name Dates/duration of use

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe why proton pump inhibitors are not appropriate for this member.

2. Has the member tried budesonide or fluticasone propionate to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why budesonide and fluticasone propionate are not appropriate for this member.

Section X. Please complete for Dupixent requests for prurigo nodularis.

1. Has the member tried a superpotent or potent topical corticosteroid to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why a superpotent or potent topical corticosteroid is not appropriate for this member.

2. Has the member tried an intralesional corticosteroid to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why intralesional corticosteroids are not appropriate for this member.

3. Has the member tried phototherapy to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcome below.*

   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe why phototherapy is not appropriate for this member.

** Please attach a letter documenting additional trials as necessary.*

over

Section XI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Benign Prostatic Hyperplasia (BPH) Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

BPH medication requested

☐ dutasteride/tamsulosin
☐ Entadfi (finasteride/tadalafil)
☐ silodosin
☐ tadalafil 5 mg

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ BPH
☐ S/P transurethral resection of the prostate (TURP)
☐ Other

Please note: MassHealth does not pay for any drug when used for the treatment of sexual dysfunction, cosmetic purposes, or for hair growth as described in 130 CMR 406.413(B): Drug Exclusions. For additional information go to: www.mass.gov/regulations/130-CMR-406000-pharmacy-services.

Section I. Please complete for silodosin requests.

Has the member had a trial with alfuzosin and tamsulosin?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please provide clinical rationale for not using alfuzosin and tamsulosin.

Section II. Please complete for dutasteride/tamsulosin requests.

1. Has the member had a trial with an alpha-1 blocker (alfuzosin, doxazosin, tamsulosin, or terazosin)?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please provide clinical rationale for not using an alpha-1 blocker.

2. Has the member had a trial with finasteride?
   ☐ Yes. Please list the dates/duration of trials and outcomes.*

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please provide clinical rationale for not using finasteride.

3. Please provide medical necessity for use of the combination product instead of the commercially available separate agents.

Section III. Please complete for Entadfi requests.

1. Please provide medical necessity for use of the combination product instead of the commercially available separate agents.
2. For requests for use beyond 26 weeks of therapy, please provide medical necessity for continued use.

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

over

Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Benzodiazepines and Other Antianxiety Agents Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about benzodiazepines or other antianxiety agents and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form**

Medication information

Medication requested (check one or all that apply.)

- ☐ alprazolam extended-release (ER) >2 units/day
- ☐ alprazolam orally disintegrating tablet (ODT)
- ☐ amitriptyline/chlordiazepoxide
- ☐ Byfavo (remimazolam) MB
- ☐ clonazepam ODT 0.125 mg, 0.25 mg, 0.5 mg, 1 mg >3 units/day
- ☐ clonazepam ODT 2 mg >2 units/day
- ☐ clorazepate
- ☐ estazolam >1 unit/day
- ☐ flurazepam
- ☐ Loreev XR (lorazepam extended-release)
- ☐ meprobamate
- ☐ oxazepam
- ☐ quazepam
- ☐ temazepam 7.5 mg, 15 mg, 30 mg >1 unit/day
- ☐ temazepam 22.5 mg
- ☐ triazolam >1 unit/day
- ☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

MB *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested _____ **Quantity requested per month** _____

Indication(s) or ICD-10 code(s), if applicable _____

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code _____

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

_____

Section I. Concomitant Opioid and Benzodiazepine Polypharmacy. Please complete information for medications requested and clinical rationale for polypharmacy with opioids and benzodiazepines [one or more benzodiazepine(s), excluding clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations, and one or more opioid(s) for ≥15 days within a 45-day period].

Please document the indication or ICD-10 code(s), if applicable, for the agents requested.

1. Benzodiazepine

Name/dose/frequency _____ Indication _____

Name/dose/frequency _____ Indication _____

Name/dose/frequency _____ Indication _____

2. Opioid

Name/dose/frequency _____ Indication _____

Name/dose/frequency _____ Indication _____

Name/dose/frequency _____ Indication _____

Please document clinical rationale for concomitant use of opioids and benzodiazepines for this member.

Please describe the ongoing treatment plan for continued use.

For the diagnosis of a seizure disorder, is the member currently receiving a non-benzodiazepine anticonvulsant?

☐ Yes. Drug name _____ Dates _____ Outcome _____

☐ No. Please explain why not. _____

For the diagnosis of a sleep disorder, has the member had trials with three non-benzodiazepine sleep medications?

☐ Yes. Drug name _____ Dates _____ Outcome _____

Drug name _____ Dates _____ Outcome _____

Drug name _____ Dates _____ Outcome _____

☐ No. Please explain why not. _____

For the diagnosis of a psychiatric disorder (e.g., generalized anxiety disorder, panic disorder, post-traumatic stress disorder, etc.), has the member had trials with three antidepressants?

☐ Yes. Drug name _____ Dates _____ Outcome _____

Drug name _____ Dates _____ Outcome _____

Drug name _____ Dates _____ Outcome _____

☐ No. Please explain why not. _____

over

For the diagnosis of a musculoskeletal disorder, has the member had trials with three skeletal muscle relaxants?

☐ Yes. Drug name Dates Outcome

Drug name Dates Outcome

Drug name Dates Outcome

☐ No. Please explain why not.

Has consideration been given for possible taper of benzodiazepine or opioid?

☐ Yes. Please describe plan for taper and plan to reevaluate in the future.

☐ No. Please describe why taper is not possible at this time and plan to reevaluate in the future.

Has the member been hospitalized for a psychiatric condition (non-overdose related) within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months.

☐ No

On the current regimen, is the member considered to be a risk of harm to self or others?

☐ Yes. Please provide details.

☐ No

Has the member been offered and/or given a prescription for naloxone treatment?

☐ Yes ☐ No. Please provide details.

**Attach a letter with additional information regarding medication trials as applicable.*

Section II. Benzodiazepine Polypharmacy for members ≥ 18 years of age. Please complete information for medications requested and clinical rationale for polypharmacy with benzodiazepines (two or more benzodiazepines, excluding clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations for ≥ 60 days within a 90-day period).

Please document complete treatment plan (include all agents requested from the same medication class and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Benzodiazepine name/dose/frequency Indication
2. Benzodiazepine name/dose/frequency Indication
3. Benzodiazepine name/dose/frequency Indication

Please document clinical rationale for polypharmacy within the same medication class for this member (include prior therapy trials, severity of symptoms, etc.)

Has consideration been given for consolidation to a single benzodiazepine agent?

☐ Yes. Please describe plan for cross-titration or taper.

☐ No

over

Please describe why dose consolidation is not possible at this time and plan to reevaluate in the future.

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months.

☐ No

On the current regimen, is the member considered to be a risk of harm to self or others?

☐ Yes. Please provide details.

☐ No

Section III. Please complete for requests for alprazolam ODT.

Please describe the medical necessity for use of the requested dosage formulation. Include prior trials of agents and describe dose consolidation as appropriate.

Section IV. Please complete for requests for > 2 units/day of alprazolam ER and clonazepam ODT 2 mg, and > 3 units/day of clonazepam ODT 0.125 mg, 0.25 mg, 0.5 mg, and 1 mg.

1. Can the dose be consolidated within quantity limits? ☐ Yes ☐ No
2. Please describe clinical rationale for dosing higher than the FDA approved limits.
3. Please attach medical records documenting titration of medication up to current dose.
4. For clonazepam ODT, please indicate prescriber specialty below.

   ☐ Psychiatry ☐ Neurology ☐ Other

   ☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

   Name(s) of the specialist(s) Date(s) of last visit or consult

   Contact information

Section V. Please complete for requests for flurazepam, quazepam and temazepam 22.5 mg.

For requests for flurazepam, quazepam and ≤1 unit/day of temazepam 22.5 mg, please complete question 1. For requests for 2 units/day of temazepam 22.5 mg, please complete all of the following questions.

1. Please attach medical records documenting an inadequate response or adverse reaction to all hypnotic benzodiazepines (e.g., estazolam, temazepam 7.5 mg, 15 mg, or 30 mg, triazolam). Please describe dose consolidation.
2. Has the member had an inadequate response to a dose of 30 mg/day? ☐ Yes ☐ No
3. Please attach medical records documenting titration of medication up to current dose.
4. Please describe clinical rationale for dosing higher than the FDA approved limits.

Section VI. Please complete for requests for > 1 unit/day of estazolam, flurazepam, temazepam (7.5 mg, 15 mg, 22.5 mg, and 30 mg), triazolam, and quazepam.

1. Can the dose be consolidated within quantity limits? ☐ Yes ☐ No
2. Was a higher dose effective in alleviating symptoms? ☐ Yes ☐ No

over

3. Has the member had an inadequate response to 1 unit/day? ☐ Yes ☐ No
4. For triazolam 0.25 mg, has the member had an inadequate response to a dose of 0.25 mg/day?
   ☐ Yes ☐ No
5. For requests exceeding the FDA-approved maximum dose, has the member experienced an inadequate response or adverse reaction to other alternatives for sleep?
   ☐ Yes

Drug name Dates Outcome

Drug name Dates Outcome

Drug name Dates Outcome

Drug name Dates Outcome

☐ No. Please explain why not.

Section VII. Please complete for requests for meprobamate.

1. Has the member had a trial with at least two benzodiazepines?
   ☐ Yes

Drug name Dates Outcome

Drug name Dates Outcome

☐ No. Please explain why not.

2. If requesting recertification, please provide clinical rationale for continued therapy and details of trials with alternatives (e.g., SSRIs, SNRIs, TCAs, buspirone).

Section VIII. Please complete for requests for Byfavo.

1. Will Byfavo be used for induction and maintenance of procedural sedation?
   ☐ Yes. Please provide procedure date.
   ☐ No.
2. Please provide clinical rationale for use instead of intravenous midazolam.

Section IX. Please complete for requests for amitriptyline/chlordiazepoxide.

Please describe the medical necessity for use of the combination product instead of the commercially available separate agents.

Section X. Please complete for requests for clorazepate and oxazepam.

Has the member had a trial with two of the following benzodiazepines: alprazolam, chlordiazepoxide, clonazepam, diazepam, or lorazepam?

☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.*

Drug name Dates/duration of use

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not.

**Attach a letter with additional information regarding medication trials as applicable.*

Section XI. Please complete for requests for Loreev XR.

Please attach medical records documenting stability with lorazepam tablets in three evenly divided daily doses and trials with two intermediate/long- or long-acting benzodiazepines. If all other long-acting benzodiazepines are contraindicated, please describe. For requests for > 1 unit/day, describe medical necessity for exceeding the quantity limit.

Section XII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

over

MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name Dose/frequency Indication
2. Medication name Dose/frequency Indication
3. Medication name Dose/frequency Indication
4. Medication name Dose/frequency Indication
5. Medication name Dose/frequency Indication
6. Medication name Dose/frequency Indication
7. Other(s)

Is the member currently in an acute care setting?

☐ Yes (Inpatient) ☐ Yes (Community Based Acute Treatment)
☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name Contact information

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months.
☐ No

On the current regimen, is the member considered to be a risk of harm to self or others?

☐ Yes. Please provide details.
☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g. weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain.

Has informed consent from a parent or legal guardian been obtained? * ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other
☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s) Date(s) of last visit or consult

Contact information

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

over

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility

☐ Uncertain ☐ Other

Please document agency involvement.

☐ Department of Children and Families (DCF) ☐ Department of Mental Health (DMH)

☐ Department of Developmental Services (DDS) ☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions, if applicable.

☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

** Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to: https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information*

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation.

☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

Section II. Benzodiazepine Polypharmacy. Complete this section for all members < 18 years of age, if request will result in prescription of two or more benzodiazepine agents for ≥ 60 days within a 90-day period (excluding hypnotic benzodiazepine agents, clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations).

Please document if monotherapy trials (include drug name, dates/duration of use, and outcome) with benzodiazepine agents were tried before prescribing polypharmacy with two or more benzodiazepine agents in this member. *

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Other(s)

over

Please document clinical rationale for polypharmacy within the same medication class for this member.

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

**Attach a letter with additional information regarding medication trials as applicable.*

Section III. Benzodiazepine Request for Members < six years of age.

Please document if member has other behavioral health comorbidities (e.g., anxiety, sleep disorder).

For hypnotic benzodiazepine requests, please document medication trials with melatonin and/or clonidine, if clinically appropriate. Include drug name, dates/duration of use, and outcome.*

Please document clinical rationale for the use of a benzodiazepine agent in this member < six years of age.

Has the member been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Section IV. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

Please document clinical rationale for use of multiple behavioral health medications for this member < 18 years of age.

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Adakveo (crizanlizumab-tmca)[MB]
- ☐ Casgevy (exagamglogene autotemcel) [MB]
- ☐ l-glutamine
- ☐ Lyfgenia (lovotibeglogene autotemcel) [MB]
- ☐ Oxbryta (voxelotor)
- ☐ Reblozyl (luspatercept-aamt) [MB]
- ☐ Siklos (hydroxyurea tablet)
- ☐ Zynteglo (betibeglogene autotemcel) [MB]

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Beta Thalassemia (provide documentation of genetic testing)
- ☐ Myelodysplastic syndromes associated anemia
- ☐ Sickle Cell Disease (SCD)
- ☐ Other

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Is the prescriber a hematologist?

- ☐ Yes
- ☐ No. Please attach consultation notes from a hematologist addressing the use of the requested agent.

Member's current weight Date

Section I. Please complete for Adakveo and Oxbryta requests.

1. Has the member experienced sickle cell crises in the last 12 months (two or more for Adakveo and at least one or more for Oxbryta)?

   ☐ Yes. Please provide dates. ☐ No
2. Has the member had an inadequate response to hydroxyurea for at least three months? Please note: Trial will be evaluated to ensure titration to maximally tolerated dose.*

☐ Yes. Please note: Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to this agent.

Dose and frequency ☐ Dates of use ☐ Outcome ☐

Please attach hematologic laboratory data (e.g., absolute neutrophil count [ANC], platelet count, hemoglobin, reticulocyte count) supporting dosing regimen.

☐ No

3. Has the member tried hydroxyurea and had an adverse reaction or does the member have a contraindication to this agent?*

☐ Yes. Please explain. ☐ ☐ No

4. For Oxbryta requests, please document current hemoglobin (Hb). ☐ Date Hb obtained ☐
5. For Oxbryta 300 mg tablet for oral suspension requests, please document medical necessity for the requested formulation.

☐

6. For Adakveo recertification requests, please attach medical records documenting positive response to therapy (e.g., follow up information on vasoocclusive crises, pain management, hospitalizations, and/or member's improvement).
7. For Oxbryta recertification requests, please attach medical records documenting positive response to therapy (e.g., follow up information on vasoocclusive crises, Hb level, laboratory markers associated with hemolysis, and/or member's improvement).

Section II. Please complete for l-glutamine requests.

1. Has the member experienced two or more sickle cell crises in the last 12 months?

☐ Yes. Please provide dates. ☐ ☐ No

2. Has the member had a trial with hydroxyurea?*

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration of use ☐ ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐

☐ No. Please explain why not. ☐

Section III. Please complete for Reblozyl for beta thalassemia requests.

1. Please attach a copy of genetic test confirming diagnosis of beta thalassemia.
2. Is the member transfusion-dependent?

☐ Yes. Please attach medical records supporting regular blood transfusions and/or chronic iron chelator use.

☐ No

3. For recertification requests, please attach medical records documenting positive response to therapy (e.g., follow up information on transfusion requirements and/or member's improvement).

Section IV. Please complete for Siklos requests.

Please document medical necessity for the use of tablet formulation.

☐

☐

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Section V. Please complete for Zynteglo requests.

1. Please attach a copy of genetic test confirming diagnosis of beta thalassemia.
2. Is the member transfusion-dependent?
   ☐ Yes. Please attach medical records supporting regular blood transfusions.
   ☐ No
3. Please provide anticipated dates and dosing for the following as applicable.
   Apheresis ____ Admission ____ Infusion ____ Dose ____ Discharge ____
4. Does the member have pre-existing human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) infection? ☐ Yes. Please describe. ____ ☐ No
5. Has the member required ≥100 mL/kg/year of pRBC or ≥ eight transfusions within the last 12 months?
   ☐ Yes. Please describe. ____ ☐ No
6. Will the infusion take place in a qualified treatment center? ☐ Yes ____ ☐ No
7. Is the member clinically stable and eligible for hematopoietic stem cell transplantation (HSCT)? ☐ Yes ☐ No
8. Outreach for both short- and long-term monitoring for efficacy and durability of response will be conducted by MassHealth. The applicable information (including but not limited to: medical records, dates of procedures, infusions, and admissions; adverse reactions experienced; agents used to treat adverse reactions; response to therapy [e.g., necessity of pRBC transfusions, including date, frequency, volume, reason for transfusion (e.g., planned procedure, accident, low hemoglobin level, etc.)]) will be provided to MassHealth upon request.
   ☐ Yes ☐ No

Section VI. Please complete for Casgevy requests.

1. Please attach a copy of genetic test confirming diagnosis of SCD.
2. Has the member experienced at least two sickle cell crises per year in the last two years?
   ☐ Yes. Please provide dates. ____ ☐ No
3. Has the member had an inadequate response to hydroxyurea for at least three months? Please note: Trial will be evaluated to ensure titration to maximally tolerated dose.*
   ☐ Yes. Please note: Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to this agent.
   Dose and frequency ____ Dates of use ____ Outcome ____
   Please attach hematologic laboratory data (e.g., absolute neutrophil count [ANC], platelet count, hemoglobin, reticulocyte count) supporting dosing regimen.
   ☐ No
4. Please provide anticipated dates and dosing for the following as applicable.
   Apheresis ____ Admission ____ Infusion ____ Dose ____ Discharge ____
5. Will the infusion take place in a qualified treatment center? ☐ Yes ____ ☐ No
6. Is the member clinically stable and eligible for hematopoietic stem cell transplantation (HSCT)? ☐ Yes ☐ No
7. Does the member have active human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) infection? ☐ Yes. Please describe. ____ ☐ No
8. Has the member received any prior SCD gene therapy?
   ☐ Yes. Please describe. ____ ☐ No

over

Section VII. Please complete for Lyfgenia requests.

1. Please attach a copy of genetic test confirming diagnosis of SCD.
2. Has the member experienced at least two sickle cell crises per year in the last two years?

   ☐ Yes. Please provide dates. ☐ No
3. Has the member had an inadequate response to hydroxyurea for at least three months? Please note: Trial will be evaluated to ensure titration to maximally tolerated dose.*

   ☐ Yes. Please note: Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to this agent.

   Dose and frequency Dates of use Outcome

   Please attach hematologic laboratory data (e.g., absolute neutrophil count [ANC], platelet count, hemoglobin, reticulocyte count) supporting dosing regimen.

   ☐ No
4. Please provide anticipated dates and dosing for the following as applicable.

   Apheresis Admission Infusion Dose Discharge
5. Will the infusion take place in a qualified treatment center? ☐ Yes ☐ No
6. Is the member clinically stable and eligible for hematopoietic stem cell transplantation (HSCT)? ☐ Yes ☐ No
7. Does the member have active human immunodeficiency virus (HIV) infection? ☐ Yes. Please describe.

   ☐ No
8. Does the member have α-thalassemia trait (-α3.7/-α3.7)? ☐ Yes. Please describe.

   ☐ No
9. Please provide medical necessity for use of requested agent instead of Casgevy.
10. Has the member received any prior SCD gene therapy?

    ☐ Yes. Please describe. ☐ No

Section VIII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

over

If yes, please provide details for the previous trial.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Brand-Name and Non-Preferred Generic Drug Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Dose, frequency, and duration of medication requested

Height Weight Date

Drug NDC (if known) or service code

Indication or ICD-10 code, if applicable

Section I. Please complete for brand-name requests.

Has the member tried a generic product therapeutically equivalent to the brand-name product requested?

☐ Yes. Please list the drug name, dates/duration of use, and outcomes below. In addition, provide supporting documentation (e.g., copies of medical records and/or office notes).

Drug name Dates/duration of use

Dose and frequency

Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not. Attach a letter with additional information regarding trials as applicable.

Section II. Please complete for non-preferred generic requests.

Has the member tried a brand-name product therapeutically equivalent to the non-preferred generic product requested?

☐ Yes. Please list the drug name, dates/duration of use, and outcomes below. In addition, provide supporting documentation (e.g., copies of medical records and/or office notes).

Drug name Dates/duration of use

Dose and frequency

Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not. Attach a letter with additional information regarding trials as applicable.

Section III. Please complete for all requests for non-preferred drug products if one or more preferred drug products have been designated for this class of drugs.

If one or more preferred drug products have been designated for this class of drugs, and if you are requesting PA for a non-preferred drug product, please provide medical necessity for prescribing the non-preferred drug product rather than the preferred drug product.

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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Breast Cancer Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

- ☐ Enhertu (fam-trastuzumab deruxtecan-nxki) [MB]
- ☐ everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg
- ☐ everolimus tablets for oral suspension
- ☐ fulvestrant [MB]
- ☐ Halaven (eribulin) [MB]
- ☐ Herceptin (trastuzumab) [MB]
- ☐ Herceptin Hylecta (trastuzumab-hyaluronidase-oysk) [MB]
- ☐ Herzuma (trastuzumab-pkrb) [MB]
- ☐ Ibrance (palbociclib)
- ☐ Kadcyla (ado-trastuzumab) [MB]
- ☐ Kanjinti (trastuzumab-anns) [MB]
- ☐ Kisqali (ribociclib)
- ☐ Kisqali-Femara Co-Pack (ribociclib/letrozole)
- ☐ Margenza (margetuximab-cmkb) [MB]
- ☐ Nerlynx (neratinib)
- ☐ Ogivri (trastuzumab-dkst) [MB]
- ☐ Ontruzant (trastuzumab-dttb) [MB]
- ☐ Orserdu (elacestrant)
- ☐ Perjeta (pertuzumab) [MB]
- ☐ Phesgo (pertuzumab/trastuzumab/hyaluronidase-zzxf) [MB]
- ☐ Piqray (alpelisib)
- ☐ Trazimera (trastuzumab-qyyp) [MB]
- ☐ Trodelvy (sacituzumab govitecan-hziy) [MB]
- ☐ Truqap (capivasertib)
- ☐ Tukysa (tucatinib)
- ☐ Verzenio (abemaciclib)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Height Weight Date

Please indicate prescriber specialty below.

☐ Oncology ☐ Other

Will the requested agent be used as monotherapy for this indication? ☐ Yes ☐ No

If no, please list all other medications currently prescribed for the member that will be used concomitantly for this indication.

Will the requested agent be used as adjuvant or neoadjuvant therapy for this indication? ☐ Yes ☐ No

If yes, please describe. ☐ Adjuvant ☐ Neoadjuvant

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ **Breast cancer**

☐ Early ☐ Advanced ☐ Metastatic ☐ Recurrent ☐ Unresectable

Other Oncologic Indications

☐ Liposarcoma

☐ Locally advanced or metastatic urothelial cancer

☐ Metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma

☐ Metastatic non-small cell lung cancer (NSCLC) with activating HER2 (ERBB2) mutations

☐ Unresectable or metastatic colorectal cancer

Please describe pertinent mutations if applicable.

☐ ER-positive ☐ ER-negative ☐ HER2-positive ☐ HER2-negative ☐ HER2-low ☐ HR-positive ☐ HR-negative ☐ RAS wild-type ☐ Triple negative ☐ Other

Please describe the stage and severity of disease.

Has the member had persistent or recurring disease following surgery and/or radiation therapy? ☐ Yes ☐ No

Is the member a candidate for surgery and/or radiation?

☐ Yes ☐ No. Please describe.

Section I. Please complete for all requests.

Please list any other prior trials. Please list the drug names, dates/duration of use and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

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** Please attach a letter documenting additional trials as necessary.*

Section II. Please complete for requests for agents with a preferred alternative.

Please describe the clinical rationale for use of the requested agent instead of the preferred alternative.

Section III. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit, including a detailed treatment plan.

Section IV. Please include any other pertinent information (if needed).

Section V. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

over

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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Cerebral Stimulant and ADHD Drugs
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about ADHD medications and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form.**

Medication information

Medication requested (Check all that apply. Where applicable, the brand name is provided in brackets for reference.)

Long-Acting Cerebral Stimulants

- ☐ Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablet)
- ☐ amphetamine extended-release 1.25 mg/mL oral suspension
- ☐ amphetamine salts extended-release [Adderall XR] > 2 units/day
- ☐ amphetamine salts extended-release [Mydayis]
- ☐ Azstarys (serdexmethylphenidate/ dexmethylphenidate)
- ☐ Cotempla XR-ODT (methylphenidate extended-release orally disintegrating tablet)
- ☐ dexmethylphenidate extended-release [Focalin XR] > 2 units/day
- ☐ Dyanavel XR (amphetamine extended-release 2.5 mg/mL oral suspension)
- ☐ Dyanavel XR (amphetamine extended-release chewable tablet)
- ☐ Jornay PM (methylphenidate extended-release)
- ☐ lisdexamfetamine capsule > 2 units/day
- ☐ lisdexamfetamine chewable tablet
- ☐ methylphenidate extended-release [Aptensio XR]
- ☐ methylphenidate extended-release [Concerta] > 2 units/day
- ☐ methylphenidate extended-release 72 mg tablet
- ☐ methylphenidate extended-release, CD
- ☐ methylphenidate long-acting capsule [Ritalin LA]
- ☐ methylphenidate transdermal [Daytrana] > 1 unit/day
- ☐ Quillichew ER (methylphenidate extended-release chewable tablet)
- ☐ Quillivant XR (methylphenidate extended-release oral suspension)
- ☐ Relexxii (methylphenidate extended-release tablet)
- ☐ Xelstrym (dextroamphetamine transdermal)

Intermediate/Short-Acting Cerebral Stimulants

- ☐ amphetamine salts [Adderall] > 3 units/day
- ☐ amphetamine sulfate
- ☐ dexmethylphenidate [Focalin] > 3 units/day
- ☐ dextroamphetamine 5 mg, 10 mg, 15 mg capsule [Dexedrine Spansule] > 3 units/day
- ☐ dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg tablet
- ☐ dextroamphetamine 5 mg, 10 mg tablet > 3 units/day
- ☐ dextroamphetamine solution > 40 mL/day
- ☐ Evekeo ODT (amphetamine sulfate orally disintegrating tablet)
- ☐ methylphenidate [Ritalin] > 3 units/day
- ☐ methylphenidate chewable tablet > 3 units/day
- ☐ methylphenidate oral solution [Methylin oral solution] > 30 mL/day
- ☐ methylphenidate sustained-release tablet > 3 units/day

Non-Stimulant Medications

- ☐ clonidine extended-release 0.1 mg tablet > 4 units/day
- ☐ Qelbree (viloxazine)

Other Medication

- ☐ Other* _____

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/ or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose, frequency, and duration of requested drug _____

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Attention Deficit Hyperactivity Disorder (ADHD) ☐ Narcolepsy ☐ Other

Quantity requested per month **Total quantity of all stimulants combined**

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for cerebral stimulant requests above quantity limits.

1. Has dose consolidation been attempted? ☐ Yes ☐ No. Please explain why not.
2. Is the member under the care of a psychiatrist or behavioral specialist? ☐ Yes ☐ No
3. Please list all medications currently prescribed for this member for this condition.
4. Please describe your new treatment plan for managing this member's condition, including discontinuation of any medications because of the addition of medication requested.

Section II. Please complete for dextroamphetamine 2.5 mg, 7.5 mg, 15 mg, 20 mg, and 30 mg tablet requests.

Please provide medical necessity for requested strength instead of dextroamphetamine 5 mg and 10 mg tablets available without prior authorization.

Section III. Please complete for Azstarys, Cotempla XR-ODT, Jornay PM, methylphenidate extended-release [Aptensio XR] and long-acting capsule [Ritalin LA], methylphenidate extended-release CD, Quillichew ER, and Quillivant XR requests.

1. Please provide clinical rationale for use of the requested agent instead of Concerta (methylphenidate extended-release), or medical necessity for requested formulation instead of solid oral formulations (e.g., member utilizes a feeding tube, has a swallowing disorder or condition affecting ability to swallow, is < 13 years of age).
2. Please provide clinical rationale for use of the requested agent instead of methylphenidate transdermal and Focalin XR (dexmethylphenidate extended-release).

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Section IV. Please complete for Adzenys XR-ODT, amphetamine extended-release 1.25 mg/mL oral suspension, amphetamine salts extended-release [Mydayis], Dyanavel XR chewable tablet and oral suspension, lisdexamfetamine chewable tablet, and Xelstrym requests.

Please provide clinical rationale for use of the requested agent instead of Adderall XR (amphetamine salts extended-release) and lisdexamfetamine capsule.

Section V. Please complete for amphetamine sulfate requests.

Has the member tried an amphetamine immediate-release product that is available without prior authorization to treat this condition?

☐ Yes. Attach documentation of trials, including drug name, dose and frequency, dates of use, and outcomes.

☐ No. Explain why not.

Section VI. Please complete for methylphenidate extended-release 72 mg tablet and Relexxii requests.

Please provide clinical rationale for requested agent instead of Concerta (methylphenidate extended-release) (including use of two tablets to achieve the requested dose when applicable), methylphenidate transdermal, and Focalin XR (dexmethylphenidate extended-release).

Section VII. Please complete for Evekeo ODT requests.

Please provide medical necessity for requested formulation instead of solid oral formulations (e.g., member utilizes a feeding tube, has a swallowing disorder or condition affecting ability to swallow, is < 13 years of age).

Section VIII. Please complete for Qelbree requests.

Has the member tried atomoxetine to treat this condition?

☐ Yes. Please list the dates/duration of use, dose and frequency, and outcome below.

Dates of use Dose and frequency

Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Explain why not.

Section IX. Please also complete for members ≥ 21 years of age (new to therapy).

1. For a diagnosis of ADHD, were symptoms present before 12 years of age according to the DSM-5 diagnostic criteria? ☐ Yes ☐ No ☐ Unknown

   Please provide detail regarding diagnosis if answered no or unknown.

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2. For all other diagnoses, please describe alternative first-line treatment options and non-pharmacologic interventions that have been implemented or trialed prior to cerebral stimulants.

Section X. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name Dose/frequency Indication
2. Medication name Dose/frequency Indication

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3. Medication name _____ Dose/frequency _____ Indication _____
4. Medication name _____ Dose/frequency _____ Indication _____
5. Medication name _____ Dose/frequency _____ Indication _____
6. Medication name _____ Dose/frequency _____ Indication _____
7. Other(s) _____

Is the member currently in an acute care setting?

☐ Yes (Inpatient) ☐ Yes (Community Based Acute treatment)
☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name _____ Contact information _____

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months.

_____ ☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?

☐ Yes. Please provide details. _____ ☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g., weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain. _____

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other _____

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

_____

Name(s) of the specialist(s) _____ Date(s) of last visit or consult _____

Contact information _____

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable. _____

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility

☐ Uncertain ☐ Other _____

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH) ☐ Department of Developmental Services (DDS)

☐ Department of Youth Services (DYS)

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Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

** Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to: https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information*

Section II. Cerebral Stimulant Polypharmacy. Complete this section for all members < 18 years of age, if request will result in prescription of two or more cerebral stimulants for ≥ 60 days within a 90-day period. Please note, immediate-release and extended-release formulations of the same chemical entity are counted as one.

Please document amphetamine and methylphenidate monotherapy trials (include drug name, dates/duration of use, and outcome) and rationale for polypharmacy with two or more cerebral stimulants in this member.*

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

** Attach a letter with additional information regarding medication trials as applicable.*

Section III. Alpha$_2$ Agonist or Cerebral Stimulant Request for Members < three years of age.

Please document any previous medication trial(s). Include the drug name, dates/duration of use, and outcome. For requests for an amphetamine product, include drug name, dates/duration of use, and outcome to a trial with a methylphenidate product.*

Please document clinical rationale for use of an alpha$_2$ agonist or cerebral stimulant for this member < three years of age.

** Attach a letter with additional information regarding medication trials as applicable.*

Section IV. Atomoxetine or Qelbree Request for Members < six years of age.

Please document any previous medication trial(s). Include the drug name, dates/duration of use, and outcome.*

Please document clinical rationale for use of atomoxetine or viloxazine for this member < six years of age.

** Attach a letter with additional information regarding medication trials as applicable.*

over

Section V. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

Please document clinical rationale for use of multiple behavioral health medications for this member < 18 years of age.

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

** Attach a letter with additional information regarding medication trials as applicable.*

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Constipation Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Constipation agent requested

- ☐ Ibsrela (tenapanor 50 mg tablet)
- ☐ lactulose packet
- ☐ lubiprostone
- ☐ Motegrity (prucalopride)
- ☐ Movantik (naloxegol)
- ☐ Relistor (methylnaltrexone)
- ☐ Symproic (naldemedine)
- ☐ Trulance (plecanatide)

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Chronic idiopathic constipation (CIC)
- ☐ Irritable bowel syndrome with constipation (IBS-C)
- ☐ Opioid-induced constipation
- ☐ Other

Section I. Please complete for all requests, excluding lactulose packet. For Ibsrela, Motegrity, Movantik, Relistor, Symproic, and Trulance requests, please also complete Section II below as appropriate.

1. Has the member had a trial with a bulk-forming laxative? ☐ Yes. Drug name ☐ No
2. Has the member had a trial with a saline laxative? ☐ Yes. Drug name ☐ No
3. Has the member had a trial with an osmotic laxative? ☐ Yes. Drug name ☐ No
4. Has the member had a trial with a stimulant laxative? ☐ Yes. Drug name ☐ No
5. For lubiprostone for the treatment of IBS-C or CIC, has the member had a trial with Linzess?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use Outcome
   ☐ No. Please document if there is a contraindication to Linzess therapy.
6. For lubiprostone for the treatment of IBS-C or CIC, has the member had a trial with Trulance?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use Outcome
   ☐ No. Please document if there is a contraindication to Trulance therapy.
7. For lubiprostone, Movantik, Relistor, and Symproic does the member have chronic, non-cancer pain?
   ☐ Yes ☐ No

8. For Relistor, does the member have an advanced illness for which the member is receiving palliative care?
   ☐ Yes. Diagnosis _____ ☐ No
9. For Relistor injection, please provide medical necessity for use of the requested formulation instead of the tablet formulation.
   _____

Section II. Please also complete for Ibsrela, Motegrity, Movantik, Relistor, Symproic, and Trulance requests. Please complete Section I above as appropriate.

1. Has the member had a trial with lubiprostone?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use _____ Outcome _____
   ☐ No. Please document if there is a contraindication to lubiprostone therapy.
   _____
2. Has the member had a trial with Linzess?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use _____ Outcome _____
   ☐ No. Please document if there is a contraindication to Linzess therapy.
   _____
3. For Relistor, has the member had a trial with Movantik?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use _____ Outcome _____
   ☐ No. Please document if there is a contraindication to Movantik therapy.
   _____
4. For Ibsrela and Motegrity, has the member had a trial with Trulance?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use _____ Outcome _____
   ☐ No. Please document if there is a contraindication to Trulance therapy.
   _____
5. For Movantik, has the member had a trial with Symproic?
   ☐ Yes. Please list the dates/duration of use and outcomes below.*
   Dates/duration of use _____ Outcome _____
   ☐ No. Please document if there is a contraindication to Symproic therapy.
   _____

Section III. Please complete for lactulose packet requests.

Please attach medical records documenting an adverse reaction or contraindication to lactulose solution.

** Attach a letter with additional information regarding medication trials as applicable.*

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
   _____
   _____

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2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Cystic Fibrosis Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested (Where applicable, the brand name is provided in brackets for reference.)

- ☐ Bronchitol (mannitol inhalation powder)
- ☐ Kalydeco (ivacaftor)
- ☐ Orkambi (lumacaftor/ivacaftor)
- ☐ Symdeko (tezacaftor/ivacaftor)
- ☐ Tobi Podhaler (tobramycin inhalation powder)
- ☐ tobramycin inhalation solution [Bethkis]
- ☐ Trikafta (elexacaftor/tezacaftor/ivacaftor)

Dose, frequency, and duration of medication requested

Is the member stabilized on the requested medication? ☐ Yes. Please provide start date. ☐ No

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Cystic Fibrosis [Please specify genetic mutation(s) below.]

Does the member have *Pseudomonas aeruginosa*? ☐ Yes ☐ No

☐ Other

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial.

Section I. Please complete for initial requests for Kalydeco, Orkambi, Symdeko, and Trikafta.

1. Please document member's baseline body mass index (BMI). Date
2. For members > 6 years of age, please document member's baseline percent predicted forced expiratory volume in one second (ppFEV1). Date

Section II. Please complete for recertification requests for Kalydeco, Orkambi, Symdeko, and Trikafta.

1. Please document member's current BMI. Date
   Has the member demonstrated an improvement in BMI? ☐ Yes ☐ No
2. For members > 6 years of age, please document member's current ppFEV1.
   Date
   Has the member demonstrated an improvement in lung function? ☐ Yes ☐ No

3. Has the member demonstrated a reduced frequency of clinical exacerbations since initiating the requested medication? ☐ Yes ☐ No

   If yes, please describe.

4. If member has not demonstrated improvement in the ppFEV1, BMI or frequency of clinical exacerbations, please document response to therapy.

Section III. Please complete for Tobi Podhaler and tobramycin inhalation solution (generic Bethkis) requests.

Has the member had a trial with tobramycin inhalation solution?

☐ Yes. Please list the dose and frequency, dates/duration of trials, and outcomes below.

Dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain.

Section IV. Please complete for Bronchitol requests.

1. Documentation that member has passed the Bronchitol Tolerance Test ☐ Yes ☐ No
2. Has the member had a trial with Pulmozyme?

   ☐ Yes. Please list the dose and frequency, dates/duration of trials, and outcomes below.

   Dose and frequency Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

3. Has the member had a trial with sodium chloride for inhalation?

   ☐ Yes. Please list the dose and frequency, dates/duration of trials, and outcomes below.

   Dose and frequency Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

Section V. Please include any other pertinent information (if needed).

Section VI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

over

If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Dermatological Agents (Topical Chemotherapy and Genital Wart Therapy) Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication requested

☐ Ameluz (aminolevulinic acid) [MB]
☐ imiquimod 3.75% cream
☐ Levulan (aminolevulinic acid) [MB]
☐ Veregen (sinecatechins)
☐ Ycanth (cantharidin) [MB]
☐ Zyclara (imiquimod 2.5% cream)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Indication (Check all that apply) or ICD-10 code, if applicable

☐ Actinic keratosis
  ☐ Face ☐ Scalp ☐ Upper extremities
☐ External genital warts
☐ Perianal warts
☐ Molluscum contagiosum
☐ Other
(Attach a letter regarding medical necessity.)

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Is the prescriber a dermatologist?
☐ Yes
☐ No. For Ameluz, Levulan, and Ycanth requests, please attach consultation notes from a dermatologist addressing the use of the requested agent.

Section I. Please complete for treatment of actinic keratosis with imiquimod 3.75% cream, or Zyclara.

1. Has the member had a trial with topical fluorouracil?
   ☐ Yes. Please list the dates/duration of use and outcomes below.
   Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please document if there is a contraindication to topical fluorouracil therapy.
2. If the request is for imiquimod 3.75% cream or Zyclara, has the member tried imiquimod 5% cream?
   ☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please document if there is a contraindication to imiquimod 5% cream.

Section II. Please complete for Ameluz and Levulan requests.

1. Has the member had a trial with topical fluorouracil or topical imiquimod?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes below.

   Drug name

   Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please document if there is a contraindication to topical fluorouracil and topical imiquimod.
2. Has the member tried and failed cryosurgery? ☐ Yes ☐ No
3. Will the requested agent be used in conjunction with photodynamic therapy? ☐ Yes ☐ No
4. If the request is for Ameluz, has the member had a trial with Levulan used in conjunction with photodynamic therapy?
   ☐ Yes. Please list the dates/duration of use and outcomes below.

   Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please document if there is a contraindication to Levulan used in conjunction with photodynamic therapy.

Section III. Please complete for Ycanth requests.

1. Has the member had a trial with topical podofilox?
   ☐ Yes. Please list the dates/duration of use and outcomes below.

   Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please document if there is a contraindication to topical podofilox.
2. Has the member tried and failed cryotherapy? ☐ Yes ☐ No
3. Has the member tried and failed curettage? ☐ Yes ☐ No

Section IV. Please complete for treatment of external genital warts or perianal warts with imiquimod 3.75% cream or Veregen.

1. Has the member had a trial with topical podofilox, or podophyllum resin applied by a provider?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes below.

   Drug name

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Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please document if there is a contraindication to topical podofilox and podophyllum resin.

2. If the request is for imiquimod 3.75% cream, has the member had a trial with imiquimod 5% cream?

Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please document if there is a contraindication to imiquimod 5% cream.

Section V. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Diabetes Medical Supplies
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Product information

Device requested

- ☐ Cequr Simplicity
  - ☐ Cequr Simplicity 2U 3-Day Patch
  - ☐ Cequr Simplicity 2U 4-Day Patch
  - ☐ Cequr Simplicity Inserter
- ☐ Dexcom G6
  - ☐ Receiver
  - ☐ Sensor
  - ☐ Transmitter
- ☐ Dexcom G7
  - ☐ Receiver
  - ☐ Sensor
- ☐ Freestyle Libre 14 Day
  - ☐ Reader
  - ☐ Sensor
- ☐ Freestyle Libre 2
  - ☐ Reader
  - ☐ Sensor
- ☐ Freestyle Libre 3
  - ☐ Reader
  - ☐ Sensor
- ☐ Omnipod 5
  - ☐ Omnipod 5 Pod Pack
  - ☐ Omnipod 5 Intro Kit
- ☐ Omnipod Classic
  - ☐ Omnipod Classic Personal Diabetes Manager
  - ☐ Omnipod Classic Pod Pack
- ☐ Omnipod Dash
  - ☐ Omnipod Dash Intro Kit
  - ☐ Omnipod Dash Personal Diabetes Manager
  - ☐ Omnipod Dash Pod Pack
- ☐ V-Go

Non-drug product requested **Qty/30 days**

- ☐ Blood glucose testing strips > 100 units/30 days
  - ☐ Freestyle _____
  - ☐ Freestyle Insulinx _____
  - ☐ Freestyle Lite _____
  - ☐ Precision Xtra _____
- ☐ Non-preferred blood glucose testing strips (Please specify brand, e.g. Freestyle Neo, etc.)

Dose, frequency, and duration of medication or medical supplies requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Type 1 Diabetes Mellitus ☐ Type 2 Diabetes Mellitus ☐ Other

What is the member's most recent hemoglobin A1C? Date

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial.

Section I. Please complete for Dexcom G6, Dexcom G7, Freestyle Libre 14 Day, Freestyle Libre 2, and Freestyle Libre 3 requests.

1. Is the member stabilized on the requested device? ☐ Yes. Please provide start date. _____ ☐ No
2. Is the member currently receiving treatment with insulin administration or an insulin pump? ☐ Yes ☐ No

   Please explain. _____

3. Does the member exhibit any of the following clinical characteristics? (Check all that apply.)

   ☐ Yes
   - ☐ An A1c ≥7%, or does not meet documented target treatment goal
   - ☐ Frequent hypoglycemia or nocturnal hypoglycemia
   - ☐ History of hypoglycemia unawareness
   - ☐ Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
   - ☐ History of emergency room visit or hospitalization related to ketoacidosis or hypoglycemia
   - ☐ Use of a compatible insulin pump to achieve glycemic control
   - ☐ Pregnancy

   ☐ No. Please explain why the member is a candidate for continuous blood glucose monitoring.

   _____

Section II. Please complete for Cequr Simplicity, Omnipod 5, Omnipod Classic, Omnipod Dash, Omnipod Go, and V-Go requests.

1. Is the member stabilized on the requested device? ☐ Yes. Please provide start date. _____ ☐ No
2. Is the member currently testing blood glucose at least four times per day or using continuous glucose monitoring? ☐ Yes ☐ No
3. Is the member currently receiving treatment with insulin administration at least three times per day or an insulin pump? ☐ Yes ☐ No
4. Does the member have an A1c >7%, or does not meet documented target treatment? ☐ Yes ☐ No
5. Does the member exhibit any of the following clinical characteristics? (Check all that apply.)

   ☐ Yes
   - ☐ Frequent hypoglycemia
   - ☐ Fluctuations of more than 100 mg/dL in blood glucose before mealtime
   - ☐ Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
   - ☐ History of severe glycemic excursions

   ☐ No. Please explain why the member is a candidate for continuous subcutaneous insulin infusion.

   _____

Section III. Please complete for Cequr Simplicity, Dexcom G6, Dexcom G7, Freestyle Libre 14 Day, Freestyle Libre 2, Freestyle Libre 3, Omnipod 5, Omnipod Classic, Omnipod Dash, Omnipod Go, and V-Go recertification requests.

For Cequr Simplicity, Omnipod 5, Omnipod Classic, Omnipod Dash, Omnipod Go, and V-Go, only question 1 is required.

1. Has the member demonstrated improvement in diabetic control or relative stability?

   ☐ Yes

   ☐ No. Please describe why not. _____

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2. Has the member's continuous blood glucose monitoring data been reviewed and used to monitor or adjust the antidiabetic treatment plan?
   ☐ Yes
   ☐ No. Please describe why not.

Section IV. Please complete for Freestyle Neo requests.

Will the member be using a compatible continuous glucose monitoring device (i.e., Freestyle Libre 2, Freestyle Libre 3, Freestyle Libre 14 Day)?

☐ Yes

☐ No. Please provide medical necessity for use of Freestyle Neo.

Section V. Please complete for all requests exceeding the quantity limit.

1. Is the member currently receiving treatment with insulin administration or an insulin pump?
   ☐ Yes. Please provide units/day.
   ☐ No
2. Does the member exhibit any of the following clinical characteristics? (Check all that apply.)
   ☐ Yes
   - ☐ Injection site irritation. Were mitigation strategies attempted? ☐ Yes ☐ No
   - ☐ Adhesion failure. Were mitigation strategies attempted? ☐ Yes ☐ No
   - ☐ Lipoatrophy or lipohypertrophy at the injection site
   - ☐ Pooling of insulin at the injection site

   ☐ No. Please provide medical necessity for the requested quantity.

Section VI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No

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If yes, please provide details for the previous trial.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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Erythropoiesis-Stimulating Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Drug name requested

Dose, frequency, and duration

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Section I. Please complete for all requests.

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ **Anemia due to chronic renal failure**

Is the member receiving hemodialysis? ☐ Yes ☐ No (Please note, if the member is receiving hemodialysis, contact the dialysis clinic for proper billing procedure.)

Current hemoglobin Date

Glomerular Filtration Rate (GFR)

☐ **Anemia due to chemotherapy treatment for cancer**

Current hemoglobin Date

☐ **Anemia due to a myelosuppressive medication regimen for HIV**

Is member currently on zidovudine or zidovudine-containing products? ☐ Yes ☐ No

If yes, please provide current medication regimen.

Have other causes of anemia been ruled out (hemolysis, iron, vitamin B12, and folate deficiency)?
☐ Yes ☐ No. If no, please provide medical necessity for the use of requested agent.

Current hemoglobin Date

☐ **Decrease need for blood transfusions due to surgery**

Type of procedure Date of procedure

Please provide medical necessity for the use of requested agent.

☐ **Other**

Please provide medical necessity for the use of erythropoietin (including diagnosis with etiology, current hemoglobin, other disease states, etc.).

Section II. Please also complete for recertification requests.

1. Is the member's hemoglobin currently > 12 g/dL?
   ☐ Yes. Please answer both questions below.
   Please provide the treatment plan to hold or reduce the erythropoietin dose.

   Date last erythropoietin dose was administered
   ☐ No
2. For members with anemia due to chemotherapy or myelosuppressive medication, please provide the most recent date of use for the causative agent.
   Medication(s) Date

Section III. Please complete for Procrit requests.

Please provide clinical rationale for use of the requested agent instead of Epogen and Retacrit.

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.
☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Gastrointestinal Agents — Antidiarrheals and Bowel Preparation Agents Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Antidiarrheals (See Sections I and II as applicable.)

☐ alosetron ☐ Motofen (difenoxin/atropine) ☐ Mytesi (crofelemer)
☐ opium tincture ☐ Viberzi (eluxadoline

Bowel Preparation Agents (See Section III.)

☐ Clenpiq (sodium picosulfate/magnesium oxide/anhydrous citric acid)
☐ Suflave (polyethylene glycol 3350/sodium sulfate/potassium chloride/magnesium sulfate/and sodium chloride)
☐ Sutab (sodium sulfate/magnesium sulfate/potassium chloride)

Dose and frequency of medication requested

Section I. Please complete for all Antidiarrheal Agent requests.

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Chronic diarrhea ☐ Irritable bowel syndrome with diarrhea ☐ Diarrhea in an HIV/AIDS member
☐ Other

Previous Trials (Check all that apply.)

Antidiarrheals

☐ bismuth subsalicylate
☐ diphenoxylate/atropine
☐ loperamide

☐ Bile acid sequestrant
☐ Selective serotonin reuptake inhibitor
☐ Tricyclic antidepressant
☐ Other (please specify)

Other

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

If the member has a contraindication to these trials please describe.

Section II. Please also complete for alosetron and Viberzi requests.

Is the prescriber a gastroenterologist? ☐ Yes ☐ No. Please attach consultation notes from a gastroenterologist addressing the use of the requested agent.

Please provide details for the previous trials.

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response. _____

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response. _____

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response. _____

Section III. Please complete for Bowel Preparation Agent requests.

Has the member had a trial with one bowel prep product that is available without prior authorization?

☐ Yes. Please provide details for the previous trial.

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response. _____

☐ No. Please explain why. _____

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

   _____

   _____

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

   _____

   _____

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name _____ Dates/duration of use _____

over

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.
☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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General Drug
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Please note: the requested drug may have a specific form that contains information pertinent to this PA request. Please see more drug-specific PA forms within the MassHealth Drug List at **www.mass.gov/druglist.**

In addition, the **Pediatric Behavioral Health Medication Initiative** requires PA for pediatric members (generally members < 18 years of age) for certain behavioral health medication classes and/or specific medication combinations (i.e., polypharmacy) that have limited evidence for safety and efficacy in the pediatric population.

Additional information about medications and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form.**

Medication information

Medication requested

Dose, frequency, and duration of medication requested

Height Weight Date

Drug NDC (if known) or service code

Indication or ICD-10 code, if applicable

Section I. Please complete the following for all requests.

1. Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
2. Has member tried other medications to treat this condition?
   ☐ Yes. Provide the information below. You may be asked to provide supporting documentation (e.g., copies of medical records, office notes, and/or completed FDA MedWatch form).

   Drug name Dates of use

   Dose and frequency

   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   Drug name Dates of use

   Dose and frequency

   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Explain why not (attach a letter describing medical necessity as applicable).

Section II. Please complete the following as applicable for all requests.

Explain medical necessity of requested drug.

List all current medications.

Diagnostic studies and/or laboratory tests performed (include dates and results).

Please include any other pertinent information (if needed).

Section III. Please complete for all requests for non-preferred drug products if one or more preferred drug products have been designated for this class of drugs.

If one or more preferred drug products have been designated for this class of drugs, and if you are requesting PA for a non-preferred drug product, please provide medical necessity for prescribing the non-preferred drug product rather than the preferred drug product.

Section IV. Please complete for all requests for pharmaceutical compounds.

1. Please list all submitted ingredients of the pharmaceutical compound requested.

Ingredient

Ingredient

Ingredient

Ingredient

Ingredient

over

Other(s)

Please attach a letter documenting additional ingredients as applicable.

2. For topical route of administration, please describe medical necessity for use of the requested product for the requested route of administration.
3. Is the requested compounded product commercially available? ☐ Yes ☐ No
4. Have commercial products been discontinued by the pharmaceutical manufacturer for reasons other than lack of safety or effectiveness? ☐ Yes ☐ No
5. Does the member have a medical need for a dosage form or dosage strength that is not commercially available?

   ☐ Yes. Please describe.

   ☐ No
6. Please describe the medical necessity for the included inactive ingredients.

Section V. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details.

   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Glaucoma Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Betimol (timolol)
- ☐ bimatoprost 0.03% ophthalmic solution
- ☐ brimonidine/timolol, ophthalmic
- ☐ dorzolamide/timolol preservative free
- ☐ Durysta (bimatoprost implant) [MB]
- ☐ Iyuzeh (latanoprost solution)
- ☐ Rhopressa (netarsudil)
- ☐ Rocklatan (netarsudil/latanoprost)
- ☐ tafluprost
- ☐ timolol ophthalmic gel forming solution
- ☐ timolol ophthalmic unit dose solution
- ☐ Vyzulta (latanoprostene)
- ☐ Xelpros (latanoprost emulsion)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Open-angle glaucoma ☐ Ocular hypertension ☐ Other

Dose, frequency, and duration of medication requested

Drug NDC (if known) or service code

Section I. Please complete for Betimol, timolol ophthalmic gel forming solution and timolol ophthalmic unit dose solution requests.

Has the member had a trial with an ophthalmic timolol formulation that is available without PA?

☐ Yes ☐ No. Please provide clinical rationale for not using an ophthalmic timolol formulation that is available without PA.

Section II. Please complete for bimatoprost 0.03% requests.

Has the member had a trial with latanoprost solution or travoprost 0.004% eye drop?

☐ Yes. Please list the drug name, dates/duration of use, and outcomes below.

Drug name Dates/duration

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please provide clinical rationale for not using latanoprost solution and travoprost 0.004% eye drops.

Section III. Please complete for Durysta requests.

1. Has the member had a trial with Lumigan?
   ☐ Yes. Please list the dates/duration of use and outcomes below.

   Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe medical necessity for an implantable formulation instead of eye drops.
2. Please specify affected eye. ☐ Left eye ☐ Right eye
3. Is the request for retreatment of the same eye? ☐ Yes ☐ No

Section IV. Please complete for dorzolamide/timolol preservative free and Xelpros requests.

Has the member experienced sensitivity to benzalkonium chloride or any other preservatives used in ophthalmic preparations?

☐ Yes ☐ No. Please provide clinical rationale for the use of the requested formulation instead of the respective formulation that is available without PA.

Section V. Please complete for brimonidine/timolol, ophthalmic requests.

Has the member had a trial with dorzolamide/timolol?

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please provide clinical rationale for not using dorzolamide/timolol.

Section VI. Please complete for Rhopressa and Rocklatan requests.

1. Has the member had a trial of combination therapy with a prostaglandin analog and an ophthalmic beta-blocker?
   ☐ Yes. Please list the drug names, dates/duration of use and outcomes below.*
   ☐ No. Please provide clinical rationale for not using combination therapy with a prostaglandin analog and an ophthalmic beta-blocker.
2. Does the member have a contraindication to ophthalmic beta-blockers?
   ☐ Yes. Please describe. ☐ No

   If yes, has the member had a trial of combination therapy with a prostaglandin analog and either an ophthalmic alpha-2 adrenergic agonist, parasympathomimetic, or carbonic anhydrase inhibitor?

over

☐ Yes. Please list the drug names, dates/duration of use and outcomes below.* ☐ No

3. For Rhopressa, does the member have a contraindication to prostaglandin analogs?

☐ Yes. Please describe. ☐ No

If yes, has the member had a trial of combination therapy with an ophthalmic beta-blocker and either an ophthalmic alpha-2 adrenergic agonist, parasympathomimetic, or carbonic anhydrase inhibitor?

☐ Yes. Please list the drug names, dates/duration of use and outcomes below.* ☐ No

Please provide details for the previous trials.

Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

**Please attach a letter documenting additional trials as necessary.*

Section VII. Please complete for Vyzulta requests.

Has the member had an inadequate response to a trial of combination therapy with latanoprost solution and an ophthalmic beta-blocker? ☐ Yes ☐ No.

If no, has the member had a trial with latanoprost solution?

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration Outcome

If no, has the member had an adverse reaction to an ophthalmic beta-blocker?

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration Outcome

☐ No. Please provide clinical rationale for not using ophthalmic beta-blocker.

Section VIII. Please complete for Iyuzeh and tafluprost requests.

1. Has the member had a trial with latanoprost solution available without PA?

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please provide clinical rationale for not using latanoprost solution available without PA.

2. Has the member had a trial with Xelpros?

☐ Yes. Please list the dates/duration of use and outcomes below.

Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please provide clinical rationale for not using Xelpros.

over

Section IX. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

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Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Gonadotropin-Releasing Hormone Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Camcevi (leuprolide)
- ☐ Eligard (leuprolide)
- ☐ Fensolvi (leuprolide) [MB]
- ☐ Firmagon (degarelix)
- ☐ leuprolide 22.5 mg vial
- ☐ Lupron (leuprolide)
- ☐ Myfembree (relugolix/estradiol/norethindrone)
- ☐ Orgovyx (relugolix)
- ☐ Oriahnn (elagolix/estradiol/norethindrone)
- ☐ Orilissa (elagolix)
- ☐ Supprelin LA (histrelin) [MB]
- ☐ Synarel (nafarelin)
- ☐ Trelstar (triptorelin) [MB]
- ☐ Triptodur (triptorelin)

[MB] This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Advanced breast cancer
- ☐ Advanced prostate cancer
- ☐ Endometrial thinning prior to ablation for abnormal uterine bleeding
- ☐ Endometriosis
- ☐ Gender Dysphoria
- ☐ Idiopathic or neurogenic central precocious puberty (CPP)
- ☐ Uterine leiomyomata (fibroids)
- ☐ Other

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Section I. Please complete for requests for idiopathic or neurogenic CPP.

1. Provide age of secondary sex characteristics onset.
2. Is the member under the care of a pediatric endocrinologist?
   ☐ Yes. Name of member's pediatric endocrinologist Date of last visit
   ☐ No. Please attach medical records of a consultation with a pediatric endocrinologist.
3. For members ≥11 years of age and < 12 years of age (female sex assigned at birth/biologic females) or ≥12 years of age and <13 years of age (male sex assigned at birth/biologic males), does the member require one additional year of prolonged therapy due to developmental delay? ☐ Yes. ☐ No.

4. For Fensolvi and Triptodur, has the member tried Lupron Ped and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) _____ Outcome(s) _____
   ☐ No. Please explain. _____

Section II. Please complete for requests for endometriosis.

1. Has the member tried non-steroidal anti-inflammatory drugs (NSAIDs) and experienced an adverse reaction or inadequate response?
   ☐ Yes. Provide drug names, dates, and outcomes for trials below.
   Drug name(s) _____ Date(s) _____ Outcome(s) _____
   ☐ No. Please explain if there is a contraindication to this trial. _____
2. Has the member tried hormonal contraceptives and experienced an adverse reaction or inadequate response?
   ☐ Yes. Provide drug names, dates, and outcomes for trials below.
   Drug name(s) _____ Date(s) _____ Outcome(s) _____
   ☐ No. Please explain if there is a contraindication to this trial. _____
3. For Myfembree and Orilissa, has the member tried Lupron and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) _____ Outcome(s) _____
   ☐ No. Please explain if there is a contraindication to this trial. _____

Section III. Please complete for requests for endometrial thinning prior to ablation for abnormal uterine bleeding and uterine leiomyomata (fibroids).

1. Is surgery planned?
   ☐ Yes. Please provide anticipated date of surgery. _____
   ☐ No. Please explain. _____
2. Has the member tried hormonal contraceptives and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) _____ Outcome(s) _____
   ☐ No. Please explain. _____
3. For Myfembree and Oriahhn, has the member tried Lupron and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) _____ Outcome(s) _____
   ☐ No. Please explain. _____
4. For Myfembree, has the member tried Oriahhn and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) _____ Outcome(s) _____

over

☐ No. Please explain.

Section IV. Please complete for requests for advanced prostate cancer.

1. Please indicate prescriber specialty. ☐ Oncology ☐ Urology ☐ Other
2. For Lupron Depot 7.5 mg, Lupron Depot 22.5 mg, Lupron Depot 30 mg or Lupron Depot 45 mg, please describe clinical rationale for use instead of the equivalent dose of Eligard.
3. For Orgovyx, has the member tried Eligard, leuprolide 22.5 mg vial, or Lupron Depot and experienced an adverse reaction or inadequate response?
   ☐ Yes. Provide drug names, dates, and outcomes for trials below.
   Drug name(s) Date(s) Outcome(s)
   ☐ No. Please explain.
4. For Orgovyx, has the member tried Firmagon and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please provide date and outcome for trial.
   Date(s) Outcome(s)
   ☐ No. Please explain.

Section V. Please complete for requests for gender dysphoria.

For Lupron 7.5 mg, 22.5 mg, 30 mg, and 45 mg adult kit, please describe clinical rationale for use instead of the equivalent dose of Eligard.

Section VI. Please complete for all other diagnoses, excluding advanced breast cancer.

Please describe the medical necessity for the use of gonadotropin-releasing hormone, including previous trials and outcomes, and dates of any relevant lab tests (including but not limited to bone mineral density).

Section VII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

over

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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Gout Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

- ☐ allopurinol 200 mg tablet
- ☐ colchicine capsule
- ☐ febuxostat
- ☐ Gloperba (colchicine solution)
- ☐ Krystexxa (pegloticase) [MB]

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose and frequency of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Prophylaxis of gout
- ☐ Treatment of gout
- ☐ Other
  (Attach a letter regarding medical necessity.)

Please provide any serum urate level results and date obtained.

1. Lab value Date obtained
2. Lab value Date obtained
3. Lab value Date obtained
4. Lab value Date obtained

Please provide creatinine clearance level result and date obtained. Date obtained

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Section I. Please complete for prophylactic use of colchicine capsule or Gloperba (colchicine solution) for gout with urate lowering therapy.*

1. Will the member be taking the requested medication concurrently with a new start of allopurinol, febuxostat, or probenecid?
   - ☐ Yes. Please document drug name with dose and frequency and dates of use.
     Drug Dose and Frequency Dates/Duration
   - ☐ No. Please describe clinical rationale why concurrent therapy is not appropriate for this member.

2. What is the expected duration of therapy? **Please note:** requests for > six months will require additional clinical rationale for need of further treatment.

3. Does the member have tophaceous gout? ☐ Yes ☐ No
4. For Gloperba, is there a medical necessity for the use of a solution formulation?

   ☐ Yes. Please explain.
   ☐ No
5. For colchicine capsule, please provide clinical rationale for the use instead of colchicine tablet.

Section II. Please complete for prophylactic use of colchicine capsule or Gloperba (colchicine solution) for gout without urate lowering therapy.*

1. Has the member tried allopurinol and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document dose and frequency, dates of use, and outcome.

   Dose and Frequency Dates/Duration Outcome
   ☐ No. Please document if there is a contraindication to allopurinol therapy.
2. Has the member tried febuxostat and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document dose and frequency, dates of use, and outcome.

   Dose and Frequency Dates/Duration Outcome

   ☐ No. Please document if there is a contraindication to febuxostat therapy.
3. For Gloperba, is there a medical necessity for the use of a solution formulation?

   ☐ Yes. Please explain.
   ☐ No
4. For colchicine capsule, please provide clinical rationale for the use instead of colchicine tablet.

Section III. Please complete for treatment of gout with Krystexxa (pegloticase).*

1. Has the member tried allopurinol and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document dose and frequency, dates of use, and outcome.

   Dose and Frequency Dates/Duration Outcome
   ☐ No. Please document if there is a contraindication to allopurinol therapy.
2. Has the member tried febuxostat and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document dose and frequency, dates of use, and outcome.

   Dose and Frequency Dates/Duration Outcome
   ☐ No. Please document if there is a contraindication to febuxostat therapy.

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3. Has the member tried a uricosuric agent in combination with allopurinol or febuxostat and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document drug names with dose and frequency, dates of use, and outcome.
   Drug Dose and Frequency
   Dates/Duration Outcome
   Drug Dose and Frequency
   Dates/Duration Outcome
   ☐ No. Please document if there is a contraindication to uricosuric agent therapy.

Section IV. Please complete for treatment of gout with febuxostat.*

1. Has the member tried allopurinol and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please document dose and frequency, dates of use, and outcome.
   Dose and Frequency Dates/Duration Outcome
   ☐ No. Please document if there is a contraindication to allopurinol therapy.
2. For requests exceeding quantity limits, please provide medical necessity for dosing.

Section V. Please complete for treatment of gout with allopurinol 200 mg tablet.*

1. Please attach medical records documenting an inadequate response or adverse reaction to allopurinol two-100 mg tablets.
2. Please describe the medical necessity for use of allopurinol 200 mg tablet instead of two 100 mg tablets.

**Please attach a letter documenting additional trials as necessary.*

Section VI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

over

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details. _____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Growth Hormone and Increlex
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested (check one)

- ☐ Genotropin
- ☐ Genotropin Miniquick
- ☐ Humatrope
- ☐ Increlex
- ☐ Ngenla
- ☐ Norditropin Flexpro
- ☐ Nutropin AQ Nuspin
- ☐ Omnitrope
- ☐ Saizen
- ☐ Saizen Click.easy
- ☐ Serostim
- ☐ Skytrofa
- ☐ Sogroya
- ☐ Zomacton

Dose and frequency of medication requested

Duration of therapy

Cartridge/vial strength

Indication for Growth Hormone agent (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Growth hormone deficiency (Section I or III)
- ☐ Growth deficiency due to chronic renal failure (Section I & II)
- ☐ Hypoglycemia due to growth hormone deficiency (Section I)
- ☐ Human Immunodeficiency Virus-related wasting (Section IV)
- ☐ Noonan syndrome (provide documentation of genetic testing) (Section I)
- ☐ Prader Willi syndrome (provide documentation of genetic testing) (Section I)
- ☐ Small for gestational age with failed catch-up growth between age two to four (Section I)
- ☐ Turner syndrome (provide documentation of genetic testing) (Section I)
- ☐ Other (Section VI or any section that may apply)

Indication for Increlex (Check all that apply.)

- ☐ Growth failure with severe primary IGF-1 deficiency
- ☐ Growth hormone gene deletion with neutralizing antibodies to growth hormone
- ☐ Other (Section VI or any section that may apply)

Section I. Please complete for growth hormone for pediatric indications and attach supporting documentation (e.g., copies of medical records, office notes, growth charts, diagnostic studies, laboratory tests).

Pre-treatment height ____ cm ____ percentile ____ SD below mean. Please attach most recent growth chart.

Current height ____ Current weight ____ Date ____ Growth velocity in past year ____ cm

Please provide information regarding diagnostic tests and assessments including type of growth hormone stimulation test performed, date, and results.

Stimulation Test ____ Peak Result ____ Date ____

Stimulation Test ____ Peak Result ____ Date ____

IGF-1 level ____ Reference Range ____ Date ____

IGFBP-3 level ____ Reference Range ____ Date ____

1. Is the member under the care of a Pediatric Endocrinologist? ☐ Yes ☐ No
   If no, have other causes of short stature (hypothyroidism, malnutrition, chronic illness, skeletal disorders, pituitary tumor) been excluded? ☐ Yes ☐ No
2. Does the member have open epiphyses? ☐ Yes (Please attach most recent bone age, if available.) ☐ No
   (Please attach clinical rationale for continued treatment and/or refer to Section III.)
3. Has pituitary imaging revealed abnormalities?
   ☐ Yes Please attach medical records documenting abnormality. ☐ No
4. Does the member have hypoglycemia-symptoms and low glucose level?
   ☐ Yes. Please provide glucose level ____ Date ____ ☐ No

Section II. Please complete for growth hormone requests for the diagnosis of pediatric-growth deficiency due to chronic renal failure.

1. Have other etiologies for chronic renal failure been excluded including: acidosis, secondary hyperparathyroidism, malnutrition, or zinc deficiency? ☐ Yes ☐ No
2. Is the member under the care of a renal specialist? ☐ Yes ☐ No

Section III. Please complete for growth hormone requests for growth hormone deficiency in adult members.

Please provide information regarding diagnostic tests and assessments including type of growth hormone stimulation test performed, date, and results.

Stimulation Test ____ Peak Result ____ Date ____

Stimulation Test ____ Peak Result ____ Date ____

IGF-1 level ____ Reference Range ____ Date ____

IGFBP-3 level ____ Reference Range ____ Date ____

1. Has pituitary imaging revealed abnormalities?
   ☐ Yes (Please attach medical records documenting abnormality.) ☐ No
2. Has the member experienced a symptom consistent with growth hormone deficiency? ☐ Yes ☐ No
   If yes, please describe. ____

Section IV. Please complete for growth hormone requests for HIV-related wasting.

Current height ____ Current weight ____ Date ____ Premorbid weight ____ Date ____

1. Is decreased caloric intake the etiology of the cachexia or wasting? ☐ Yes ☐ No

If yes, has member attempted therapy with dronabinol or megestrol acetate? If so, provide dates and duration. If not, please explain why.

____

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2. Have other causes of weight loss been excluded including: gastrointestinal tract opportunistic infections, decrease in food intake due to oral, pharyngeal, esophageal lesions or candidiasis, gonadal dysfunction, adverse effects due to medications, or psychosocial factors. ☐ Yes ☐ No
3. Is the member under the care of an Infectious Disease specialist? ☐ Yes ☐ No
4. Is the member receiving concurrent antiretroviral therapy? ☐ Yes ☐ No

Section V. Please complete for Increlex requests.

Height cm

Date

SD below mean for age

IGF-1 level

Reference Range

Date

Peak growth hormone level

Provocative Agent

Date

1. Is the member under the care of a Pediatric Endocrinologist or other specialist trained to diagnose and treat growth disorders?
   ☐ Yes. Please specify.
   ☐ No. Please indicate why not.
2. Does the member have open epiphyses?
   ☐ Yes. Please attach most recent bone age, if available.
   ☐ No. Please indicate clinical rationale for continued treatment.
3. Have other secondary forms of IGF-1 deficiency such as growth hormone deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids been ruled out?
   ☐ Yes.
   ☐ No. Please indicate clinical rationale for Increlex (mecasermin) in the presence of any of these conditions.

Section VI. Please complete for requests for any indication not listed above.

Please describe the medical necessity for the use of growth hormone or Increlex in this member including trials and outcomes of any alternative treatments (if appropriate).

Section VII. Please complete for Humatrope, Norditropin Flexpro, Nutropin AQ Nuspin, Omnitrope, Saizen, Saizen Click.easy, Serostim, Skytrofa, Sogroya, and Zomacton requests.

Please provide clinical rationale for use of the requested agent instead of Genotropin.

Section VIII. Please complete for Sogroya or Ngenla requests.

Please provide clinical rationale for use of the requested agent instead of Skytrofa.

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Section IX. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Headache Therapy (Butalbital Combination Agents) Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ butalbital/acetaminophen (50 mg/300 mg)
- ☐ butalbital/acetaminophen (50 mg/325 mg)
- ☐ butalbital/acetaminophen/caffeine (50 mg/ 300 mg/40 mg)
- ☐ butalbital/acetaminophen/caffeine capsule (50 mg/325 mg/40 mg)
- ☐ butalbital/acetaminophen/caffeine tablet (50 mg/325 mg/40 mg) > 20 units/30 days, < 18 years of age
- ☐ butalbital/acetaminophen/caffeine/codeine (50 mg/300 mg/40 mg/30 mg)
- ☐ butalbital/acetaminophen/caffeine/codeine (50 mg/325 mg/40 mg/30 mg) > 20 units/30 days, < 18 years of age
- ☐ butalbital/aspirin/caffeine capsule (50 mg/325 mg/40 mg) > 20 units/30 days, < 18 years of age
- ☐ butalbital/aspirin/caffeine/codeine (50 mg/325 mg/40 mg/30 mg)
- ☐ Other butalbital agent

Quantity requested per month

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Cluster headache. Frequency of headaches (number/month)
- ☐ Migraine headache. Frequency of migraine attacks (number/month)
- ☐ Tension headache. Frequency of headaches (number/month)
- ☐ Other. Specify pertinent medical history, diagnostic studies, and/or laboratory tests.

Section I. Please complete for requests for butalbital agents that require PA for members < 18 years of age or with a diagnosis of migraine headache, or for requests exceeding quantity limits.

1. For migraine headache requests, has the member tried two triptans?
   - ☐ Yes. Please list the drug names and outcomes below.

     Drug name ☐ Adverse reaction ☐ Inadequate response

     Briefly describe the details of adverse reaction or inadequate response.

Drug name ☐ Adverse reaction ☐ Inadequate response

Briefly describe the details of adverse reaction or inadequate response.

☐ No. Explain why triptans are not appropriate in this member.

2. For migraine headache requests, has the member tried an oral calcitonin gene-related peptide (CGRP) inhibitor?

☐ Yes. Please list the drug name and outcome below.

Drug name ☐ Adverse reaction ☐ Inadequate response

Briefly describe the details of adverse reaction or inadequate response.

☐ No. Explain why oral CGRP inhibitors are not appropriate in this member.

3. For both migraine and tension headache requests in members exceeding quantity limits or < 18 years of age, is the member currently receiving prophylaxis?

☐ Yes. Please specify.

Drug name Dose and frequency

Drug name Dose and frequency

☐ No. Explain why prophylaxis is not appropriate in this member.

4. Is the member under the care of a neurologist? ☐ Yes ☐ No
5. Please list any other prior headache therapy trials. Please list the drug names and outcomes below.

Drug name ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

over

Section II. Please also complete for requests for butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg capsule.

Has the member tried butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg tablet?

☐ Yes. Please list the dates/duration of use and outcome below.

Dates/duration of use ☐ Adverse reaction ☐ Inadequate response ☐ Other Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Explain why butalbital 50 mg/acetaminophen 325 mg/caffeine 40 mg tablet is not appropriate in this member.

Section III. Please also complete for requests for all other butalbital agents that require PA for the diagnosis of tension-type headache and requests for codeine-containing products for members < 12 years of age.

Please provide clinical rationale for the requested agent. Please address the need for the requested agent instead of formulations available without PA, requested dosage formulation instead of conventional dosage forms, or use in the requested age group as appropriate.

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.

over

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details.

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

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Printed name of prescribing provider Date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Headache Therapy (Calcitonin Gene-Related Peptide [CGRP] Inhibitors) Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Aimovig (erenumab-aooe)
- ☐ Ajovy (fremanezumab-vfrm)
- ☐ Emgality (galcanezumab-gnlm)
- ☐ Nurtec (rimegepant)
- ☐ Qulipta (atogepant)
- ☐ Ubrelvy (ubrogepant)
- ☐ Vyepti (eptinezumab-jjmr)[MB]
- ☐ Zavzpret (zavegepant)

Dose, frequency, and duration of medication requested

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Cluster headache
- ☐ Migraine headache
  - ☐ Prophylaxis. Frequency of migraine attacks (days/month)
  - ☐ Acute treatment. Frequency of migraine attacks (number/month)
- ☐ Other

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Section I. Please complete for Aimovig, Ajovy, Emgality, Nurtec, Qulipta, and Vyepti requests for migraine prophylaxis.

1. For all requests except Nurtec, has the member had a trial with a beta-blocker (atenolol, metoprolol, nadolol, propranolol, timolol)?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not.

2. For Aimovig, Ajovy, and Emgality requests, please document a trial of topiramate, a tricyclic antidepressant, valproic acid, or venlafaxine. For Qulipta and Vyepti requests, please document a trial of Botox, topiramate, a tricyclic antidepressant, valproic acid, or venlafaxine. Alternatively, provide clinical rationale for use of Aimovig, Ajovy, Emgality, Qulipta, or Vyepti instead of these agents.
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain why not.
3. For Aimovig requests, has the member had a trial with Ajovy or Emgality?
   ☐ Yes. Please list the dates/duration of use and outcomes below. *

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain why not.
4. For Nurtec, Qulipta, and Vyepti requests, please document a trial of Aimovig, Ajovy, or Emgality. Alternatively, provide clinical rationale for use of Nurtec, Qulipta, or Vyepti instead of these agents.
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain why not.

Section II. Please complete for Nurtec and Ubrelvy requests for acute treatment of migraine.

1. Has the member had a trial with two triptans?
   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.*

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain why not.

over

For requests for quantities above 16 units/30 days for Nurtec and Ubrelvy, is the member currently receiving prophylaxis?

☐ Yes. Please specify.

Drug name Dose and frequency

Drug name Dose and frequency

☐ No. Please explain why prophylaxis is not appropriate for this member.

**Attach a letter with additional information regarding medication trials as applicable.*

Section III. Please complete for recertification requests for Emgality for cluster headache.

1. Is the member still actively having a cluster headache? ☐ Yes. ☐ No.
2. Has the member been initiated on prophylactic therapy for the cluster headache?

   ☐ Yes. Please specify.

   Drug name Dose and frequency

   Drug name Dose and frequency

   ☐ No. Please explain why prophylaxis is not appropriate for this member.

Section IV. Please complete for Zavzpret requests for acute treatment of migraine.

1. Has the member had a trial with two triptan nasal sprays?

   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes below.*

   Drug name Dose and frequency

   Drug name Dose and frequency

   ☐ No. Please explain why triptan nasal sprays are not appropriate for this member.

2. Please describe medical necessity for the use of the requested dosage formulation.

Section V. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

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3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details. _____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
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over

Headache Therapy (Ergot Alkaloids and Serotonin Receptor Agents) Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Ergot Alkaloids

- ☐ dihydroergotamine injection
- ☐ dihydroergotamine nasal spray
- ☐ ergotamine/caffeine suppository

Serotonin Receptor Agents

- ☐ almotriptan
- ☐ eletriptan
- ☐ frovatriptan
- ☐ naratriptan > quantity limits
- ☐ Reyvow (lasmiditan)
- ☐ rizatriptan orally disintegrating tablet > quantity limits
- ☐ rizatriptan tablet > quantity limits
- ☐ sumatriptan injection
- ☐ sumatriptan 5 mg, 20 mg nasal spray > quantity limits
- ☐ sumatriptan tablet > quantity limits
- ☐ sumatriptan/naproxen
- ☐ Tosymra (sumatriptan 10 mg nasal spray)
- ☐ Zembrace (sumatriptan injection)
- ☐ zolmitriptan nasal spray
- ☐ zolmitriptan orally disintegrating tablet
- ☐ zolmitriptan tablet > quantity limits

☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Quantity requested per 30 days _____

Dose, frequency, and duration of requested drug _____

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Cluster headache. Frequency of headaches (number/30 days) _____

☐ Migraine headache. Frequency of migraine attacks (number/30 days) _____

☐ Other. Specify pertinent medical history, diagnostic studies, and/or laboratory tests. _____

_____

Section I. Please complete for all serotonin receptor agent requests, excluding generic naratriptan, rizatriptan orally disintegrating tablet, rizatriptan tablets, sumatriptan 5 mg, 20 mg nasal spray, sumatriptan tablets, and zolmitriptan tablets. Please note, this section must be completed for brand name Imitrex tablet, Maxalt MLT, Maxalt tablet, or Zomig tablet requests.

1. Has the member tried sumatriptan tablets?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why sumatriptan tablets are not appropriate for this member.
2. Has the member tried rizatriptan?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why rizatriptan is not appropriate for this member.
3. Has the member tried zolmitriptan tablets?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.
   ☐ No. Explain why zolmitriptan tablets are not appropriate for this member.

Section II. Please complete for all requests for quantities above quantity limits.

1. Is the member under the care of a neurologist? ☐ Yes ☐ No
2. Is the member currently receiving prophylaxis?
   ☐ Yes. Please specify.
   Drug Dose and frequency
   Drug Dose and frequency
   ☐ No. Explain why prophylaxis is not appropriate for this member.

Section III. Please complete for requests for sumatriptan injection, Tosymra, Zembrace, zolmitriptan nasal spray and zolmitriptan orally disintegrating tablets.

1. Please describe medical necessity for the use of the requested dosage formulation instead of tablet formulation.
2. For Tosymra requests, has the member had a trial with zolmitriptan or sumatriptan 5 mg, 20 mg nasal spray?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.

over

☐ No. Explain why zolmitriptan or sumatriptan 5 mg, 20 mg nasal spray is not appropriate for this member.

3. For Zembrace requests, has the member had a trial with sumatriptan injection?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.

   ☐ No. Explain why sumatriptan injection is not appropriate for this member.

Section IV. Please complete for requests for sumatriptan/naproxen.

Please describe medical necessity for the use of the combination product (sumatriptan/naproxen) instead of the commercially-available separate agents.

Section V. Please complete for requests for Reyvow.

1. Is the member under the care of a neurologist? ☐ Yes ☐ No
2. Has the member had a trial with two different triptan agents?
   ☐ Yes. Please describe the drug names and outcomes.

   Drug name ☐ Adverse reaction ☐ Inadequate response
   Briefly describe the details of adverse reaction or inadequate response.

   Drug name ☐ Adverse reaction ☐ Inadequate response
   Briefly describe the details of adverse reaction or inadequate response.

   ☐ No. Explain why triptan agents are not appropriate for this member.

Section VI. Please complete for dihydroergotamine nasal spray requests.

1. Has the member tried sumatriptan nasal spray?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.

   ☐ No. Explain why sumatriptan nasal spray is not appropriate in this member.

2. Has the member tried zolmitriptan nasal spray?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.

   ☐ No. Explain why zolmitriptan nasal spray is not appropriate in this member.

over

Section VII. Please complete for dihydroergotamine injection and ergotamine/caffeine suppository requests.

1. Please describe medical necessity for the use of the requested dosage formulation.

2. For dihydroergotamine injection requests, has the member tried sumatriptan injection?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.

   ☐ No. Explain why sumatriptan injection is not appropriate in this member.

3. For ergotamine/caffeine suppository requests, has the member tried sumatriptan nasal spray?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.

   ☐ No. Explain why sumatriptan nasal spray is not appropriate in this member.

Section VIII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
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☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Heart Failure Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Entresto (sacubitril/valsartan) ☐ Verquvo (vericiguat)
☐ ivabradine

Dose, frequency, and duration of medication requested

Is the member stabilized on the requested medication? ☐ Yes. Please provide start date. ☐ No

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Chronic heart failure with reduced left ventricular ejection fraction (LVEF)

LVEF ☐ ≤ 35% ☐ ≤ 40% ☐ < 45% ☐ Other

New York Heart Association (NYHA) ☐ Class I ☐ Class II ☐ Class III ☐ Class IV

☐ Heart failure due to dilated cardiomyopathy

☐ Other (please specify)

Please indicate prescriber specialty below.

☐ Cardiology ☐ Other

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s) Date(s) of last visit or consult

Contact information

Section I. Please complete for all ivabradine requests.

For ivabradine in pediatric members, please complete questions 2 through 4. For ivabradine in adult members, please complete questions 1 through 3. For all ivabradine solution requests, please also complete question 5.

1. For ivabradine requests in adult members, is the member's resting heart rate ≥ 70 beats per minute? ☐ Yes ☐ No
2. Has the member tried a beta-blocker (e.g., carvedilol, metoprolol succinate, or bisoprolol) at maximally tolerated doses?
   ☐ Yes. Please list the specific drug name, dose, dates/duration of use, and outcomes below.

   Drug name/dose Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe the details of adverse reaction or inadequate response.

☐ No. Please explain why oral beta-blockers are not appropriate for this member.

3. Has the member tried an angiotensin-converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB) or angiotensin receptor neprilysin inhibitor (ARNI)?
   ☐ Yes. Please list the specific drug name(s), dates/duration of use, and outcomes below.

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe the details of adverse reaction or inadequate response.

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe the details of adverse reaction or inadequate response.

   ☐ No. Please explain why an ACE-I, ARB, or ARNI is not appropriate for this member.
4. For ivabradine requests in pediatric members, does the member have normal sinus rhythm with an elevated heart rate? ☐ Yes ☐ No
5. For ivabradine solution requests, is there a medical necessity for the solution formulation?
   ☐ Yes. Please explain.
   ☐ No

Section II. Please complete for Verquvo requests in adult members.

1. Has the member tried an ACE-I, ARB, or ARNI in combination with a beta blocker?
   ☐ Yes. Please list the specific drug name(s), dates/duration of use, and outcomes below.

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe the details of adverse reaction or inadequate response.

   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe the details of adverse reaction or inadequate response.

   ☐ No. Please explain contraindication to the use of an ACE-I, ARB, or ARNI in combination with a beta blocker for this member.
2. Has the member had a heart failure hospitalization within six months?
   ☐ Yes. Date ☐ No
3. Has the member had outpatient IV diuretic therapy for heart failure within three months?
   ☐ Yes. Date ☐ No

over

Section III. Please include any other pertinent information (if needed).

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
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☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Hemophilia Gene Therapies
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Hemgenix (etranacogene dezparvovec-drlb) [MB]
☐ Roctavian (valoctocogene roxaparvovec-rvox) [MB]

Dose and frequency of medication requested

Indication or ICD-10 code, if applicable

☐ Severe hemophilia A
☐ Moderately severe to severe hemophilia B

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

If applicable, please also complete the section for professionally administered medications at end of form.

Is the prescriber a hematologist? ☐ Yes
☐ No. Please attach consultation notes from a hematologist.

Section I. Please complete for all requests.

1. Please provide anticipated dates and dosing for the following as applicable.
   Admission Infusion Dose Discharge
2. Will the member be screened for acute infection prior to administration? ☐ Yes ☐ No
3. Baseline weight Date
4. Baseline annualized bleeding rate (ABR) Date

Section II. Please also complete for requests for Hemgenix.

1. Is the member currently receiving immunosuppressive therapy? ☐ Yes ☐ No
2. Does the member currently have a life-threatening hemorrhage? ☐ Yes ☐ No
3. Does the member have a history of life-threatening hemorrhage? ☐ Yes ☐ No
4. Has the member had repeated, serious spontaneous bleeding episodes? ☐ Yes ☐ No
5. Does the member currently use FIX prophylaxis therapy?
   ☐ Yes. Please provide details. ☐ No
6. FIX activity level Date

7. NAb titer (AAV5) _____ Date _____

Section III. Please also complete for requests for Roctavian.

1. Has the member been assessed for their ability to receive corticosteroids and/or immunosuppressive therapy? ☐ Yes ☐ No
2. Does the member currently use FVIII prophylaxis therapy?
   ☐ Yes. Please provide details. _____
   ☐ No. If no, does the member currently use Hemlibra (emicizumab)? ☐ Yes ☐ No
3. FVIII activity level _____ Date _____
4. Does the member have a detectable pre-existing immunity to AAV5? ☐ Yes ☐ No
5. Does the member have a history of factor VIII inhibitor? ☐ Yes ☐ No
6. Does the member have hepatic fibrosis? ☐ Yes ☐ No
7. Does the member have cirrhosis? ☐ Yes ☐ No
8. Does the member have history of thrombosis or thrombophilia? ☐ Yes ☐ No
9. Does the member have an active malignancy? ☐ Yes ☐ No

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
   _____
   _____
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen? ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
   _____
   _____
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details. _____
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Hepatitis Antiviral Agents
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Diagnosis

☐ Hepatitis C

☐ Acute ☐ Chronic

☐ HIV-coinfection ☐ Renal impairment. Creatinine clearance _____ ☐ Status post-liver transplant

HCV Genotype ☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ Other _____

☐ Treatment-experienced (Please complete the section for Prior Hepatitis Treatment.) ☐ Treatment-naïve

☐ Treatment initiation Anticipated start date _____ Anticipated end date _____

☐ Continuation of therapy, current week _____

☐ Chronic Hepatitis B

Fibrosis Staging

Please indicate below and attach documentation including medical records and results of diagnostic tests assessing liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4). Staging information must clearly demonstrate early stage (Metavir Score F0 to F2) or advance liver disease (Metavir Score F3 to F4). If results are inconclusive or if imaging studies are performed and are not suggestive of cirrhosis, further diagnostic testing may be required.

☐ Metavir Score F0 to F2 ☐ Metavir Score F3 to F4 ☐ Other _____

Does the member have cirrhosis? ☐ Yes ☐ No

If yes, please indicate Child-Turcotte-Pugh (CTP) class. (Please attach calculations.) ☐ A ☐ B ☐ C

Lab Values

Baseline HCV RNA lab value _____ Date drawn _____

Prior Hepatitis Treatment

Drug name _____ Dates/duration of use _____

Please indicate treatment outcome. ☐ Adverse reaction ☐ Null responder ☐ Partial responder ☐ Relapser ☐ Other

Briefly describe details. _____

Drug name _____ Dates/duration of use _____

Please indicate treatment outcome. ☐ Adverse reaction ☐ Null responder ☐ Partial responder ☐ Relapser ☐ Other

Briefly describe details. _____

Drug name _____ Dates/duration of use _____

Please indicate treatment outcome. ☐ Adverse reaction ☐ Null responder ☐ Partial responder ☐ Relapser ☐ Other

Briefly describe details. _____

Complete Treatment Regimen (Check All that Apply)

HCV Combination Agents

☐ ledipasvir/sofosbuvir
☐ Mavyret (glecaprevir/pibrentasvir)
☐ sofosbuvir/velpatasvir
☐ Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
☐ Zepatier (elbasvir/grazoprevir)

Dose/frequency _____ Duration of therapy _____

For sofosbuvir/velpatasvir requests only, for members with HCV genotype 3 who are treatment-experienced without cirrhosis, please indicate if NS5A resistance-associated substitution Y93H is present. (Please attach laboratory testing results.) ☐ Yes ☐ No

For Zepatier requests only, for members with HCV genotype 1a, please indicate if baseline NS5A polymorphisms at amino acid positions 28, 30, 31 or 93 are present. (Please attach laboratory testing results.) ☐ Yes ☐ No

HCV Single Agents

☐ Sovaldi (sofosbuvir)

Dose/frequency _____ Duration of therapy _____

Pegylated Interferon

☐ Pegasys (peginterferon alfa-2a)

Dose/frequency _____ Duration of therapy _____

Ribavirin

☐ ribavirin 200 mg capsule
☐ None. Please explain the clinical rationale for not using ribavirin below.

Dose/frequency _____ Duration of therapy _____

Please indicate if using ribavirin 200 mg tablets. ☐ Yes ☐ No

Please describe medical necessity for use of the other products instead of the 200 mg tablet.

_____

If applicable, please explain the clinical rationale for not using ribavirin. _____

_____

Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

over

If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Hereditary Angioedema Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Diagnosis

Is the member diagnosed with hereditary angioedema? ☐ Yes ☐ No

Please provide any lab tests that confirm the diagnosis.

Test _____ Lab value _____ Lab reference range _____ Date obtained _____

Test _____ Lab value _____ Lab reference range _____ Date obtained _____

Test _____ Lab value _____ Lab reference range _____ Date obtained _____

Please document the baseline frequency of hereditary angioedema attacks: _____ attacks/month

Medication information

Medication requested

☐ Berinert (c1 esterase inhibitor, human)
☐ Cinryze (c1 esterase inhibitor, human)
☐ Haegarda (c1 esterase inhibitor, human)
☐ icatibant
☐ Kalbitor (ecallantide)[MB]
☐ Orladeyo (berotralstat)
☐ Ruconest (c1 esterase inhibitor, recombinant)
☐ Takhzyro (lanadelumab-flyo)

Instructions for use _____

[MB] This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed,PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

☐ Prophylaxis therapy ☐ Treatment of acute attacks

Place of administration ☐ Clinician's office ☐ Home

Has the member been instructed to self-administer the medication? ☐ Yes ☐ No

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code _____

Is the member under the care of an allergist or immunologist? ☐ Yes ☐ No

If yes, and the requesting provider is not the allergist or immunologist, please provide consult notes regarding the member's diagnosis.

Section I. For Cinryze, Haegarda, Orladeyo, and Takhzyro requests, please complete the following.

1. Is the member experiencing more than one HAE event per month? ☐ Yes ☐ No
2. Does the member have a history of recurrent laryngeal attacks? ☐ Yes ☐ No

Section II. For recertification requests for Berinert, icatibant, Kalbitor, or Ruconest, please complete the following.

1. Has the member used the previously approved product?

   ☐ Yes. Please indicate the quantity used.
   ☐ No
2. Has the previously approved product expired?

   ☐ Yes. Please indicate the quantity expired.
   ☐ No
3. Does the member have sufficient medication available to treat one attack? ☐ Yes ☐ No

Section III. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Hyaluronan Injections
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Device information

Device requested

- ☐ Durolane (hyaluronate) [MB]
- ☐ Euflexxa (hyaluronate) [MB]
- ☐ Gel-One (cross-linked hyaluronate) [MB]
- ☐ Gelsyn (hyaluronate) [MB]
- ☐ Genvisc (hyaluronate) [MB]
- ☐ Hyalgan (hyaluronate) [MB]
- ☐ Hymovis (hyaluronate modified) [MB]
- ☐ Monovisc (hyaluronate) [MB]
- ☐ Orthovisc (high molecular weight hyaluronan) [MB]
- ☐ Supartz (hyaluronate) [MB]
- ☐ Synojoynt (hyaluronate) [MB]
- ☐ Synvisc (hylan G-F 20) [MB]
- ☐ Synvisc-One (hylan G-F 20) [MB]
- ☐ Triluron (hyaluronate) [MB]
- ☐ Trivisc (hyaluronate) [MB]
- ☐ Visco-3 (hyaluronate) [MB]

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above,this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency and duration of device requested

Device NDC (if known) or service code

Indication (Check all that apply, or ICD-10 code, if applicable.)

☐ Osteoarthritis of the knee ☐ Left knee ☐ Right knee ☐ Both knees

☐ Other (Please indicate.)

Is the request for retreatment of the same knee(s)? ☐ Yes ☐ No

Section I. Please complete the following for all requests.

1. Please indicate billing preference. ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
2. Has the member tried acetaminophen?

   ☐ Yes. Please provide the following information.* Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

☐ No. Does the member have a contraindication to acetaminophen? Please explain.

3. Has the member tried an intra-articular corticosteroid injection?
   ☐ Yes. Please provide the following information.*

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Does the member have a contraindication to all intra-articular corticosteroid injections? Please explain.

4. Has the member tried a non-steroidal anti-inflammatory drug (NSAID)?
   ☐ Yes. Please provide the following information.*

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Does the member have a contraindication to all NSAIDs? Please explain.

* *Please attach a letter documenting additional trials as necessary.*

Section II. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

over

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Hypnotic Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about hypnotic agents and the **Pediatric Behavioral Health Medication Initiative**, including PA requirements, a complete list of all behavioral health medications, and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**. The related PA form is available at: **Pediatric Behavioral Health Medication Initiative PA Request Form.**

Medication information

Hypnotic requested	Qty/month	Hypnotic requested	Qty/month
☐ Belsomra (suvorexant)		☐ zaleplon > 1 unit/day	
☐ Dayvigo (lemborexant)		☐ zolpidem 1.75 mg, 3.5 mg sublingual	
☐ doxepin tablet		☐ zolpidem extended-release tablet > 1 unit/day	
☐ Edluar (zolpidem 5 mg, 10 mg sublingual)		☐ zolpidem tablet > quantity limits	
☐ eszopiclone > 1 unit/day		☐ zolpidem 7.5 mg capsule	
☐ Quviviq (daridorexant)			
☐ ramelteon > 1 unit/day			

Dose and frequency _____ **Intended duration** _____

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Insomnia
- ☐ Acute ☐ Chronic

☐ Insomnia characterized by middle of the night awakenings with difficulty falling back asleep

☐ Other _____

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

Section I. Please complete for all requests exceeding the quantity limit.

Please provide medical necessity for exceeding the quantity limit.

Section II. Hypnotic Polypharmacy for all members. Please complete information for medications requested and select the reason for polypharmacy with hypnotics (two or more hypnotics, including benzodiazepine hypnotics [estazolam, flurazepam, quazepam, temazepam, and triazolam] and non-benzodiazepine hypnotics, for ≥ 60 days within a 90-day period).

Please document complete treatment plan (include all hypnotic agents [benzodiazepine and/or non-benzodiazepine] and indication or ICD-10 code, if applicable).

1. Hypnotic name/dose/frequency _____ Indication _____
2. Hypnotic name/dose/frequency _____ Indication _____
3. Hypnotic name/dose/frequency _____ Indication _____
4. Please indicate prescriber specialty below.

   ☐ Psychiatry ☐ Neurology ☐ Sleep Medicine ☐ Other _____

   If prescriber is not a specialist, please attach consult notes from specialist.

   For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable. _____
5. Please describe the severity of sleep diagnosis (e.g., symptoms, recent hospitalizations, risk of harm to self or others, etc.) _____

   Has the member had a trial with all alternative hypnotics indicated for diagnosis?

   ☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*

   ☐ No. If these trials are contraindicated, please describe.

Section III. Please complete for all requests for Belsomra, Dayvigo, and Quviviq.

1. Has the member had a trial with two of the following: eszopiclone, ramelteon, zaleplon, or zolpidem (immediate-release or extended-release)?

   ☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*

   ☐ No. If these trials are contraindicated, please describe.

   For Dayvigo, has the member had a trial with Belsomra?

   ☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*

   ☐ No. If these trials are contraindicated, please describe.

   For Quviviq, has the member had a trial with Belsomra and Dayvigo?

   ☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*

   ☐ No. If these trials are contraindicated, please describe.

over

Section IV. Please complete for all requests for Edluar.

Please provide medical necessity for sublingual formulation.

Section V. Please complete for all requests for doxepin tablet.

Has the member had a trial with two of the following: doxepin (capsule or liquid), eszopiclone, ramelteon, suvorexant or lemborexant or Quviviq, zaleplon, or zolpidem (immediate-release or extended-release)?

☐ Yes. Please list the drug name, dose and frequency, dates/duration, and outcome in Section VIII below.*

☐ No. If these trials are contraindicated, please describe.

Section VI. Please complete for all requests for zolpidem 1.75 mg, and 3.5 mg sublingual.

Has the member had a trial with three of the following: eszopiclone, zaleplon, zolpidem extended-release, zolpidem immediate-release?

☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*

☐ No. If there is a medical necessity for sublingual formulation, please describe.

Section VII. Please complete for all requests for zolpidem 7.5 mg capsule.

Has the member had a trial with both of the following: zolpidem 5 mg tablet and zolpidem 10 mg tablet?

☐ Yes. Please list the drug names, dose and frequency, dates/durations, and outcomes in Section VIII below.*

Please provide medical necessity for 7.5 mg capsule instead of formulations available without prior authorization.

Section VIII. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug name ____ Dose and frequency ____ Dates/duration of use ____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ____ Dose and frequency ____ Dates/duration of use ____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ____ Dose and frequency ____ Dates/duration of use ____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name ____ Dose and frequency ____ Dates/duration of use ____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

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Section IX. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

MassHealth Pediatric Behavioral Health Medication Initiative

Please fill out all the sections below, as applicable, for pediatric members only. You may also use the Pediatric Behavioral Health Medication Initiative PA Request Form if the member is prescribed other behavioral health medications.

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name Dose/frequency Indication
2. Medication name Dose/frequency Indication
3. Medication name Dose/frequency Indication
4. Medication name Dose/frequency Indication

over

5. Medication name _____ Dose/frequency _____ Indication _____

6. Medication name _____ Dose/frequency _____ Indication _____

7. Other(s) _____

Is the member currently in an acute care setting?

☐ Yes (Inpatient) ☐ Yes (Community Based Acute Treatment)

☐ Yes (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name _____ Contact information _____

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months. _____

☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?

☐ Yes. Please provide details. _____ ☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g. weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain. _____

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other _____

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

_____

Name(s) of the specialist(s) _____ Date(s) of last visit or consult _____

Contact information _____

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable. _____

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility ☐ Uncertain

☐ Other _____

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH) ☐ Department of Developmental Services (DDS)

☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

_____

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

** Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to: https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information*

over

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation. ☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

Section II. Hypnotic Requests for Members < six years of age.

Please document if member has other behavioral health comorbidities (e.g., anxiety, depression, ADHD).

Please document medication trials with melatonin and/or clonidine, if clinically appropriate. Include drug name, dates/duration of use, and outcome.*

Please document clinical rationale for the use of a hypnotic agent in this member < six years of age.

Has the member been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

* *Attach a letter with additional information regarding medication trials as applicable.*

Section III. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.*

Please document clinical rationale for use of multiple behavioral health medications for this member < 18 years of age.

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

* *Attach a letter with additional information regarding medication trials as applicable.*

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Imcivree
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Dose, frequency, and duration of medication requested

Indication or ICD-10 code, if applicable

☐ Obesity due to Bardet-Biedl syndrome

☐ Obesity due to genetic deficiency (Specify type of deficiency below.)

☐ Leptin receptor (LEPR) ☐ Proprotein convertase subtilisin/kexin type 1 (PCSK1)

☐ Proopiomelanocortin (POMC)

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Is the prescriber an endocrinologist? ☐ Yes ☐ No

Section I. Please complete for all requests.

Current height Baseline weight Baseline body mass index (BMI) Date

For adult members, BMI, height, and weight are required. For pediatric members, BMI and most recent growth chart are required.

Section II. Please complete for obesity due to genetic deficiency.

1. Please attach a copy of genetic test(s) confirming obesity due to a homozygous or presumed homozygous variant in at least one of the following genes: LEPR, PCSK1, or POMC.
2. Please specify interpretation of the variant(s) in LEPR, PCSK1, or POMC genes as confirmed by genetic testing:

   ☐ Pathogenic ☐ Likely pathogenic ☐ Of uncertain significance (VUS) ☐ Other

Section III. Please complete for recertification requests.

Current height Current weight Current BMI Date

For adult members, weight is required. For pediatric members, BMI is required.

1. For pediatric members, does the member have continued growth potential? ☐ Yes ☐ No
2. Has the member been adherent to Imcivree?
   ☐ Yes. Please note: Continued approval of the requested agent will be contingent upon MassHealth pharmacy claims history or additional documentation addressing adherence.
   ☐ No

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Immune Globulin
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Alyglo	☐ Flebogamma	☐ Gammaplex	☐ Panzyga
☐ Asceniv	☐ Gamastan S/D	☐ Gamunex-C	☐ Privigen
☐ Bivigam	☐ Gammagard	☐ Hizentra	☐ Xembify
☐ Cutaquig	☐ Gammagard S/D	☐ Hyqvia	
☐ Cuvitru	☐ Gammaked	☐ Octagam	

Dose of medication requested _____ mg per kg = _____ g

Frequency and duration of medication requested _____

Please specify dosing schedule. ☐ Scheduled ☐ Intermittent

Member's current actual body weight (ABW) _____ Date _____

Member's current height _____ Date _____

Member's current Body Mass Index (BMI) _____ Date _____

For initiation of intravenous immune globulin (IVIG), if a member's BMI is ≥ 30 kg/m^2 or ABW is > 120% of ideal body weight (IBW), dosing calculated using adjusted body weight has been demonstrated to have similar clinical effect as using ABW. MassHealth suggests the use of this dosing strategy to promote cost effective care. This is not meant to replace clinical decision making when initiating medication therapy. Please complete the below question.

If member meets the criteria noted above (BMI ≥ 30 kg/m^2 or ABW > 120% of IBW), is the member a candidate for adjusted body weight dosing? If criteria are not applicable, this may be left blank.

☐ Yes. MassHealth to calculate total dose based on adjusted body weight* (may round dose to vial size).

☐ No. Please explain why adjusted body weight* dosing is not appropriate for this member. _____

_____

** Adjusted Body Weight = IBW + 0.4 (ABW - IBW)*

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code _____

Indication or ICD-10 code, if applicable _____

Is the member stabilized on the requested medication?

☐ Yes. Please provide start date. _____ ☐ No

Section I. Please specify the indication for all requests except for a diagnosis of dermatomyositis (DM). For Asceniv requests, please also complete Section III as appropriate.

☐ Primary immunodeficiency disorders (PID)

Please attach laboratory documentation supporting diagnosis.

Provide date and results of most recent serum immunoglobulin levels (including laboratory reference ranges).

☐ Immune thrombocytopenia (ITP)

Provide date and results of most recent platelet count (including laboratory reference ranges).

Does the member have clinically significant bleeding? ☐ Yes. Please describe below. ☐ No

Does the member have a history of or risk of significant bleeding? ☐ Yes. Please describe below. ☐ No

Does the member have a medical necessity to raise platelet count within 12 to 24 hours?
☐ Yes. Please describe below. ☐ No

☐ Kawasaki disease (mucocutaneous lymph node syndrome)

Provide date of onset.

Does the member have an unexplained persistent fever? ☐ Yes ☐ No

Does the member have evidence of aneurysm? ☐ Yes ☐ No

Does the member exhibit signs of persistent inflammation? ☐ Yes ☐ No

☐ B-cell chronic lymphocytic leukemia (CLL)

☐ Chronic inflammatory demyelinating polyneuropathy (CIDP)

☐ Multifocal motor neuropathy (MMN)

☐ Other

Please describe the medical necessity for the use of immune globulin including previous trials and outcomes.

Section II. Please complete for treatment of dermatomyositis (DM). For Asceniv requests, please also complete Section III as appropriate.

1. Has the member had a trial with one systemic corticosteroid?

   ☐ Yes. Please list the dates/duration of trials and outcomes.* Dates/duration of trial

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain if there is a contraindication.
2. Does the member have severe disease? ☐ Yes ☐ No
3. Has the member had a trial with one of the following: azathioprine, chloroquine, hydroxychloroquine, methotrexate, mycophenolate mofetil, or rituximab?

over

☐ Yes. Please list the drug names, dates/duration of trials and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

Section III. Please also complete for requests for Asceniv. Please complete Section I or II above as appropriate.

Please provide clinical rationale for the use of this product instead of other available IVIG products.

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details.

   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Inhaled Respiratory Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested (Check one or all that apply. Where applicable, the brand name is provided in brackets for reference.)

Anticholinergics

- ☐ Lonhala (glycopyrrolate)
- ☐ Yupelri (revefenacin)

Combination Products

- ☐ Airduo Digihaler (fluticasone/salmeterol)
- ☐ Airsupra (albuterol/budesonide)
- ☐ Bevespi (glycopyrrolate/formoterol)
- ☐ Breztri (budesonide/glycopyrrolate/formoterol)
- ☐ Duaklir (aclidinium/formoterol)
- ☐ fluticasone/salmeterol [Airduo Respiclick]
- ☐ Stiolto (tiotropium/olodaterol)
- ☐ Trelegy (fluticasone furoate/umeclidinium/ vilanterol)

Corticosteroids

- ☐ Alvesco (ciclesonide inhaler)
- ☐ Armonair Digihaler (fluticasone propionate inhalation powder)
- ☐ Asmanex (mometasone) 110 mcg ≥ 12 years
- ☐ Asmanex (mometasone) 220 mcg < 12 years
- ☐ budesonide inhalation suspension ≥ 13 years
- ☐ fluticasone propionate inhalation aerosol [Flovent] ≥ 12 years
- ☐ fluticasone propionate inhalation powder [Flovent]
- ☐ Qvar Redihaler (beclomethasone inhaler)

Long-acting Beta Agonists

- ☐ arformoterol
- ☐ formoterol
- ☐ Striverdi (olodaterol)

Short-acting Beta Agonists

- ☐ albuterol inhaler ‡
- ☐ levalbuterol inhalation solution
- ☐ Proair Digihaler (albuterol inhalation powder)

‡Brand name Ventolin is available without prior authorization.

Other Medication

- ☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose and frequency of medication requested _____

Number of inhalers/month _____

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Asthma (Specify severity below.)

☐ Intermittent ☐ Mild Persistent ☐ Moderate Persistent ☐ Severe Persistent

☐ Chronic Obstructive Pulmonary Disease (COPD) (Specify severity and subtype below.)

Severity ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe

Subtype ☐ Chronic bronchitis ☐ Emphysema

☐ Exercise-induced bronchospasm

☐ Reactive airway disease

☐ Other

Please list all other medications currently prescribed for the member for this indication.

Is this member a referral candidate for care coordination? ☐ Yes ☐ No
If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial.

Section I. Please complete for albuterol inhaler and Proair Digihaler requests.

1. For requests for albuterol inhaler, please attach medical records documenting an inadequate response or adverse reaction to an albuterol product available without prior authorization. *
2. For requests for Proair Digihaler, has the member had a trial with brand name Proair Respiclick, or Ventolin?
   ☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
   ☐ No. Please describe the clinical rationale why an albuterol inhaler is not appropriate for this member.

** Brand name Ventolin does not require prior authorization*.

Section II. Please complete for Asmanex 110 mcg requests in members ≥ 12 years of age and 220 mcg in members < 12 years of age.

Please describe the clinical rationale for the use of requested Asmanex strength in the requested age group.

Section III. Please complete for all arformoterol, budesonide inhalation suspension, formoterol, levalbuterol inhalation solution, Lonhala, and Yupelri requests.

1. Please describe the medical necessity for a nebulized formulation.
2. For levalbuterol inhalation solution, has the member had a trial with albuterol solution?
   ☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
   ☐ No. Please describe the clinical rationale why albuterol solution is not appropriate for this member.
3. For Lonhala and Yupelri, has the member had a trial with ipratropium inhalation nebulizer solution?
   ☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
   ☐ No. Please describe the clinical rationale why ipratropium inhalation nebulizer solution is not appropriate for this member.

Section IV. Please complete for Airduo Digihaler, and fluticasone/salmeterol (generic Airduo Respiclick) requests.

1. Has the member had a trial with fluticasone/salmeterol inhalation aerosol, powder (generic Advair)?
   ☐ Yes. Please list the dates/duration of trials and the outcomes in Section X.
   ☐ No. Please describe the clinical rationale for use of the requested agent in this member.

over

2. For Airduo Digihaler, has the member had a trial with fluticasone/salmeterol (generic Airduo Respiclick)?
   ☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
   ☐ No. Please describe the clinical rationale for use of the requested agent in this member.

Section V. Please complete for Alvesco, Armonair Digihaler, fluticasone propionate inhalation aerosol (generic Flovent) for members ≥ 12 years of age, fluticasone propionate inhalation powder (generic Flovent), and Qvar Redihaler requests.

Has the member had a trial with two inhaled corticosteroids?
☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
☐ No. Please document if there is a contraindication to all other inhaled corticosteroids.

Section VI. Please complete for Bevespi and Duaklir requests.

Has the member had a trial with Anoro or Stiolto?
☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
☐ No. Please describe the clinical rationale for use of the requested agent in this member.

Section VII. Please complete for Trelegy requests.

Has the member had a trial with fluticasone/vilanterol and Incruse or Anoro and Arnuity?
☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
☐ No. Please describe the clinical rationale for use of the requested agent in this member.

Section VIII. Please complete for Breztri requests.

Has the member had a trial with the following combination of the separate agents: Bevespi and Pulmicort inhalation powder?
☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
☐ No. Please describe the clinical rationale for use of the requested agent in this member.

Section IX. Please complete for Airsupra requests.

Has the member had a trial with budesonide/formoterol or albuterol and Pulmicort inhalation powder?
☐ Yes. Please list the dates/duration of trials, and outcomes in Section X.
☐ No. Please describe the clinical rationale for use of the requested agent in this member.

Section X. Please complete as instructed in sections above.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, or other.

over

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

** Please attach a letter documenting additional trials as necessary.*

Section XI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Injectable Antibiotic
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Avycaz (ceftazidime/avibactam)
- ☐ Baxdela (delafloxacin injection)
- ☐ Dalvance (dalbavancin)
- ☐ Fetroja (cefiderocol)
- ☐ Kimyrsa (oritavancin)
- ☐ linezolid injection
- ☐ Nuzyra (omadacycline injection)
- ☐ Orbactiv (oritavancin)
- ☐ Recarbrio (imipenem/cilastatin/relebactam)
- ☐ Sivextro (tedizolid injection)
- ☐ tigecycline
- ☐ Vabomere (meropenem/vaborbactam)
- ☐ Vibativ (telavancin)
- ☐ Xerava (eravacycline)
- ☐ Zemdri (plazomicin)
- ☐ Zerbaxa (ceftolozane/tazobactam)

Dose, frequency, and duration of medication requested

☐ Initial request ☐ Recertification request ☐ Naïve to therapy ☐ Continuation of therapy

Is the member stabilized on the requested medication? ☐ Yes. Dates of use ☐ No

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Bacteremia
- ☐ Bone or joint infection:
- ☐ Central nervous system (CNS) infection:
- ☐ Community-acquired bacterial pneumonia (CABP)
- ☐ Complicated intra-abdominal infection (cIAI)
- ☐ Complicated urinary tract infection (cUTI)
- ☐ Endocarditis
- ☐ Hospital-acquired (nosocomial) bacterial pneumonia (HABP)
- ☐ Skin and soft tissue infection (SSTI): ☐ Acute ☐ Complicated ☐ Uncomplicated
- ☐ Ventilator-associated bacterial pneumonia
- ☐ Other infection:

Please indicate the infecting organism.

- ☐ Methicillin-resistant Staphylococcus aureus (MRSA) ☐ Confirmed ☐ Suspected
- ☐ Vancomycin-resistant Enterococcus (VRE)
- ☐ Non-MRSA/non-VRE: ☐ Confirmed ☐ Suspected

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Section I. Please complete for all requests.

1. Were cultures and susceptibility testing performed?
   ☐ Yes. Please attach a copy of the culture and sensitivity report with submission.
   ☐ No. Please provide clinical rationale why cultures and susceptibility testing were not performed.
2. Please list previous antibiotic trials for the requested indication including outcomes.*

   Drug Outcome Dates of use
   Drug Outcome Dates of use
   Drug Outcome Dates of use
3. Is the member ≥ 18 years of age? ☐ Yes ☐ No
4. For Avycaz and Zerbaxa requests for a diagnosis of complicated intra-abdominal infection (cIAI), will the member be using the requested medication concurrently with metronidazole?
   ☐ Yes
   ☐ No. Please explain.
5. For requests for Kimyrsa, please provide clinical rationale for use instead of Orbactiv.

**Attach a letter with additional information regarding medication trials as applicable.*

Section II. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

over

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Intranasal Corticosteroids
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

- ☐ Beconase AQ (beclomethasone nasal spray) > 1 inhaler/month
- ☐ flunisolide nasal spray
- ☐ fluticasone propionate 50 mcg nasal spray > 1 inhaler/month
- ☐ mometasone nasal spray
- ☐ Omnaris (ciclesonide 50 mcg nasal spray) > 1 inhaler/month
- ☐ Qnasl (beclomethasone nasal aerosol)
- ☐ Ryaltris (olopatadine/mometasone)
- ☐ Sinuva (mometasone sinus implant)
- ☐ Xhance (fluticasone propionate 93 mcg nasal spray)
- ☐ Zetonna (ciclesonide 37 mcg nasal aerosol)

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Allergic rhinitis
- ☐ Nasal polyps
- ☐ Nasal polyps with a history of ethmoid sinus surgery
- ☐ Non-allergic rhinitis
- ☐ Seasonal allergic rhinitis
- ☐ Other (please indicate)

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Section I. Please complete for requests for flunisolide nasal spray, mometasone nasal spray, Qnasl, and Zetonna

For members ≥ 6 years of age, please complete questions 1 through 3. For members 4 to 5 years of age, please complete questions 1 and 3. For members < 4 years of age, please complete question 3. For all Zetonna requests, please complete questions 1 through 3.

1. Has the member had a trial with fluticasone propionate 50 mcg nasal spray?

   ☐ Yes. Please list the dates/duration of trials, and outcomes.* Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe clinical rationale for not using fluticasone propionate 50 mcg nasal spray.

2. Has the member had a trial with budesonide over-the-counter (OTC) nasal spray?

☐ Yes. Please list the dates/duration of trials, and outcomes.* Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using budesonide OTC nasal spray.

3. Has the member had a trial with triamcinolone OTC nasal spray?

☐ Yes. Please list the dates/duration of trials, and outcomes.* Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using triamcinolone OTC nasal spray.

Section II. Please complete for any agent at a quantity > one inhaler per month. Please complete Section I above as appropriate.

1. Has the member had a trial with two intranasal or second-generation oral antihistamines?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using intranasal or second-generation oral antihistamines.

2. For requests for any agent at a quantity > one inhaler per month, please attach medical records documenting an inadequate response to the manufacturer's recommended dosing.

Section III. Please complete for requests for Ryaltris.

1. Has the member had a trial with one intranasal corticosteroid agent used in combination with one intranasal antihistamine agent?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

over

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using intranasal corticosteroids in combination with intranasal antihistamines.

2. Has the member had a trial with azelastine/fluticasone propionate nasal spray?

☐ Yes. Please list the dates/duration of trials and outcomes below.*

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using azelastine/fluticasone propionate nasal spray.

Section IV. Please complete for requests for Sinuva.

3. Please indicate prescriber specialty below.

☐ Otolaryngologist ☐ Other

4. Has the member had a trial with two intranasal corticosteroids?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using intranasal corticosteroids.

5. Has the member had a trial with an oral corticosteroid?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

over

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using an oral corticosteroid.

**Please attach a letter documenting additional trials as necessary.*

Section V. Please complete for requests for Xhance.

Please describe medical necessity for use of the requested agent instead of all other intranasal corticosteroids.

Section VI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Lenmeldy
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Dose, frequency, and duration requested

Drug NDC (if known) or service code

Indication or ICD-10 code, if applicable

☐ Metachromatic leukodystrophy (MLD)

- ☐ Presymptomatic late infantile
- ☐ Presymptomatic early juvenile
- ☐ Early symptomatic early juvenile

☐ Other

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Please indicate prescriber specialty below.

☐ Neurologist ☐ Geneticist ☐ Other

Section I. Please complete for all requests.

1. Does the member have deficient arylsulfatase A (ARSA) enzyme activity in leukocytes? ☐ Yes ☐ No
2. Please describe ARSA mutation(s).
3. Does the member have elevated sulfatides on 24-hour urine collection? ☐ Yes ☐ No
4. Does the member have neurological signs and symptoms of MLD?
   - ☐ Yes. If yes, are the signs and symptoms limited to the following?
     - ☐ Absence of neurological signs and symptoms of MLD with the exception of abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia).
     - ☐ Absence of neurological signs and symptoms of MLD or physical exam findings limited to abnormal reflexes and/or clonus with the exception of abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (e.g., no tremor, no peripheral ataxia).
   - ☐ No
5. Does the member have peripheral neuropathy as determined by electroneurographic study? ☐ Yes ☐ No

6. For early symptomatic early juvenile MLD, please provide the following:

   Age of MLD disease onset. ☐

   Intelligence quotient score on age-appropriate neurodevelopmental testing. ☐

   Gross Motor Function Classification score in metachromatic leukodystrophy (GMFC-MLD). ☐

7. Please provide results for the following serology tests.

Human immunodeficiency virus (HIV)-1/2	☐ Positive	☐ Negative	☐ Not completed
Human T-lymphotrophic virus (HTLV)-1/2	☐ Positive	☐ Negative	☐ Not completed
Hepatitis B virus (HBV)	☐ Positive	☐ Negative	☐ Not completed
Hepatitis C virus (HCV)	☐ Positive	☐ Negative	☐ Not completed
Mycoplasma	☐ Positive	☐ Negative	☐ Not completed

8. Has the member received any prior MLD gene therapy?

   ☐ Yes. Please describe. ☐

   ☐ No

9. Will the infusion take place in a qualified treatment center?

   ☐ Yes. Please indicate. ☐

   ☐ No

Section II. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member?

   ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

   ☐

   ☐

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

   ☐

   ☐

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name ☐ Dates/duration of use ☐

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

   ☐

   ☐

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details. ☐

   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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Lipid-Lowering Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Statins

- ☐ Altoprev (lovastatin extended-release)
- ☐ Atorvaliq (atorvastatin suspension)
- ☐ atorvastatin > quantity limits
- ☐ atorvastatin/amlodipine
- ☐ Ezallor (rosuvastatin sprinkle capsule)
- ☐ fluvastatin
- ☐ fluvastatin extended-release
- ☐ Leqvio (inclisiran)
- ☐ lovastatin > quantity limits
- ☐ pitavastatin calcium
- ☐ pravastatin > quantity limits
- ☐ rosuvastatin > quantity limits
- ☐ simvastatin > quantity limits
- ☐ simvastatin/ezetimibe > quantity limits
- ☐ Zypitamag (pitavastatin magnesium)

Fibric Acids

- ☐ fenofibrate tablet 40 mg, 120 mg

Miscellaneous Agents

- ☐ Evkeeza (evinacumab-dgnb) [MB]
- ☐ icosapent ethyl
- ☐ Juxtapid (lomitapide)
- ☐ Nexletol (bempedoic acid)
- ☐ Nexlizet (bempedoic acid/ezetimibe)

PCSK9 Inhibitors

- ☐ Praluent (alirocumab)
- ☐ Repatha (evolocumab)

Other Lipid-Lowering Agents

Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

[MB]*This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of requested medication _____ **Quantity requested per month** _____

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Atherosclerotic cardiovascular (CV) disease
- ☐ CV risk reduction
- ☐ Heterozygous familial hypercholesterolemia
- ☐ Homozygous familial hypercholesterolemia
- ☐ Hypercholesterolemia
- ☐ Hypercholesterolemia with previous history of any cardiovascular event
- ☐ Hypertriglyceridemia
- ☐ Mixed dyslipidemia
- ☐ Primary hyperlipidemia
- ☐ Other. Specify pertinent medical history, diagnostic studies, and/or laboratory results.

_____

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Please indicate prescriber specialty.

☐ Cardiology ☐ Other

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s)

Date(s) of last visit or consult

Contact Information

Is this member a referral candidate for care coordination? ☐ Yes ☐ No
If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial.

Lab Values and Treatment Plan: Please complete for all requests.

1. Is this a request for treatment initiation?
   ☐ Yes. Please provide the current baseline laboratory values.
   Date
   Total cholesterol mg/dl LDL/LDL-C mg/dl
   HDL mg/dl Triglycerides mg/dl
   ☐ No
2. Is this a request for continuation of treatment?
   ☐ Yes. Please provide the current laboratory values following treatment demonstrating efficacy of the requested agent.
   Date
   Total cholesterol mg/dl LDL/LDL-C mg/dl
   HDL mg/dl Triglycerides mg/dl
   ☐ No
3. Please summarize treatment goals including target cholesterol levels.

Please note: High-intensity statin therapy is defined as atorvastatin 40 mg, 80 mg, and rosuvastatin 20 mg, 40 mg.

Section I. Please complete if this request is for Altoprev, fluvastatin, fluvastatin extended-release, pitavastatin calcium, or Zypitamag.

1. Has the member had an inadequate response to a high-intensity statin for at least three months?
   ☐ Yes ☐ No
2. Has the member tried a high-intensity statin and had an adverse reaction or does the member have a contraindication to all high-intensity statins?
   ☐ Yes. Please explain.

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☐ No. Clinical rationale for not trying a high intensity statin.

Section II. Please complete if this request is for quantities above quantity limits.

Please attach documentation of the clinical rationale for the requested dose, quantity, and frequency, including a detailed treatment plan. Specify pertinent medical history, diagnostic studies, and/or lab results.

Section III. Please complete if this request is for fenofibrate tablet 40 mg or 120 mg.

Please attach medical records documenting failure with a therapeutically equivalent fenofibrate formulation available without prior authorization.

Section IV. Please complete if this request is for atorvastatin/amlodipine.

Please describe medical necessity for use of the combination product instead of the commercially available separate agents.

Section V. Please complete if this request is for icosapent ethyl for hypertriglyceridemia (not inclusive of those with established cardiovascular disease (CVD) or diabetes mellitus and CV risk factors).

1. Has the member had a trial with omega-3 acid ethyl esters?
   ☐ Yes. Please list the dose and frequency, dates/duration of trial, and outcome below.
   Dose and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please document if there is a contraindication to omega-3 acid ethyl esters.
2. Has the member had a trial with a fibric acid derivative?
   ☐ Yes. Please list the drug name, dose and frequency, dates/duration of trials, and outcomes below.
   Drug name Dose and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please document if there is a contraindication to all fibric acid derivatives.

Section VI. Please complete if this request is for icosapent ethyl for cardiovascular risk reduction.

1. Does the member have established cardiovascular disease (CVD)?
   ☐ Yes. Please describe.
   ☐ No

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2. Does the member have diabetes mellitus with at least one risk factor for CVD?

☐ Yes. Please describe. _____

☐ No

3. Will icosapent ethyl will be used in combination with a statin?

☐ Yes

☐ No. Clinical rationale why member cannot take a statin. _____

Section VII. Please complete if this request is for Leqvio, Nexletol, Nexlizet, Praluent, or Repatha.

For Nexletol, Nexlizet, Praluent and Repatha requests, please complete questions 1, 2 and 3. For Leqvio requests, please complete questions 1 through 7.

1. Has the member had an inadequate response to a high-intensity statin in combination with ezetimibe for at least the last three months?

☐ Yes.

☐ Name of statin _____

Dose and frequency _____ Dates of use _____ Outcome _____

☐ ezetimibe

Dose and frequency _____ Dates of use _____ Outcome _____

☐ No

2. Has the member tried a high-intensity statin and had an adverse reaction or does the member have a contraindication to all high-intensity statins?

☐ Yes. Please explain. _____ ☐ No

3. Has the member tried ezetimibe and had an adverse reaction or does the member have a contraindication to this agent?

☐ Yes. Please explain. _____ ☐ No

4. Has the member had an inadequate response to Praluent or Repatha for at least the last three months?

☐ Yes. Please note: Requests will be evaluated taking into account MassHealth pharmacy claims history or additional documentation addressing adherence to this agent.

Drug name _____

Dose and frequency _____ Dates of use _____ Outcome _____

☐ No

5. Has the member tried Praluent and had an adverse reaction or does the member have a contraindication to this agent?

☐ Yes. Please explain. _____ ☐ No

6. Has the member tried Repatha and had an adverse reaction or does the member have a contraindication to this agent?

☐ Yes. Please explain. _____ ☐ No

7. If this is a request for continuation of treatment, has the member been adherent to the lipid-lowering regimen?

☐ Yes. Please note: Continued approval of the requested agent will be contingent upon MassHealth pharmacy claims history or additional documentation addressing adherence to the entire lipid-lowering regimen.

☐ No

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Section VIII. Please complete if this request is for Atorvaliq and Ezallor.

1. Please provide medical necessity for use of the requested formulation.
2. For Atorvaliq, please provide clinical rationale for use instead of Ezallor.

Section IX. Please complete if this request is for Juxtapid.

1. Does the member have laboratory testing results confirming genetic mutation associated with homozygous familial hypercholesterolemia including low density lipoprotein receptor mutations, PCSK9 mutations, and familial defective apoB mutations? ☐ Yes. Please attach laboratory testing results. ☐ No
2. Please provide the following laboratory values:

   Baseline LDL/LDL-C mg/dl Date

   Current LDL/LDL-C mg/dl Date
3. Did the member have evidence of xanthoma before 10 years of age? ☐ Yes ☐ No
4. Does the member have evidence of heterozygous familial hypercholesterolemia in both parents? ☐ Yes ☐ No
5. Has the member had an inadequate response to a high-intensity statin for at least three months?

   ☐ Yes. Drug name Dose and frequency Dates/duration of use

   ☐ No
6. Has the member tried a high-intensity statin and had an adverse reaction or does the member have a contraindication to all high-intensity statins?

   ☐ Yes. Please explain.

   ☐ No
7. Has the member had a trial with an additional non-statin lipid-lowering agent?

   ☐ Yes. Please list the drug name, dose and frequency, dates/duration of trials, and outcomes below.

   Drug name Dose and frequency Dates/duration of use

   Did the member experience any of the following?

   ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please document if there is a contraindication to all non-statin lipid-lowering agents
8. Will the requested agent be used in combination with a high-intensity statin?

   ☐ Yes. Please list the drug name and dose and frequency below.

   Drug name Dose and frequency

   ☐ No. Please explain.

Section X. Please complete if this request is for Evkeeza.

1. Does the member have laboratory testing results confirming genetic mutation associated with homozygous familial hypercholesterolemia including low density lipoprotein receptor mutations, PCSK9 mutations, and familial defective apoB mutations? ☐ Yes. Please attach laboratory testing results. ☐ No

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2. Please provide the following laboratory values:

   Baseline LDL/LDL-C _____ mg/dl Date _____

   Current LDL/LDL-C _____ mg/dl Date _____

3. Did the member have evidence of xanthoma before 10 years of age? ☐ Yes ☐ No
4. Does the member have evidence of heterozygous familial hypercholesterolemia in both parents?
   ☐ Yes ☐ No
5. Please provide member's current weight _____ Date _____
6. Will the requested agent be used in combination with a high-intensity statin, ezetimibe, and a PCSK9 inhibitor?
   ☐ Yes. Please list the drug name(s) and dose and frequency below.

   Drug name _____ Dose and frequency _____

   Drug name _____ Dose and frequency _____

   Drug name _____ Dose and frequency _____

   ☐ No. Please explain. _____

Section XI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
   _____
   _____
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
   _____
   _____
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details. _____ ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Lung Cancer Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

- ☐ Alecensa (alectinib)
- ☐ Alunbrig (brigatinib)
- ☐ Augtyro (repotrectinib)
- ☐ erlotinib
- ☐ Exkivity (mobocertinib)
- ☐ gefitinib
- ☐ Gilotrif (afatinib)
- ☐ Lorbrena (lorlatinib)
- ☐ Lumakras (sotorasib)
- ☐ Portrazza (necitumumab) [MB]
- ☐ Rybrevant (amivantamab-vmjw) [MB]
- ☐ Tabrecta (capmatinib)
- ☐ Tagrisso (osimertinib)
- ☐ Tepmetko (tepotinib)
- ☐ Vizimpro (dacomitinib)
- ☐ Xalkori (crizotinib)
- ☐ Zepzelca (lurbinectedin) [MB]
- ☐ Zykadia (ceritinib)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Height Weight Date

Please indicate prescriber specialty below.

☐ Oncology ☐ Other

Will the requested agent be used as monotherapy for this indication? ☐ Yes ☐ No

If no, please list all other medications currently prescribed for the member that will be used concomitantly for this indication.

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ **Lung cancer**

☐ Non-small cell lung cancer (NSCLC)

☐ Adjuvant treatment for stage IB to IIIA

☐ Advanced or metastatic

☐ Small-cell lung cancer (SCLC)

☐ Advanced or metastatic

☐ **Other Oncologic Indication**

☐ Inflammatory myofibroblastic tumors (IMT)

☐ Pancreatic cancer

☐ Advanced or metastatic

☐ Systemic anaplastic large cell lymphoma

☐ Other ______

Please describe pertinent mutations.

☐ ALK-positive ☐ EGFR ☐ KRAS G12C ☐ MET exon 14 skipping ☐ ROS1 ☐ T790M resistance

Please describe details of pertinent mutations including exon deletions or mutations below.

______

Please describe the cell histology, if applicable.

______

Please describe the stage and severity of disease.

______

Has the member had persistent or recurring disease following surgery and/or radiation therapy? ☐ Yes ☐ No

Is the member a candidate for surgery and/or radiation?

☐ Yes ☐ No. Please describe. ______

Section I. Please complete for all requests.

Please list any other prior trials. Please list the drug names, dates/duration of use and outcomes below.*

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

______

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

______

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

______

Drug name ______ Dates/duration of use ______

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

______

** Please attach a letter documenting additional trials as necessary.*

Section II. Please complete for Portrazza requests.

Please describe medical necessity for the requested agent instead of all other clinically appropriate alternatives.

Section III. Please complete for Xalkori pellet requests.

Does the member have a medical condition in which they are unable to swallow tablets/capsules?

☐ Yes. Please provide details.

☐ No. Please provide clinical rationale why conventional dosage forms cannot be used.

Section IV. Please complete for requests for agents with a preferred alternative.

Please describe clinical rationale for use of the requested agent instead of the preferred alternative.

Section V. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit, including a detailed treatment plan.

Section VI. Please include any other pertinent information (if needed).

Section VII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

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If yes, please provide details for the previous trial.

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

_____

_____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details. _____

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Luxturna
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Dose, frequency, and duration requested

Drug NDC (if known) or service code

Indication or ICD-10 code, if applicable

☐ Biallelic RPE65 mutation-associated retinal dystrophy

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

Please indicate prescriber specialty below.

☐ Ophthalmologist ☐ Retinal specialist ☐ Other

Please indicate billing preference. ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form

Section I. Please complete for all requests

1. Please provide anticipated dates for retinal surgery.

   Initial treatment date

   Subsequent treatment date
2. Please provide medical records documenting the results from genetic testing showing mutations in the RPE65 gene.
3. Please provide documentation of baseline full-field light sensitivity threshold (FST) scores.
4. Does the member have viable retinal cells (e.g., retinal thickness >100 microns)? ☐ Yes ☐ No
5. Has the member had ocular surgery within the past six months? ☐ Yes ☐ No
6. Has the member discontinued retinoid compounds for at least the past 18 months? ☐ Yes ☐ No
7. Will the treatment procedure be performed at a specialized treatment center? ☐ Yes ☐ No
8. Outreach for both short- and long-term monitoring for efficacy and durability of response will be conducted by MassHealth. The applicable information [including but not limited to medical records confirming the dates of surgery and documenting the initial response to therapy (e.g. FST scores)] will be provided to MassHealth upon request. ☐ Yes ☐ No

9. Has the member received any prior gene therapy for biallelic RPE65 mutation-associated retinal dystrophy?
   ☐ Yes. Please describe.
   ☐ No

Section II. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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Multiple Myeloma Agents
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

- ☐ Blenrep (belantamab mafodotin-blmf)
- ☐ Darzalex (daratumumab) [MB]
- ☐ Darzalex Faspro (daratumumab-hyaluronidase-fihj) [MB]
- ☐ Empliciti (elotuzumab) [MB]
- ☐ Kyprolis (carfilzomib) [MB]
- ☐ Ninlaro (ixazomib)
- ☐ Pomalyst (pomalidomide)
- ☐ Sarclisa (isatuximab-irfc) [MB]
- ☐ Xpovio (selinexor)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Height Weight Date

Please indicate prescriber specialty: ☐ Hematology ☐ Oncology ☐ Other

Will the requested agent be used as monotherapy for this indication? ☐ Yes ☐ No

If no, please list all other medications currently prescribed for the member that will be used concomitantly for this indication.

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ **Multiple myeloma**

Other Oncologic Indications

- ☐ Diffuse large B-cell lymphoma (DLBCL)
- ☐ Light chain amyloidosis
- ☐ Kaposi sarcoma
  - ☐ Acquired Immunodeficiency Syndrome (AIDS) and failed highly active antiretroviral therapy
  - ☐ Negative for Human Immunodeficiency Virus (HIV)

Please describe the stage and severity of disease.

Is the cancer metastatic? ☐ Yes ☐ No

Has the member had persistent or recurring disease following surgery and/or radiation therapy? ☐ Yes ☐ No

Is the member a candidate for surgery and/or radiation?

☐ Yes ☐ No. Please describe.

Section I. Please complete for all requests.

Please list any other prior trials. Please list the drug names, dates/duration of use and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

** Please attach a letter documenting additional trials as necessary.*

Section II. Please complete for Blenrep, and Xpovio for monotherapy requests.

1. Has the member received at least four prior chemotherapy regimens? ☐ Yes. Complete Section I. ☐ No
2. Is the member's disease refractory to at least one proteasome inhibitor (for Blenrep requests) or two proteasome inhibitors (for Xpovio requests), or does the member have a contraindication to proteasome inhibitors? ☐ Yes. Complete Section I. ☐ No
3. Is the member's disease refractory to at least one immunomodulatory agent (for Blenrep requests) or two immunomodulatory agents (for Xpovio requests), or does the member have a contraindication to immunomodulatory agents? ☐ Yes. Complete Section I. ☐ No
4. Is the member's disease refractory to at least one anti-CD38 monoclonal antibody, or does the member have a contraindication to anti-CD38 monoclonal antibodies? ☐ Yes. Complete Section I. ☐ No

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Section III. Please complete for requests for agents with a preferred alternative.

Please describe clinical rationale for use of the requested agent instead of the preferred alternative.

Section IV. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit, including a detailed treatment plan.

Section V. Please include any other pertinent information (if needed).

Section VI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

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4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Multiple Sclerosis Agents
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Bafiertam (monomethyl fumarate)
- ☐ Briumvi (ublituximab-xiiy)
- ☐ dalfampridine > 2 units/day
- ☐ dimethyl fumarate > 2 units/day
- ☐ Extavia (interferon beta-1b)
- ☐ fingolimod capsule > 1 unit/day
- ☐ Kesimpta (ofatumumab prefilled syringe)
- ☐ Lemtrada (alemtuzumab)[MB]
- ☐ Mavenclad (cladribine tablet)
- ☐ Mayzent (siponimod)
- ☐ Ocrevus (ocrelizumab)
- ☐ Plegridy (peginterferon beta-1a)
- ☐ Ponvory (ponesimod)
- ☐ Tascenso ODT (fingolimod orally disintegrating tablet)
- ☐ teriflunomide > 1 unit/day
- ☐ Vumerity (diroximel fumarate)
- ☐ Zeposia (ozanimod)

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Clinically Isolated Syndrome (CIS)
- ☐ Multiple Sclerosis (MS)
  - Subtype ☐ relapsing-remitting (RR) ☐ primary progressive (PP) ☐ non-active secondary progressive (SP)
    ☐ active SP (member has had a relapse in the past two years)
- ☐ Other (Please indicate.)

Is the prescriber a neurologist?

- ☐ Yes
- ☐ No. Please attach consultation notes from a neurologist addressing the use of the requested agent.

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Is this member a referral candidate for care coordination? ☐ Yes ☐ No
If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial.

Section I. Please complete for requests for Lemtrada.

Has the member had trials with two of the following agents: Briumvi or Ocrevus, dimethyl fumarate or Vumerity, fingolimod capsule, glatiramer, interferon formulations, teriflunomide, or Tysabri?

☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XIII below.*

☐ No. Please describe why the member is not a candidate for these agents.

Section II. Please complete for requests for Ocrevus for CIS, RRMS, and active SPMS.

Has the member had a trial with Briumvi?

☐ Yes. Please list the drug name, dates/duration of use, and outcomes in Section XIII below.*

☐ No. Please describe why the member is not a candidate for Briumvi.

Section III. Please complete for requests for dalfampridine.

Is the medication requested to improve walking distance in a member with multiple sclerosis?

☐ Yes

☐ No. Please describe the clinical rationale for using the requested medication below.

Section IV. Please complete for requests for Mayzent, Ponvory and Zeposia.

1. Please provide medical necessity for use instead of fingolimod capsule.
2. Has the member had a trial with one of the following agents: Briumvi or Ocrevus, dimethyl fumarate or Vumerity, glatiramer, interferon formulations, or teriflunomide?

   ☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XIII below.*

   ☐ No. Please describe why the member is not a candidate for these agents.
3. For requests for Mayzent, please indicate CYP2C9 genotype.

   ☐ *1/*1 ☐ *1/*2 ☐ *1/*3 ☐ *2/*2 ☐ *2/*3 ☐ *3/*3 ☐ Other

Section V. Please complete for requests for Kesimpta.

Has the member had trials with two of the following agents: Briumvi or Ocrevus, dimethyl fumarate or Vumerity, fingolimod capsule, glatiramer, interferon formulations, teriflunomide, or Tysabri?

☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XIII below.*

☐ No. Please describe why the member is not a candidate for these agents.

Section VI. Please complete for requests for Extavia.

Please provide medical necessity for use instead of Betaseron (interferon beta-1b).

over

Section VII. Please complete for requests for Plegridy.

1. Please provide medical necessity for use instead of interferon beta-1a (Avonex, Rebif).

2. Has the member had a trial with one of the following agents: Briumvi or Ocrevus, dimethyl fumarate or Vumerity, fingolimod capsule, glatiramer, Lemtrada, teriflunomide, or Tysabri?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes in Section XIII below.*
   ☐ No. Please describe why the member is not a candidate for these agents.

Section VIII. Please complete for requests for fingolimod capsule.

Please indicate: Member's current weight _____ Date _____

Section IX. Please complete for requests for Mavenclad.

Has the member had trials with three of the following agents: Briumvi or Ocrevus, dimethyl fumarate or Vumerity, fingolimod capsule or Mayzent, glatiramer, interferon formulations, teriflunomide, or Tysabri?
☐ Yes. Please list the drug names, dates/duration of use, and outcomes in Section XIII below.*
☐ No. Please describe why the member is not a candidate for these agents.

Section X. Please complete for requests for Bafiertam and Vumerity.

1. Please provide medical necessity for use instead of dimethyl fumarate.

2. For requests for Bafiertam, please provide medical necessity for use instead of Vumerity.

Section XI. Please complete for requests for Tascenso ODT.

1. Please indicate: Member's current weight _____ Date _____
2. Please provide medical necessity for use instead of fingolimod capsule.

Section XII. Please complete for all requests exceeding quantity limits.

Please describe the medical necessity for using the requested agent above the quantity limit.

over

Section XIII. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

_____

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

_____

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

_____

* *Please attach a letter documenting additional trials as necessary*

Section XIV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

   _____

   _____

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

   _____

   _____

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

   _____

   _____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details. _____

   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Narcolepsy and Miscellaneous Sleep Disorder Therapy Agents Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ armodafinil > 1 unit/day
- ☐ modafinil 100 mg > 1.5 unit/day
- ☐ modafinil 200 mg > 2 units/day
- ☐ sodium oxybate
- ☐ Sunosi (solriamfetol)
- ☐ tasimelteon
- ☐ Wakix (pitolisant)
- ☐ Xywav (calcium oxybate/ magnesium oxybate/potassium oxybate/sodium oxybate)

Dose and frequency of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Cataplexy associated with narcolepsy
- ☐ Idiopathic hypersomnia
- ☐ Excessive daytime sleepiness (EDS) associated with narcolepsy
- ☐ EDS associated with obstructive sleep apnea (OSA)
- ☐ Non-24-hour sleep-wake disorder
- ☐ Smith-Magenis Syndrome (SMS)
- ☐ Other (Please specify.)

Please indicate prescriber specialty below.

☐ Neurology ☐ Sleep ☐ Other (Please specify.)

If prescriber is not a specialist, please attach consult notes from a specialist.

Section I. Please complete for sodium oxybate, Sunosi, Wakix, and Xywav for the diagnosis of narcolepsy. Please also complete Section IV or V below as appropriate.

Has the member had a sleep study (polysomnogram or multiple sleep latency test) that diagnosed narcolepsy?

☐ Yes. Please include medical records with submission.

☐ No. Please explain why this member has not had a sleep study or why treatment is required when sleep study did not document narcolepsy.

Section II. Please complete for Sunosi for the diagnosis of EDS associated with OSA.

1. Has the member had a sleep study (polysomnogram) that diagnosed obstructive sleep apnea?
   ☐ Yes. Please include medical records with submission. ☐ No
2. Is the member utilizing CPAP/BiPAP, an oral appliance, or has undergone successful surgical treatment for OSA?
   ☐ Yes. Please include medical records with submission.
   ☐ No. Please explain why this member is not utilizing CPAP/BiPAP, an oral appliance, or surgical treatment for OSA.

3. For Sunosi, has the member tried modafinil or armodafinil for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes In Section VII below.
   ☐ No. Please describe clinical rationale why modafinil and armodafinil are not appropriate for this member.

Section III. Please complete for requests for the diagnosis of non-24-hour sleep-wake disorder and SMS.

For the diagnosis of non-24-hour sleep-wake disorder, please complete questions 1 and 2. For SMS, complete questions 1 and 3.

1. Has the member tried melatonin for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   ☐ No. Please describe clinical rationale why melatonin is not appropriate for this member.
2. Is the member totally blind? ☐ Yes ☐ No
3. For tasimelteon suspension, please provide medical necessity for use instead of the capsule formulation.

Section IV. Please also complete for requests for sodium oxybate, Sunosi, Wakix, and Xywav for a diagnosis of EDS associated with narcolepsy. Please complete Section I above as appropriate.

1. Has the member tried modafinil or armodafinil for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   ☐ No. Please describe clinical rationale why modafinil and armodafinil are not appropriate for this member.
2. Has the member tried a cerebral stimulant for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   ☐ No. Please describe clinical rationale why cerebral stimulants are not appropriate for this member.
3. For Sunosi, will the requested medication be used in combination with other stimulants or stimulant-like agents?
   ☐ Yes. Please describe clinical rationale for combination therapy with other stimulants or stimulant-like agents.
   ☐ No.
4. For Wakix, has the member tried Sunosi for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   ☐ No. Please describe the clinical rationale why Sunosi is not appropriate for this member.
5. For Wakix, has the member tried sodium oxybate for the treatment of this condition?*
   ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   ☐ No. Please describe the clinical rationale why sodium oxybate is not appropriate for this member.
6. For Xywav, please describe clinical rationale why sodium oxybate is not appropriate for this member.
   ☐ Yes. Please explain.
   ☐ No

over

Section V. Please also complete for requests for sodium oxybate, Wakix, and Xywav for a diagnosis of cataplexy associated with narcolepsy. Please complete Section I above as appropriate.

1. Has the member tried atomoxetine, a selective serotonin reuptake inhibitor (SSRI), tricyclic antidepressant (TCA), or venlafaxine for the treatment of this condition?*
   - ☐ Yes. Please list the drug name, dates of trials and outcomes In Section VII below.
   - ☐ No. Please describe clinical rationale why SSRIs, TCAs, and venlafaxine are not appropriate for this member.
2. For Wakix, has the member tried sodium oxybate or Xywav for the treatment of this condition?*
   - ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   - ☐ No. Please describe the clinical rationale why sodium oxybate and Xywav are not appropriate for this member.
3. For Xywav, is there clinical rationale for use instead of sodium oxybate for the treatment of this condition?*
   - ☐ Yes. Please explain.
   - ☐ No

Section VI. Please also complete for requests for sodium oxybate and Xywav for a diagnosis of idiopathic hypersomnia.

1. Has the member had a polysomnogram ruling out other causes of hypersomnia?
   - ☐ Yes. Please include medical records with submission.
   - ☐ No. Please explain why not.
2. Has the member had a multiple sleep latency test?
   - ☐ Yes. Please include medical records with submission.
   - ☐ No. Please explain why not.
3. Does the member have hypersomnia due to another medical, behavioral, or psychiatric disorder?
   - ☐ Yes. Please explain.
   - ☐ No.
4. Please attach a current medication list. Is the member currently utilizing a drug that can cause excessive daytime sleepiness?
   - ☐ Yes. Please explain.
   - ☐ No.
5. Has the member tried a cerebral stimulant for the treatment of this condition?*
   - ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   - ☐ No. Please describe clinical rationale why cerebral stimulants are not appropriate for this member.
6. Has the member tried modafinil or armodafinil for the treatment of this condition?*
   - ☐ Yes. Please list the drug name, dates of trials and outcomes in Section VII below.
   - ☐ No. Please describe clinical rationale why modafinil and armodafinil are not appropriate for this member.
7. For Xywav, is there clinical rationale for use instead of sodium oxybate for the treatment of this condition?*
   - ☐ Yes. Please explain.
   - ☐ No

over

Section VII. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug _____ Dates of use _____

☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

_____

Drug _____ Dates of use _____

☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

_____

Drug _____ Dates of use _____

☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

_____

Section VIII. Please complete for requests for quantities above quantity limits.

Please describe medical necessity for exceeding the quantity limits.

_____

_____

Section IX. Please complete for requests for concomitant use of modafinil and armodafinil.

Please describe medical necessity for concomitant use of modafinil and armodafinil.

_____

_____

Section X. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

   _____

   _____

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

   _____

   _____

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

over

If yes, please provide details for the previous trial.

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

_____

_____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details. _____

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Neuromuscular Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Amondys 45 (casimersen)
- ☐ Elevidys (delandistrogene moxeparvovec-rokl) [MB]
- ☐ Evrysdi (risdiplam)
- ☐ Exondys 51 (eteplirsen)
- ☐ Spinraza (nusinersen) [MB]
- ☐ Viltepso (viltolarsen)
- ☐ Vyondys 53 (golodirsen)
- ☐ Zolgensma (onasemnogene abeparvovec-xioi) [MB]

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Duchenne muscular dystrophy (DMD)
- ☐ Other
- ☐ Spinal muscular atrophy (SMA)
  - ☐ pre-symptomatic ☐ symptomatic
  - Type

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Member's current weight Date

Is the member stabilized on the requested medication? ☐ Yes. Please provide start date. ☐ No

Section I. Please complete for Amondys 45, Exondys 51, Viltepso, and Vyondys 53 requests.

For initial requests, please complete questions 1 through 10. For recertification requests, please complete questions 3, 6, 8, 9 and 10.

1. Please attach laboratory testing results of a confirmed out-of-frame deletion in the DMD gene that is amenable to either exon 45 skipping (for Amondys 45 requests), exon 51 skipping (for Exondys 51 requests) or exon 53 skipping (for Viltepso and Vyondys 53 requests).
2. Is the prescriber a neuromuscular neurologist? ☐ Yes ☐ No. If no, please attach consultation notes from a neuromuscular neurologist addressing the use of the requested agent.

3. Is the member ambulatory as defined by a current six-minute walk test (6MWT-distance walked in six minutes in meters) of ≥ 200 meters?
   Please note, the test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.

   ☐ Yes. Distance _____ meters ☐ No

   Date of performance _____ Treatment at the time of test _____
4. For Amondys 45, Exondys 51 and Vyondys 53 requests, has the member received a corticosteroid for at least six months prior to use with the requested agent?
   ☐ Yes. Please list the drug name, dose and frequency, and dates of use below.

   Drug name _____ Dose and frequency _____ Dates of use _____

   ☐ No. Please explain. _____
5. For Viltepso requests, has the member received a corticosteroid for at least three months prior to use with the requested agent?
   ☐ Yes. Please list the drug name, dose and frequency, and dates of use below.

   Drug name _____ Dose and frequency _____ Dates of use _____

   ☐ No. Please explain. _____
6. Will the member be taking the requested agent concurrently with a corticosteroid?
   ☐ Yes. Please document drug name with dose and frequency below.

   Drug name _____ Dose and frequency _____

   ☐ No. Please explain. _____
7. Please provide dates and measurements and attach medical records of baseline measurements for each of the following five timed function tests: timed 10-meter walk/run, timed floor (supine) to stand, timed four-step descend, timed four-step climb, timed sit to stand. Medical records must include the times in seconds, dates of performances, and treatment at the time of tests. Please note, the test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.

   Timed 10-meter walk/run (time in seconds) _____

   Date of performance _____ Treatment at the time of test _____

   Timed floor (supine) to stand (time in seconds) _____

   Date of performance _____ Treatment at the time of test _____

   Timed four-step descend (time in seconds) _____

   Date of performance _____ Treatment at the time of test _____

   Timed four-step climb (time in seconds) _____

   Date of performance _____ Treatment at the time of test _____

   Timed sit to stand (time in seconds) _____

   Date of performance _____ Treatment at the time of test _____

over

8. Please provide dates and measurements and attach medical records of all previous and current six-minute walk tests (6MWTs). Please note, the current test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.
   Baseline 6MWT
   Distance _____ meters
   Date of performance _____ Treatment at the time of test _____
   Current 6MWT
   Distance _____ meters
   Date of performance _____ Treatment at the time of test _____
   Additional 6MWT(s)
   Date(s) of performance _____
9. Please provide dates and measurements and attach medical records of current measurements for each of the following five timed function tests: timed 10-meter walk/run, timed floor (supine) to stand, timed four-step descend, timed four-step climb, timed sit to stand. Medical records must include the times in seconds, dates of performances, and treatment at the time of tests. Please note, the test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.
   Timed 10-meter walk/run (time in seconds) _____
   Date of performance _____ Treatment at the time of test _____
   Timed floor (supine) to stand (time in seconds) _____
   Date of performance _____ Treatment at the time of test _____
   Timed four-step descend (time in seconds) _____
   Date of performance _____ Treatment at the time of test _____
   Timed four-step climb (time in seconds) _____
   Date of performance _____ Treatment at the time of test _____
   Timed sit to stand (time in seconds) _____
   Date of performance _____ Treatment at the time of test _____
10. Has the member previously received treatment with a gene therapy for DMD? ☐ Yes ☐ No

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Section II. Please complete for Evrysdi and Spinraza requests.

1. Please attach a copy of genetic test(s) confirming the diagnosis of SMA and SMN2 copy number.
2. Is the member symptomatic? ☐ Yes ☐ No
3. Is the member a pre-symptomatic infant diagnosed via newborn screening? ☐ Yes ☐ No
4. Is the prescriber a neurologist? ☐ Yes ☐ No. If no, please attach consultation notes from a neurologist addressing the use of the requested agent.
5. Please attach documentation of current motor function test.
6. Will the requested agent be used in combination with other agents for SMA?
   ☐ Yes. Please provide drug name(s). _____
   ☐ No

over

7. For initial and recertification requests, does the member have evidence of permanent ventilator, defined as any of the following?
   Member has an endotracheal tube ☐ Yes ☐ No
   Member has a tracheotomy tube ☐ Yes ☐ No
   Member has at least 14 days of continuous respiratory assistance for at least 16 hours per day ☐ Yes ☐ No
8. Has the member been previously treated with any other SMA agent? ☐ Yes ☐ No
   If yes, please list the drug names and outcomes below.
   Drug name _____ ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   _____
9. For members previously treated with another SMA agent, please attach documentation of pre-treatment baseline motor function tests and post-treatment motor function tests.
10. For members previously treated with Zolgensma, please attach pre-Zolgensma baseline motor function test (if different than the pre-treatment tests) and post-treatment motor function tests.
11. For recertification requests, please attach medical records documenting positive response to therapy (e.g., follow up information on motor function tests and/or member's improvement or stability of function).

Section III. Please complete for Zolgensma requests.

Please note, questions 7, 8, and 9 will not impact the outcome of review for approval of Zolgensma.

1. Please attach a copy of the genetic test confirming diagnosis of SMA and number of copies of SMN2 gene.
2. Is the prescriber a neuromuscular specialist? ☐ Yes ☐ No. If no, please attach the consultation notes from a neuromuscular specialist addressing the use of the requested agent.
3. Please attach a copy of baseline AAV9 antibody test.
4. Pre-treatment baseline Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) score. _____
5. Does the member have evidence of complete paralysis of limbs? ☐ Yes ☐ No
6. Does the member have evidence of permanent ventilator dependence at the time Zolgensma is to be administered, defined as any of the following?
   Member has an endotracheal tube ☐ Yes ☐ No
   Member has a tracheotomy tube ☐ Yes ☐ No
   Member has at least 14 days of continuous respiratory assistance for at least 16 hours per day ☐ Yes ☐ No
7. Has the member had a trial with Spinraza? ☐ Yes ☐ No
   If yes, please list the dose and frequency, dates of use, outcome, and treatment plan below.
   Dose and frequency _____ Dates of use _____
   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   _____
   Will the member continue Spinraza after Zolgensma? ☐ Yes ☐ No
8. Has the member had a trial with Evrysdi? ☐ Yes ☐ No
   If yes, please list the dose and frequency, dates of use, outcome, and treatment plan below.
   Dose and frequency _____ Dates of use _____
   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   _____

over

Will the member continue Evrysdi after Zolgensma? ☐ Yes ☐ No

9. Please describe the functional tests that will be used to monitor this member and attach medical records with baseline functional test scores.
10. Has the member previously received treatment with a gene therapy for DMD? ☐ Yes ☐ No
11. Does the member have an active viral infection, including human immunodeficiency virus (HIV) or positive serology for hepatitis B or C, or Zika virus? ☐ Yes ☐ No

Section IV. Please complete for Elevidys requests.

1. Please attach a copy of genetic test with a confirmed mutation in the DMD gene.
2. Please attach a copy of baseline anti-AAVrh74 total binding antibody titers < 1:400.
3. Will the infusion take place in a qualified treatment center? ☐ Yes ☐ No
4. Please provide anticipated date of administration.
5. Is the prescriber a neuromuscular specialist? ☐ Yes ☐ No
6. Does the member have any deletion in exon 8 or exon 9 of the DMD gene? ☐ Yes ☐ No
7. Is the member on a stable dose of corticosteroid? ☐ Yes ☐ No
8. Will the member continue to utilize chronic corticosteroids after Elevidys infusion? ☐ Yes ☐ No
9. Does the member have a contraindication to corticosteroids? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication.
10. Has the member been previously treated with a gene therapy for DMD? ☐ Yes ☐ No
11. Is the member currently utilizing antisense oligonucleotides? ☐ Yes ☐ No
12. Has the member had a baseline measurement for the North Star Ambulatory Assessment (NSAA)?
    ☐ Yes. Please attach medical records of NSAA, including scores and times on individual items. ☐ No
13. Is the member ambulatory as defined by a current 6MWT of ≥ 200 meters?
    Please note, the test must have been observed or completed by the treating provider or ordered by the treating provider and completed by a qualified medical practitioner.

    ☐ Yes. Distance meters ☐ No

    Date of performance Treatment at the time of test
14. Please provide dates and measurements and attach medical records of all previous and current six-minute walk tests (6MWTs). Please note, the current test must have been observed or completed by the treating provider, or ordered by the treating provider and completed by a qualified medical practitioner.

    Baseline 6MWT

    Distance meters

    Date of performance Treatment at the time of test

    Current 6MWT

    Distance meters

    Date of performance Treatment at the time of test

    Additional 6MWT(s)

    Date(s) of performance

over

Section V. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details.

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Nonsteroidal Anti-Inflammatory Drugs (NSAID) Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested (Check one or all that apply. Where applicable, the brand name is provided in brackets for reference.)

- ☐ diclofenac 25 mg capsule
- ☐ diclofenac/misoprostol < 60 years of age
- ☐ diclofenac potassium 25 mg tablet
- ☐ diclofenac powder for solution
- ☐ diclofenac topical patch [Flector]
- ☐ Elyxyb (celecoxib oral solution)
- ☐ etodolac extended-release
- ☐ fenoprofen
- ☐ ibuprofen/famotidine < 60 years of age
- ☐ indomethacin suppository
- ☐ indomethacin suspension
- ☐ ketoprofen extended-release
- ☐ ketorolac > 20 units/30 days
- ☐ ketorolac nasal spray
- ☐ Licart (diclofenac topical patch)
- ☐ meclofenamate
- ☐ meloxicam capsule
- ☐ naproxen controlled-release
- ☐ naproxen suspension < 13 years of age
- ☐ naproxen/esomeprazole < 60 years of age
- ☐ Relafen DS (nabumetone 1000 mg)
- ☐ salsalate
- ☐ tolmetin
- ☐ Other*

Dose, frequency, and duration of medication requested

Indication or ICD-10 code, if applicable

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Section I. Please complete for topical product requests.

1. Has the member tried diclofenac 1% gel?
   - ☐ Yes. Please complete Section IV.
   - ☐ No. Please indicate why not.
2. For Licart requests, has the member tried diclofenac topical patch (generic Flector)?
   - ☐ Yes. Please complete Section IV.
   - ☐ No. Please indicate why not.

Section II. Please complete for controlled-release products, extended-release products, solution products, orally disintegrating products, suspension products, and suppositories.

1. Please provide medical necessity for the use of the requested formulation.

2. For indomethacin suspension and naproxen suspension products, has the member tried ibuprofen suspension?
   ☐ Yes. Please complete Section IV.
   ☐ No. Please indicate why not.
3. For diclofenac powder for solution, has the member tried naproxen suspension?
   ☐ Yes. Please complete Section IV.
   ☐ No. Please indicate why not.
4. For Elyxyb, has the member tried celecoxib capsules?
   ☐ Yes. Please complete Section IV.
   ☐ No. Please indicate why not.
5. For indomethacin suppositories, has the member tried ibuprofen suppositories?
   ☐ Yes. Please complete Section IV.
   ☐ No. Please indicate why not.

Section III. Please complete for diclofenac/misoprostol, ibuprofen/famotidine, ketorolac nasal spray, naproxen/esomeprazole, and Relafen DS requests.

Please attach medical records/office notes documenting medical necessity. A trial with concurrent therapy of diclofenac and misoprostol is required for diclofenac/misoprostol requests. A trial of ketorolac tablets or injection is required for ketorolac nasal spray requests. A trial with concurrent therapy of ibuprofen and famotidine is required for ibuprofen/famotidine requests. A trial with concurrent therapy of naproxen and omeprazole is required for naproxen/esomeprazole requests. A trial of an equivalent dose of nabumetone 500 mg or 750 mg is required for Relafen DS requests.

Section IV. Please complete for all requests as needed.

Please provide the following information regarding previous NSAID trials.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Details of adverse reaction, inadequate response, or other.

** Please attach a letter documenting additional trials as necessary.*

over

Section V. Please complete for ketorolac requests exceeding the quantity limit.

Please describe the medical necessity for exceeding the quantity limit.

Section VI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

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Printed name of prescribing provider Date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Oncology Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Please note: Chimeric Antigen Receptor (CAR)-T Immunotherapies and Prostate Cancer Agents have specific PA Request forms that contain information pertinent to these medication classes. For these agents, please see more drug-specific PA forms within the MassHealth Drug List at **www.mass.gov/druglist.**

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Drug name

Dose and frequency

Height Weight Date

Indication or ICD-10 code, if applicable **Duration of therapy**

Please indicate prescriber specialty below.

☐ Hematology ☐ Oncology ☐ Other

Please list all other medications currently prescribed for the member for this indication.

Section I. Please complete for all requests.

1. Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
   Drug NDC (if known) or service code
2. Please describe the cancer type, histology, and any pertinent mutations as applicable.
3. Please describe the stage and severity of disease, including status of metastases as applicable.
4. Please list any other prior trials. Please list the drug names, dates/duration of use and outcomes below.*
   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

Drug _____ Dates/duration _____ ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug _____ Dates/duration _____ ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

5. For requests for agents with a preferred alternative, please describe clinical rationale for use of the requested agent instead of the preferred alternative.
6. Has the member had persistent or recurring disease following surgery and/or radiation therapy? ☐ Yes ☐ No
7. Is the member a candidate for surgery and/or radiation?

   ☐ Yes ☐ No. Please describe.

** Please attach a letter documenting additional trials as necessary.*

Section II. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit, including a detailed treatment plan.

Section III. Please complete for requests for solution and suspension dosage formulations.

Please provide medical necessity for the use of the requested dosage formulation.

Section IV. Please include any other pertinent information (if needed).

Section V. Please complete for all requests for non-preferred drug products if one or more preferred drug products have been designated for this class of drugs.

If one or more preferred drug products have been designated for this class of drugs, and if you are requesting PA for a non-preferred drug product, please provide medical necessity for prescribing the non-preferred drug product rather than the preferred drug product.

over

Section VI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Ophthalmic Anti-Allergy and Anti-Inflammatory Agents Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Ophthalmic Anti-Allergy Agents (Section I)

- ☐ Zerviate (cetirizine ophthalmic solution)

Ophthalmic Corticosteroids (Section III)

- ☐ Eysuvis (loteprednol 0.25% suspension)
- ☐ Inveltys (loteprednol 1% suspension)
- ☐ Lotemax SM (loteprednol 0.38% gel)

Ophthalmic Non-Steroidal Anti-Inflammatory Agents (Section II)

- ☐ bromfenac 0.075%
- ☐ bromfenac 0.09%
- ☐ Ilevro (nepafenac 0.3% ophthalmic solution)
- ☐ Cequa (cyclosporine 0.09% ophthalmic solution) (Section IV)

Miscellaneous

- ☐ Miebo (perfluorohexyloctane) (Section IV)
- ☐ Restasis Multidose (cyclosporine multidose 0.05% ophthalmic emulsion) (Section IV)
- ☐ Tyrvaya (varenicline nasal spray) (Section IV)
- ☐ Verkazia (cyclosporine 0.1% ophthalmic emulsion) (Section V)
- ☐ Vevye (cyclosporine 0.1% ophthalmic solution) (Section VI)
- ☐ Xdemvy (lotilaner)
- ☐ Xiidra (lifitegrast) (Section IV)

Other Medication

- ☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose, frequency, and duration of medication requested _____

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Allergic conjunctivitis (seasonal or perennial)
- ☐ Demodex Blepharitis
- ☐ Keratoconjunctivitis sicca
- ☐ Post-operative pain and/or inflammation following ocular surgery
- ☐ Vernal conjunctivitis and/or vernal keratitis
- ☐ Other (Please indicate.) _____

Symptoms and symptom frequency _____

Section I. Please complete for Zerviate requests.

For members ≥ two to < three years of age, please complete question 1. For members ≥ three years of age, please complete question 2. For members with diagnosis of vernal keratoconjunctivitis or atopic keratoconjunctivitis please complete question 3 if member is ≥ two to < three years of age, and question 4 if member is ≥ three years of age.

1. Has the member had a trial with two of the following: Alomide, bepotastine, epinastine, Lastacaft, or olopatadine ophthalmic solution?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

2. Has the member had a trial with two of the following: Alomide, azelastine ophthalmic solution,bepotastine, epinastine, ketotifen, or olopatadine ophthalmic solution?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

3. Has the member had a trial with one of the following: bepotastine, epinastine, or olopatadine ophthalmic solution?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

4. Has the member had a trial with one of the following: azelastine ophthalmic solution, epinastine, ketotifen, or olopatadine ophthalmic solution?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

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Section II. Please complete for all requests for ophthalmic non-steroidal anti-inflammatory agents.

Has the member had a trial with ophthalmic diclofenac, flurbiprofen, ketorolac, or nepafenac 0.1%?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

Section III. Please complete for all requests for ophthalmic corticosteroids.

1. For Eysuvis, has the member had a trial with a topical corticosteroid for ophthalmic use that is available without prior authorization?

   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name Dates/duration of trial

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain if there is a contraindication to this trial.

2. For Eysuvis, has the member had a trial with cyclosporine 0.05% ophthalmic emulsion?

   ☐ Yes. Please list the dates/duration of trials and outcomes.* Dates/duration of trial

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain if there is a contraindication to this trial.

   For Inveltys and Lotemax SM, has the member had a trial with loteprednol 0.5% suspension, gel or ointment?

   ☐ Yes. Please list the dates/duration of trials and outcomes.* Dates/duration of trial

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain if there is a contraindication to this trial.

Section IV. Please complete for all requests for Cequa, Miebo, Restasis Multidose, Tyrvaya, and Xiidra.

1. Has the member had a trial with cyclosporine 0.05% ophthalmic emulsion?

   ☐ Yes. Please list the dates/duration of trials and outcomes.* Dates/duration of trial

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain if there is a contraindication to this trial.

over

2. For Restasis Multidose, please provide medical necessity for the use of the requested formulation instead of cyclosporine 0.05% ophthalmic emulsion (single use vial formulation).

3. For Miebo and Tyrvaya, has the member had a trial with Xiidra?

☐ Yes. Please list the dates/duration of trials and outcomes.* Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to this trial.

Section V. Please complete for all requests for Verkazia.

1. Has the member had a trial with ophthalmic azelastine, epinastine, ketotifen, or olopatadine?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to these trials.

2. Has the member had a trial with a topical corticosteroid for ophthalmic use?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of trial

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain if there is a contraindication to this trial.

* Please attach a letter with additional information regarding medication trials as applicable.

Section VI. Please complete for all requests for Vevye.

1. Has the member had a trial with ophthalmic cyclosporine 0.05% emulsion?

☐ Yes. Please list dates/duration of use and outcomes below.*

Dates/duration of trial Outcome

☐ No. Please document if there is a contraindication to ophthalmic cyclosporine 0.05% emulsion.

2. Has the member had a trial with ophthalmic cyclosporine 0.09% emulsion?

☐ Yes. Please list dates/duration of use and outcomes below.*

Dates/duration of trial Outcome

☐ No. Please document if there is a contraindication to ophthalmic cyclosporine 0.09% emulsion.

over

3. Has the member had a trial with Tyrvaya?
   ☐ Yes. Please list dates/duration of use and outcomes below.*
   Dates/duration of trial _____ Outcome _____
   ☐ No. Please document if there is a contraindication to Tyrvaya.
   _____
4. Has the member had a trial with Xiidra?
   ☐ Yes. Please list dates/duration of use and outcomes below.*
   Dates/duration of trial _____ Outcome _____
   ☐ No. Please document if there is a contraindication to Xiidra.
   _____

* Please attach a letter with additional information regarding medication trials as applicable.

Section VII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
   _____
   _____
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
   _____
   _____
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details. _____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Opioid Dependence and Reversal Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Brixadi (buprenorphine extended-release injection)

☐ buprenorphine sublingual tablet ☐ 2 mg ☐ 8 mg

☐ buprenorphine/naloxone film ☐ 2 mg/0.5 mg ☐ 4 mg/1 mg ☐ 8 mg/2 mg ☐ 12 mg/3 mg

☐ buprenorphine/naloxone sublingual tablet ☐ 2 mg/0.5 mg ☐ 8 mg/2 mg

☐ Lifems (naloxone syringe kit)

☐ lofexidine

☐ Opvee (nalmefene nasal spray)

☐ Zubsolv (buprenorphine/naloxone sublingual tablet) ☐ 0.7 mg/0.18 mg ☐ 1.4 mg/0.36 mg ☐ 2.9 mg/0.71 mg ☐ 5.7 mg/1.4 mg ☐ 8.6 mg/2.1 mg ☐ 11.4 mg/2.9 mg

Dose, frequency, and duration of medication requested

For all requests for medications containing buprenorphine, is the member maintained on the lowest effective dose?

☐ Yes ☐ No. If no, please provide complete treatment plan.

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Management of opioid withdrawal symptoms ☐ Opioid overdose prevention/reversal

☐ Opioid dependence ☐ Other

Section I. Please complete for all requests.

1. Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
2. Drug NDC (if known) or service code
3. Has the prescriber evaluated the Massachusetts Prescription Awareness Tool (MassPAT) data? ☐ Yes ☐ No
4. Is this member a referral candidate for care coordination? ☐ Yes ☐ No
   If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial.

Section II. Please complete for buprenorphine tablet requests.

1. Is the member pregnant? ☐ Yes. Anticipated date of delivery ☐ No
2. Is the member breastfeeding? ☐ Yes ☐ No

3. Does the member have a documented allergy to naloxone? ☐ Yes ☐ No
   If yes, please provide medical records documenting the allergic reaction.
4. If you answered "No" to the three questions above, please provide medical necessity for prescribing buprenorphine rather than buprenorphine/naloxone. (Please explain below and provide medical records.)

Section III. Please complete for buprenorphine, buprenorphine/naloxone film, and buprenorphine/naloxone tablet doses exceeding 24 mg/day, and Zubsolv doses exceeding 17.2 mg/day.

Please document medical necessity for high dose of buprenorphine/naloxone and buprenorphine below and submit medical records supporting the medical necessity provided.

Section IV. Please complete for Zubsolv requests.

Has the member had an allergic reaction to buprenorphine/naloxone film?

☐ Yes. (Specify and provide medical records.)

☐ No. Please explain.

Section V. Please complete for lofexidine requests.

Has the member had a trial with oral clonidine?

☐ Yes. Please list the dose and frequency, dates/durations of use, and outcomes below.

Dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe clinical rationale why the member is not a candidate for oral clonidine.

Section VI. Please complete for Lifems requests.

Please document medical necessity for the convenience kit formulation, as it pertains to the caregiver.

Section VII. Please complete for Brixadi requests.

1. Has the member been initiated on treatment with a single dose of a transmucosal buprenorphine product or is already being treated with buprenorphine? ☐ Yes ☐ No
2. Has the member had a trial with Sublocade?
   ☐ Yes. Please describe the outcome. ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe the details of adverse reaction, inadequate response, or other.

over

☐ No. Please provide clinical rationale for use of the requested agent instead of Sublocade.

Section VIII. Please complete for Opvee requests.

Please provide medical necessity for use of a long-acting formulation for overdose reversal.

Section IX. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Opioids/Acetaminophen Analgesic
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about opioid and acetaminophen analgesic agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Drug name _____ **Dose and frequency** _____ **Duration of therapy** _____

Indication or ICD-10 code, if applicable _____

Has the prescriber evaluated Massachusetts Prescription Awareness Tool (MassPAT) data, risk factors, and potential risk factors for abuse/misuse in their assessment of this member? ☐ Yes ☐ No

Has the member been offered and/or given a prescription for naloxone treatment?

☐ Yes ☐ No. Please provide details. _____

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician. _____

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health service would be beneficial.

_____

Section I. Please complete for oxycodone extended-release (ER) tablet (Oxycontin) requests.*

Has the member tried a morphine extended-release product or a fentanyl transdermal product?

☐ Yes. Drug _____ Dose and frequency _____

Dates of use _____ Outcome _____

☐ No. If morphine and fentanyl transdermal are contraindicated in this member, please describe. _____

_____

Section II. Please complete for methadone (Dolophine, Methadose) requests.*

1. Has the member tried a morphine extended-release product?

   ☐ Yes. Dose and frequency _____ Dates of use _____ Outcome _____

   ☐ No. If morphine is contraindicated in this member, please describe. _____

   _____

2. Has the member tried a fentanyl transdermal product?

   ☐ Yes. Dose and frequency _____ Dates of use _____ Outcome _____

☐ No. If fentanyl transdermal is contraindicated in this member, please describe.

3. If the answer to questions 1 and 2 is no, please provide clinical rationale for the use of methadone instead of other long-acting opioids.
4. Is the member opioid naive? ☐ Yes ☐ No
5. Has the member had a baseline ECG showing a normal QTc interval? ☐ Yes ☐ No

---

Section III. Please complete for requests for fentanyl transmucosal system (Actiq), fentanyl buccal tablet (Fentora), oxymorphone immediate-release (IR), and tapentadol (Nucynta).*

1. Is the member currently maintained on a long-acting opioid regimen?

   ☐ Yes. Drug Dose and frequency Dates of use

   ☐ No
2. Has the member tried the following agents? ☐ Yes. Please describe below.

   hydromorphone IR Dose and frequency Dates of use Outcome

   morphine IR Dose and frequency Dates of use Outcome

   oxycodone IR Dose and frequency Dates of use Outcome

   ☐ No. If hydromorphone, morphine, and oxycodone are contraindicated in this member, please describe.
3. If the request is for fentanyl buccal tablet, has the member tried fentanyl transmucosal system (Actiq)?

   ☐ Yes. Dose and frequency Dates of use Outcome

   ☐ No. If fentanyl transmucosal system (Actiq) is contraindicated in this member, please describe.

Section IV. Please complete for requests for hydrocodone ER (Hysingla ER), hydrocodone ER capsule, hydromorphone ER, levorphanol tablet, oxycodone ER capsule (Xtampza), oxymorphone ER, and tapentadol ER (Nucynta ER).*

1. Has the member tried the following agents? ☐ Yes. Please describe below.

   fentanyl transdermal Dose and frequency Dates of use Outcome

   morphine ER Dose and frequency Dates of use Outcome

   oxycodone ER Dose and frequency Dates of use Outcome

   ☐ No. If fentanyl transdermal, morphine ER, and oxycodone ER are contraindicated in this member, please describe.
2. For levorphanol tablet requests, please provide clinical rationale for the use of levorphanol instead of other long-acting opioids.

Section V. Please complete for morphine ER capsule requests.*

1. Has the member tried morphine extended-release tablets?

   ☐ Yes. Dose and frequency Dates of use Outcome

over

☐ No. If morphine extended-release tablets are contraindicated in this member or there is medical necessity for the requested formulation, please describe.

2. Please provide medical necessity for once daily dosing.

Section VI. Please complete for meperidine (Demerol) requests.

Please attach documentation describing medical necessity due to allergy to morphine.

Section VII. Please complete for requests for benzhydrocodone/acetaminophen, dihydrocodeine/acetaminophen/caffeine, hydrocodone/acetaminophen 300mg, hydrocodone 5 mg, 10 mg/ibuprofen, and oxycodone/acetaminophen 300mg.*

Please attach documentation of prior combination analgesic trials including hydrocodone/acetaminophen, oxycodone/acetaminophen, codeine/acetaminophen, and hydrocodone/ibuprofen.

Section VIII. Please complete for buprenorphine buccal film (Belbuca) requests.*

Has the member tried a morphine extended-release product?

☐ Yes. Dose and frequency Dates of use Outcome

☐ No. If morphine is contraindicated in this member or there is medical necessity for the requested formulation, please describe.

Section IX. Please complete for fentanyl transdermal 37.5, 62.5, 87.5 mcg/hr requests.*

Please provide medical necessity for use of requested formulation instead of other strengths.

Section X. Please complete for butorphanol nasal spray requests.

Please attach documentation describing an adverse reaction or contraindication to all other short-acting opioids, or medical necessity for nasal spray formulation in addition to an adverse reaction or contraindication to morphine and oxycodone IR solutions.

Section XI. Please complete for tramadol ER (Conzip) requests.

1. Please provide medical necessity for use of an extended-release formulation.
2. Please attach documentation describing an inadequate response or adverse reaction to tramadol IR.

Section XII. Please complete for Seglentis and tramadol/acetaminophen (Ultracet) requests.

Please provide medical necessity for use of the combination product instead of the separately available ingredients.

over

Section XIII. Please complete for tramadol 100 mg requests.

1. Please provide medical necessity for use of the requested strength.
2. Please attach documentation describing an inadequate response or adverse reaction to tramadol 50 mg at the requested dose.

Section XIV. Please complete for requests for codeine and tramadol products for members < 12 years of age.

Please provide clinical rationale for use of a codeine and tramadol-containing product in a member < 12 years of age.

Section XV. Please complete for tramadol solution requests.*

Is there a medical necessity for use of an oral solution formulation?

☐ Yes. Please explain.

☐ No. Please attach medical records documenting inadequate response or adverse reaction to a tramadol immediate-release tablet formulation that is available without PA.

Section XVI. Please complete for oliceridine (Olinvyk) [MB] requests.*

1. Is the total course of therapy limited to 48 hours? ☐ Yes ☐ No
2. Has the member tried the following agents? ☐ Yes. Please describe below.

   fentanyl injection Dose and frequency Dates of use Outcome

   hydromorphone injection Dose and frequency Dates of use Outcome

   morphine injection Dose and frequency Dates of use Outcome

   ☐ No. If fentanyl injection, hydromorphone injection, and morphine injection are contraindicated in this member, please describe.
3. Please indicate billing preference. ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.

   [MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Section XVII. Please complete for requests for duplicate short-acting or long-acting opioids.

Please provide clinical rationale for duplicate therapy including plan to consolidate therapy.

over

Section XVIII. Please complete for requests above established dose limits.

For all opioids, please provide medical records documenting treatment plan including clinical rationale for high dose and titration of medication up to current dose. In addition, please provide a signed and dated patient-prescriber agreement and a consult from a pain specialist recommending the requested dose for this member. If a current pain consult is not available, please provide the anticipated date of upcoming pain consult. If there are plans to initiate a taper of the requested medication within the next 90 days, please provide medical records documenting treatment plan. For acetaminophen and aspirin products, please provide a clinical rationale for the use above 4 grams per day. For ibuprofen products, please provide a clinical rationale for the use above 3.2 grams per day.

Section XIX. Please complete for requests for high dose short-acting opioids as monotherapy.

Please provide medical records documenting treatment plan including clinical rationale for use of high dose short-acting opioids without a long-acting opioid agent. In addition, please provide clinical rationale for high dose and titration of medication up to current dose, a signed and dated patient-prescriber agreement, and a consult from a pain specialist recommending the requested dose for this member.

Section XX. Please complete for requests above established quantity limits.

Can the requested dose be obtained by using products within established quantity limits (i.e., for oxycodone ER 20 mg, 2 tablets twice daily could be consolidated to one oxycodone ER 40 mg tablet twice daily)?

☐ Yes ☐ No. If dose consolidation is not an option, please explain why.

Section XXI. Please complete for concurrent therapy with opioid dependence agents.

1. Are you the prescriber of both buprenorphine/naloxone or buprenorphine and the opioid? ☐ Yes ☐ No
2. Prior to continuing buprenorphine/naloxone or buprenorphine therapy, will the member be discontinuing the opioid(s)? ☐ Yes ☐ No
3. Please document the medical necessity for concurrent buprenorphine/naloxone or buprenorphine and opioid therapy. Please submit medical records supporting the medical necessity, including the specific pain that the current opioid is being used to treat.
4. Please document the complete treatment plan, including expected duration of therapy for this member in regard to acute pain management with concurrent buprenorphine/naloxone or buprenorphine and opioid therapy.

**Attach a letter with additional information regarding medication trials as applicable. If MassHealth pharmacy claims history of required trials is not available, medical records documenting such trials may be required.*

over

Section XXII. Concomitant Opioid and Benzodiazepine Polypharmacy. Please complete information for medications requested and clinical rationale for polypharmacy with opioids and benzodiazepines [≥ 15 days supply for one or more opioid(s) who are newly starting opioid therapy and one or more benzodiazepine(s), excluding clobazam, nasal and rectal diazepam, nasal midazolam, and injectable formulations for ≥ 15 days supply within a 45-day period].

Please document the indication or ICD-10 code(s), if applicable, for the agents requested.

1. Opioid

Name/dose/frequency Indication

Name/dose/frequency Indication

Name/dose/frequency Indication

2. Benzodiazepine

Name/dose/frequency Indication

Name/dose/frequency Indication

Name/dose/frequency Indication

Please document clinical rationale for concomitant use of opioids and benzodiazepines for this member.

Please describe the ongoing treatment plan for continued use.

Has the member had trials with three non-opioid therapies?

☐ Yes. Drug name Dates Outcome

Drug name Dates Outcome

Drug name Dates Outcome

Other Dates Outcome

☐ No. Please document clinical rationale for the use of opioids instead of non-opioid alternatives.

Has consideration been given for possible taper of benzodiazepine or opioid?

☐ Yes. Please describe plan for taper and plan to reevaluate in the future.

☐ No. Please describe why taper is not possible at this time and plan to reevaluate in the future.

over

Has the member been offered and/or given a prescription for naloxone treatment?

☐ Yes ☐ No. Please provide details.

**Attach a letter with additional information regarding medication trials as applicable.*

Section XXIII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Oral Antibiotics and Anti-Infectives Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Aemcolo (rifamycin)
- ☐ amoxicillin/clavulanate extended-release
- ☐ Augmentin (amoxicillin/clavulanate 125/31.25 mg/5 mL suspension)
- ☐ azithromycin powder packet
- ☐ Baxdela (delafloxacin tablet)
- ☐ cefaclor extended-release
- ☐ cefaclor suspension
- ☐ cefadroxil tablet
- ☐ cefixime
- ☐ cefpodoxime suspension
- ☐ cephalexin 750 mg capsule
- ☐ ciprofloxacin 100 mg tablet
- ☐ clarithromycin extended-release
- ☐ Coartem (artemether/lumefantrine) > 24 units/365 days
- ☐ Dificid (fidaxomicin)
- ☐ Doryx (doxycycline hyclate delayed-release 60 mg tablet)
- ☐ doxycycline hyclate 50 mg tablet
- ☐ doxycycline hyclate 75 mg, 150 mg tablet
- ☐ doxycycline hyclate delayed-release 50 mg, 75 mg, 80 mg, 100 mg, 150 mg, 200 mg tablet
- ☐ doxycycline monohydrate 40 mg capsule
- ☐ doxycycline monohydrate 75 mg capsule
- ☐ doxycycline monohydrate 150 mg capsule
- ☐ doxycycline monohydrate 150 mg tablet
- ☐ Egaten (triclabendazole)
- ☐ Krintafel (tafenoquine) > 2 units/365 days
- ☐ Lampit (nifurtimox)
- ☐ Likmez (metronidazole oral suspension)
- ☐ linezolid suspension
- ☐ Lymepak (doxycycline 100 mg tablet pack)
- ☐ mebendazole
- ☐ metronidazole 375 mg capsule
- ☐ minocycline extended-release 45 mg, 90 mg, 135 mg tablet
- ☐ minocycline tablet
- ☐ nitazoxanide tablet
- ☐ nitrofurantoin 25 mg/5 mL suspension
- ☐ nitrofurantoin 50 mg/5 mL suspension
- ☐ Nuzyra (omadacycline tablet)
- ☐ ofloxacin tablet
- ☐ pyrimethamine
- ☐ Sivextro (tedizolid tablet)
- ☐ Solosec (secnidazole)
- ☐ tetracycline tablet
- ☐ Xifaxan (rifaximin 550 mg)

Dose, frequency, and duration of medication requested

Indication or ICD-10 code, if applicable

Section I. Please complete for all requests.

1. Is the member under the care of an infectious disease specialist? ☐ Yes ☐ No
2. Please list previous trials for the requested indication including outcomes.*

Drug		Outcome		Dates of use	
Drug		Outcome		Dates of use	
Drug		Outcome		Dates of use	

**Attach a letter with additional information regarding medication trials as applicable.*

Section II. Please complete for all requests for antibiotics.

1. Please indicate the infecting organism.
   - ☐ Clostridium difficile
   - ☐ Methicillin-resistant Staphylococcus aureus (MRSA)
   - ☐ Vancomycin-resistant Enterococcus (VRE)
   - ☐ Other
2. Is the infecting organism confirmed or suspected? ☐ Confirmed ☐ Suspected
3. Were cultures and susceptibility testing performed?
   - ☐ Yes. Please attach a copy of the culture and sensitivity report with submission.
   - ☐ No. Please provide clinical rationale why cultures and susceptibility testing were not performed.

Section III. Please also complete for requests for amoxicillin/clavulanate extended-release, cefaclor extended-release, and clarithromycin extended-release.

Please describe the medical necessity for the use of an extended-release dosage formulation instead of immediate-release formulations of the requested agent. Please describe prior trials and outcomes with the immediate-release formulation and additional antibiotics, if applicable, in Section I above.

Section IV. Please also complete for requests for azithromycin powder packet, cefadroxil tablet, cefpodoxime suspension, cephalexin 750 mg capsule, ciprofloxacin 100 mg tablet, metronidazole 375 mg, and tetracycline tablet.

Please describe prior trials and outcomes with formulations of the requested antibiotic that are available without PA in Section I above. Please describe medical necessity for the use of the requested antibiotic instead of alternative strengths available without PA.

Section V. Please also complete for requests for doxycycline agents requiring PA, except for Lymepak.

Please describe prior trials and outcomes with doxycycline formulations that are available without PA in Section I above. Please describe medical necessity for the requested formulation instead of doxycycline formulations available without PA.

Section VI. Please also complete for requests for Lymepak.

Please describe prior trials and outcomes with all doxycycline formulations that are available without PA in Section I above. Please describe medical necessity for the requested formulation instead of doxycycline 100 mg formulations available without PA.

over

Section VII. Please also complete for requests for cefixime.

Is the member completing a course of therapy that was initiated in the hospital? ☐ Yes ☐ No

If the answer to the above question is no, has the member had a trial with cefdinir or cefpodoxime?

☐ Yes. Please describe prior trials and outcomes in Section I above.

☐ No. Please explain why not.

Section VIII. Please also complete for requests for Xifaxan 550 mg.

1. For the diagnosis of hepatic encephalopathy, has the member tried lactulose?
   ☐ Yes. Please describe prior trials and outcomes in Section I above.
   ☐ No. Please explain why not.
2. For the diagnosis of irritable bowel syndrome with diarrhea, has the member had a trial with three of the following: loperamide, diphenoxylate/atropine, bile acid sequestrant, bismuth subsalicylate, bulk-forming agent, tricyclic antidepressant (TCA)?
   ☐ Yes. Please describe prior trials and outcomes in Section I above.
   ☐ No. Please explain why not.

Section IX. Please also complete for requests for Sivextro tablet.

1. For Sivextro for the diagnosis of VRE, has the member had a trial with linezolid?
   ☐ Yes. Please describe prior trials and outcomes in Section I above.
   ☐ No. Please explain why not.
2. For the diagnosis of MRSA, has the member had a trial with clindamycin, doxycycline or minocycline, sulfamethoxazole/trimethoprim, or vancomycin IV?
   ☐ Yes. Please describe prior trials and outcomes in Section I above.
   ☐ No. Please explain why not.

Section X. Please also complete for requests for minocycline extended-release 45 mg, 90 mg, 135 mg tablets, and minocycline tablets.

1. For minocycline immediate-release tablet, please describe prior trials and outcomes with minocycline capsules in Section I above. Please describe medical necessity for the dosage formulation instead of immediate-release capsules.
2. For minocycline extended-release tablet and capsule formulations, has the member had a trial with minocycline capsules and Solodyn?
   ☐ Yes. Please describe prior trials and outcomes in Section I above.
   ☐ No. Please explain why not.

Section XI. Please also complete for requests for cefaclor suspension, linezolid suspension, nitrofurantoin 25 mg/5 mL suspension, and nitrofurantoin 50 mg/5 mL suspension.

Please describe medical necessity for use of the suspension formulation instead of the respective capsule or tablet formulation.

over

Section XII. Please also complete for requests for Augmentin 125/31.25 mg/5 mL suspension.

Please provide clinical rationale for not using 250/62.5 mg/5 mL formulation.

Section XIII. Please also complete for requests for Baxdela tablet and Nuzyra tablet.

1. For suspected or confirmed MRSA infections or mixed pathogen infections (including MRSA), has the member had a trial with clindamycin, doxycycline or minocycline, linezolid, sulfamethoxazole/trimethoprim, or vancomycin IV?
   - ☐ Yes. Please describe prior trials and outcomes in Section I above.
   - ☐ No. Please explain why not.
2. For suspected or confirmed mixed pathogen infections (including MRSA), has the member had a trial with at least one other antibiotic with gram-negative coverage available without PA?
   - ☐ Yes. Please describe prior trials and outcomes in Section I above.
   - ☐ No. Please explain why not.

Section XIV. Please also complete for requests for ofloxacin tablet.

Has the member had a trial with ciprofloxacin or levofloxacin?

☐ Yes. Please describe prior trials and outcomes in Section I above.

☐ No. Please explain why not.

Section XV. Please also complete for requests for Coartem > 24 units/365 days and Krintafel (tafenoquine) > two units/365 days.

1. Please describe the medical necessity for exceeding the quantity limit.
2. For Krintafel, is the member currently receiving chloroquine therapy?
   - ☐ Yes.
   - ☐ No. Please explain why not.

Section XVI. Please also complete for requests for Lampit.

Member's current weight Date

Section XVII. Please also complete for requests for pyrimethamine.

Will the requested agent be used in combination with other agents for the diagnosis?

☐ Yes. Please provide drug name(s).

☐ No

Section XVIII. Please also complete for requests for Likmez.

Please describe prior trials and outcomes with metronidazole tablets in Section I above. Please describe medical necessity for the requested formulation instead of formulations available without PA.

over

Section XIX. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Oral Respiratory Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested

Leukotrienes

☐ montelukast granules ☐ zafirlukast ☐ zileuton extended-release ☐ Zyflo (zileuton)

Other

☐ roflumilast tablet ☐ Ofev (nintedanib) ☐ pirfenidone

Dose and frequency of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Allergic Rhinitis (montelukast only)
☐ Asthma
☐ Chronic Obstructive Pulmonary Disease (roflumilast tablet only)
☐ Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype
☐ Exercise-Induced Bronchospasm
☐ Idiopathic Pulmonary Fibrosis
☐ Systemic sclerosis-associated interstitial lung disease (SSc-ILD)
☐ Other

Please list all other medications currently prescribed for the member for this indication.

Section I. Please complete for montelukast granule requests.

1. Has the member had a trial with montelukast chewable tablet?.
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*
   ☐ No. Please describe why montelukast chewable tablet is not appropriate for this member.
2. For the diagnosis of allergic rhinitis, has the member had a trial with an intranasal antihistamine or intranasal corticosteroid and one oral second-generation antihistamines (e.g., cetirizine, loratadine)?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*
   ☐ No. Please describe why intranasal antihistamines and corticosteroids, and oral second-generation antihistamines are not appropriate for this member.
3. For the diagnosis of exercise-induced bronchospasm, has the member had a trial with inhaled albuterol, levalbuterol, or low dose inhaled corticosteroid-formoterol (e.g., budesonide/formoterol or Dulera [mometasone/formoterol])?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*
   ☐ No. Please describe why inhaled albuterol, levalbuterol, or low dose inhaled corticosteroid-formoterol is not appropriate for this member.

Please provide details for the previous trials.

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

_____

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

_____

Drug name _____ Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

_____

Section II. Please complete for roflumilast tablet requests.

1. Has the member had a trial with a long-acting bronchodilator (e.g., long-acting beta-agonist, long-acting anticholinergic) within the past four months?

   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   _____

   ☐ No. Please describe why long-acting bronchodilators are not appropriate for this member.

   _____

2. Has the member had a trial with an inhaled corticosteroid within the past four months?

   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   _____

   ☐ No. Please describe why inhaled corticosteroids are not appropriate for this member.

   _____

Section III. Please complete for zileuton extended-release and Zyflo requests.

1. Has the member had a trial with montelukast or zafirlukast?

   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   _____

   ☐ No. Please describe why montelukast and zafirlukast are not appropriate for this member.

   _____

2. For requests for zileuton extended-release, has the member had a trial with Zyflo?

   ☐ Yes. Please describe the dates/duration of trial and outcomes below*.

over

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe why Zyflo is not appropriate for this member.

Section IV. Please complete for Ofev requests for a diagnosis of SSc-ILD.

Has the member had a trial with cyclophosphamide or mycophenolate?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe why cyclophosphamide and mycophenolate are not appropriate for this member.

**Please attach a letter documenting additional trials as necessary*

Section V. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

over

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Oral/Injectable Antifungal Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Brexafemme (ibrexafungerp)
- ☐ Cresemba (isavuconazonium)*
- ☐ Noxafil (posaconazole powder for oral suspension)
- ☐ Oravig (miconazole buccal tablet)
- ☐ posaconazole injection, suspension*
- ☐ Rezzayo (rezafungin)
- ☐ Tolsura (itraconazole 65 mg capsule)
- ☐ Vivjoa (oteseconazole)
- ☐ voriconazole suspension, 50 mg tablet
- ☐ Other**

*For posaconazole IV and Cresemba IV, Section VII is also required.
**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).

Dose and frequency of medication requested

Indication (check all that apply or include ICD-10 code, if applicable)
***voriconazole requests only **Cresemba and posaconazole**

- ☐ *Aspergillus* endophthalmitis*
- ☐ *Aspergillus* keratitis*
- ☐ *Scedosporium* infection*
- ☐ *Aspergillus* infection
- ☐ *Fusarium* infection*
- ☐ *Zygomycosis* (mucormycosis)**

Please note: For posaconazole or voriconazole for the above indications, Sections I through VIII are not required.

For all indications checked below, please complete sections in parentheses

- ☐ Blastomycosis (Section V)
- ☐ Candidemia (Section II) †
- ☐ Disseminated candidiasis (Section II)
- ☐ Esophageal candidiasis (Section III)
- ☐ Histoplasmosis (Section V)
- ☐ Invasive candidiasis (Section X)
- ☐ Onychomycosis (Section V)
- ☐ Oropharyngeal candidiasis (Section IV)
- ☐ Prevention of *Aspergillus* and *Candida* infections (Section I)
- ☐ Vulvovaginal candidiasis (Section IX)
- ☐ Other

(Please attach a letter regarding medical necessity.)

† For Rezzayo, please complete Section X

Section I. Please complete for posaconazole and voriconazole for prevention of Aspergillus and Candida infections.

1. For posaconazole requests, is the member's age within the FDA-approved range for use (posaconazole suspension ≥ 13 years; posaconazole powder for oral suspension ≥ 2 years to < 18 years; posaconazole IV ≥ 2 years)?
   ☐ Yes ☐ No. Please provide clinical rationale for use in non-FDA approved age.

   For both posaconazole and voriconazole requests, does the member have one of the following?
   ☐ Hematologic malignancy with neutropenia ☐ Graft-versus-host disease
   ☐ Hematopoietic stem cell transplantation
   ☐ No. Please describe why the member requires antifungal prophylaxis.
2. For posaconazole IV, please provide clinical rationale for use of IV formulation instead of oral formulations.
3. For posaconazole powder for oral suspension, is the member's weight ≤ 40 kg?
   ☐ Yes ☐ No. Please provide clinical rationale for use in non-FDA approved weight.

Section II. Please complete for voriconazole for candidemia and disseminated candidiasis.

Has the member had a trial of oral fluconazole?

☐ Yes. Dates/durations of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for oral fluconazole.

Section III. Please complete for posaconazole suspension and voriconazole for esophageal candidiasis.

1. For posaconazole requests, is the member 13 years of age or older?
   ☐ Yes ☐ No. Please provide clinical rationale for use in non-FDA-approved age.
2. For posaconazole requests, has the member had a trial of voriconazole?
   ☐ Yes. Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   ☐ No. Please describe why the member is not a candidate for voriconazole.

over

3. For both posaconazole and voriconazole requests, has the member had a trial of fluconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for fluconazole.

4. For both posaconazole and voriconazole requests, has the member had a trial of itraconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for itraconazole.

Section IV. Please complete for Oravig, posaconazole suspension, and voriconazole for oropharyngeal candidiasis.

1. For posaconazole requests, is the member 13 years of age or older?

☐ Yes ☐ No. Please provide clinical rationale for use in non-FDA approved age.

2. For voriconazole requests, has the member had a trial of posaconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for posaconazole.

3. For both posaconazole and voriconazole requests, has the member had a trial of oral fluconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for oral fluconazole.

4. For both posaconazole and voriconazole requests, has the member had a trial of itraconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for itraconazole.

over

5. For Oravig requests, has the member had a trial of clotrimazole troches?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for clotrimazole troches.

6. For Oravig requests, has the member had a trial of nystatin suspension?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for nystatin suspension.

Section V. Please complete for Tolsura.

Please provide medical necessity for the requested formulation instead of itraconazole 100 mg capsules.

Section VI. Please complete for Cresemba for the treatment of Aspergillus infection.

1. Has the member had a trial of voriconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for voriconazole.

2. Has the member had a trial of posaconazole?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for posaconazole.

Section VII. Please complete for Cresemba IV and posaconazole IV.

Please provide medical necessity for use of IV formulation instead of oral formulations.

over

Section VIII. Please complete for Cresemba for Zygomycosis (mucormycosis).

1. Has the member had a trial of posaconazole?

   ☐ Yes. Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Please describe why the member is not a candidate for posaconazole.

Section IX. Please complete for Brexafemme and Vivjoa for vulvovaginal candidiasis (VVC).

For Brexafemme requests for a diagnosis of acute VVC, please complete questions 1 and 2. For Brexafemme requests for a diagnosis of recurrent VVC, please complete questions 1 through 5. For Vivjoa requests, please complete question 1 and questions 2 through 6.

1. Has the member had a trial of oral fluconazole?

   ☐ Yes. Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Please describe why the member is not a candidate for oral fluconazole.

2. Is the member post-menarchal? ☐ Yes ☐ No
3. Please attach results from a potassium hydroxide (KOH) test to confirm diagnosis.
4. Has the member had ≥ three acute VVC episodes within past 12 months? ☐ Yes ☐ No
5. Is the member not of reproductive potential? ☐ Yes ☐ No
6. Is the member post-menopausal? ☐ Yes ☐ No

Section X. Please complete for Rezzayo.

1. Has the member had a trial of Eraxis?

   ☐ Yes. Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Please describe why the member is not a candidate for Eraxis.

2. Has the member had a trial of caspofungin?

   ☐ Yes. Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   ☐ No. Please describe why the member is not a candidate for caspofungin.

over

3. Has the member had a trial of micafungin?

☐ Yes. Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

☐ No. Please describe why the member is not a candidate for micafungin.

Section XI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen? ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details.

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Osteoporosis Agents and Calcium Regulators
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Bisphosphonates

- ☐ alendronate solution
- ☐ Binosto (alendronate effervescent tablet)
- ☐ Fosamax Plus D (alendronate/cholecalciferol)
- ☐ ibandronate IV [MB]
- ☐ risedronate
- ☐ risedronate delayed-release

Miscellaneous Agents

- ☐ calcitonin salmon injection
- ☐ Evenity (romosozumab-aqqg)
- ☐ Duavee (conjugated estrogens/bazedoxifene)
- ☐ Prolia (denosumab)
- ☐ teriparatide 620 mcg/2.48 mL
- ☐ teriparatide 600 mcg/2.4 mL
- ☐ Tymlos (abaloparatide)
- ☐ Xgeva (denosumab)

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Giant cell tumor of the bone (Xgeva) (Section VIII)
- ☐ Glucocorticoid-Induced Osteoporosis (GIO) (Section II)
- ☐ Hypercalcemia
- ☐ Hypercalcemia of malignancy (Xgeva) (Section VII)
- ☐ Hypocalcemia with hypoparathyroidism
- ☐ Osteopenia
- ☐ Paget's Disease
- ☐ Postmenopausal Osteoporosis (PMO)
- ☐ Prevention of postmenopausal osteoporosis
- ☐ Prevention of bone loss in men receiving androgen deprivation therapy for prostate cancer
- ☐ Prevention of bone loss in women receiving aromatase inhibitors for breast cancer
- ☐ Prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors (Xgeva) (Section VII)
- ☐ Prevention of skeletal-related events secondary to multiple myeloma (Xgeva) (Section VII)
- ☐ Primary/Hypogonadal Osteoporosis
- ☐ Treatment of moderate-severe vasomotor symptoms associated with menopause
- ☐ Other

[MB] This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

Section I. Please complete for bisphosphonates, Prolia, teriparatide 600 mcg/2.4 mL, and teriparatide 620 mcg/2.48 mL as indicated above.

1. Please provide results of bone mineral density (BMD) measurements (T-scores of total hip and lumbar vertebrae).
2. Has the member had a radiographically confirmed fracture?
   ☐ Yes. Please provide site and date below.
   Site Date
   ☐ No
3. Please list all non-modifiable risk factors for fracture in this member.
4. Has the member tried an oral bisphosphonate and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please list the dates/duration of oral bisphosphonate trial and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to oral bisphosphonates.
5. If the request is for teriparatide 600 mcg/2.4 mL or teriparatide 620 mcg/2.48 mL, has the member tried Prolia or an intravenous bisphosphonate and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please list the drug names, dates/duration of trials and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to Prolia and intravenous bisphosphonates.

Section II. Please complete for all agents being requested for the treatment or prevention of Glucocorticoid-Induced Osteoporosis (GIO).

Please provide specifics of the member's chronic glucocorticoid use.

Drug Dose and Frequency Dates/Duration

Section III. Please complete for calcitonin salmon injection, Evenity, and Tymlos requests.

Please attach supporting documentation of the diagnosis, BMD measurements, medical necessity for the requested agent, fracture risk factors, and previous trials including oral bisphosphonates, IV bisphosphonates (ibandronate, pamidronate, zoledronic acid 5 mg), or Prolia as applicable. For Evenity and Tymlos requests, please also attach supporting documentation of previous trials including teriparatide 600 mcg/2.4 mL as applicable. For calcitonin salmon injection, please also attach supporting documentation of previous trials including teriparatide 600 mcg/2.4 mL and calcitonin nasal spray as applicable.

Section IV. Please complete for teriparatide 620 mcg/2.48 mL requests.

Please provide medical necessity for the use of teriparatide 620 mcg/2.48 mL instead of teriparatide 600 mcg/2.4 mL.

over

Section V. Please complete for Fosamax Plus D requests.

Please provide medical necessity for the combination product instead of the individual agents.

Section VI. Please complete for Xgeva requests for a diagnosis of prevention of skeletal-related events secondary to bone metastases in cancer related to solid tumors, prevention of skeletal-related events secondary to multiple myeloma, and hypercalcemia of malignancy.

Please indicate prescriber specialty below.

☐ Hematology ☐ Oncology ☐ Orthopedic Specialist ☐ Other

If prescriber is not a specialist, please attach consult notes from specialist.

Section VII. Please complete for Xgeva requests for a diagnosis of giant cell tumor of the bone.

Please describe surgical history and/or prognosis. If surgery is not appropriate for this member, please explain.

Section VIII. Please complete for alendronate solution and Binosto requests.

Does the member have a medical condition in which they are unable to swallow tablets/capsules?

☐ Yes. (Please list reason.)

☐ No. (Please provide clinical rationale why conventional dosage forms cannot be used.)

Section IX. Please complete for Duavee requests.

For the diagnosis of moderate- severe vasomotor symptoms associated with menopause, please complete question 1. For indication of prevention of postmenopausal osteoporosis, please complete questions 1 – 3.

1. Has the member had a trial with one menopausal hormonal agent available without prior authorization?
   ☐ Yes. Please list the dates/duration of menopausal hormonal agent trial and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to menopausal hormonal agents.
2. Has the member tried an oral bisphosphonate and experienced an adverse reaction or inadequate response?
   ☐ Yes. Please list the dates/duration of oral bisphosphonate trial and outcomes in Section X below.*
   ☐ No. Please document if there is a contraindication to oral bisphosphonates.
3. Has the member had a trial with raloxifene and zoledronic acid 5 mg?
   ☐ Yes. Please list the dates/duration of trials and outcomes in Section X below.*
   ☐ No. Please explain if there is a contraindication to these trials.

Section X. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug name/Therapy Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

over

Briefly describe details of adverse reaction or inadequate response.

Drug name/Therapy Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

** Please attach a letter documenting additional trials as necessary*.

Section XI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details.

   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Otic Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ ciprofloxacin 0.2% otic solution
☐ ciprofloxacin/dexamethasone otic suspension
☐ Otovel (ciprofloxacin/fluocinolone)

Dose, frequency, and duration of medication requested

Drug NDC (if known) or service code

Indication(s) or ICD-10 code, if applicable

☐ Acute otitis media
Does the member have tympanostomy tubes?
☐ Yes ☐ No
☐ External otitis
☐ Other (please indicate)

Section I. Please complete for ciprofloxacin 0.2% otic solution requests for the diagnosis of external otitis.

Has the member had a trial with two of the following: Cipro HC, Cortisporin TC, a neomycin/polymyxin B/hydrocortisone product, or ofloxacin otic solution?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please explain why not.

Section II. Please complete for ciprofloxacin/dexamethasone otic suspension requests.

Has the member had a trial with Cipro HC?

☐ Yes. Please list the dates/duration of trial and outcomes below.*

Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please explain why not.

Section III. Please complete for Otovel requests for the diagnosis of acute otitis media with tympanostomy tubes.

Has the member had a trial with ciprofloxacin/dexamethasone otic suspension?

☐ Yes. Please list the dates/duration of trial and outcome below.*

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please explain why not.

* *Please attach a letter documenting additional trials as necessary.*

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details.

   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Pediatric Behavioral Health Medication Initiative
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

The **Pediatric Behavioral Health Medication Initiative** requires prior authorization for pediatric members (generally members < 18 years of age) for certain behavioral health medication classes and/or specific medication combinations (i.e. polypharmacy) that have limited evidence for safety and efficacy in the pediatric population. For a comprehensive medication list and additional information about the **Pediatric Behavioral Health Medication Initiative**, including PA requirements and preferred products please refer to the MassHealth Drug List at **www.mass.gov/druglist.**

Please refer to the following table for guidance on filling out this PA form.
Complete Section I, and all pertinent Sections as described below.

For all requests, complete Section I in its entirety.	
Next, please complete all pertinent Sections as described below.	
Polypharmacy Request Within the Same Medication Class [e.g., regimen includes more than one antidepressant, benzodiazepine, cerebral stimulant, mood stabilizer (agents considered to be used only for seizure diagnoses are not included)]	Section II
Antipsychotic Polypharmacy Request	Section III
Behavioral Health Medication Request for Members < six years of age [e.g., antidepressant, armodafinil, atomoxetine, benzodiazepine, buspirone, donepezil, memantine, meprobamate, modafinil, mood stabilizer (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, or viloxazine]	Section IV
Antipsychotic Request for Members < ten years of age	Section V
Alpha$_2$ Agonist or Cerebral Stimulant Request for Members < three years of age	Section VI
Hypnotic Request for Members < six years of age	Section VII
Request for Members on Multiple Behavioral Health Medications	Section VIII
Request for Non-Preferred Drug Products	Section IX
Request for Exceptions to Step Therapy	Section X

Thank you for helping to ensure that MassHealth pediatric members receive medically necessary behavioral health medications that are safe, effective, and optimize patient care.

Medication Information

Section I. Please complete for all requests for medications subject to the Pediatric Behavioral Health Medication Initiative for members < 18 years of age.

Please document complete treatment plan listing all requested agents (include all behavioral health agents, corresponding strength, dose, directions of use and indication(s) or ICD-10 code(s), if applicable, for each medication(s)).

1. Medication name Dose/frequency Indication
2. Medication name Dose/frequency Indication
3. Medication name Dose/frequency Indication
4. Medication name Dose/frequency Indication
5. Medication name Dose/frequency Indication
6. Medication name Dose/frequency Indication
7. Other(s)

Is the member currently in an acute care setting?

☐ Yes. (Inpatient) ☐ Yes. (Community Based Acute Treatment) ☐ Yes. (Partial Hospitalization) ☐ No

For members who are in an acute care setting, please document the outpatient prescriber after discharge.

Prescriber name Contact information

Has the member been hospitalized for a psychiatric condition within the past three months?

☐ Yes. Please document dates of hospitalization within the past three months. ☐ No

On the current regimen, is the member considered to be a severe risk of harm to self or others?

☐ Yes. Please provide details. ☐ No

For regimens including an antipsychotic, are appropriate safety screenings and monitoring being conducted (e.g., weight, metabolic, movement disorder, cardiovascular, and prolactin-related effects)?

☐ Yes ☐ No. Please explain.

Has informed consent from a parent or legal guardian been obtained?* ☐ Yes ☐ No

Please indicate prescriber specialty below.

☐ Psychiatry ☐ Neurology ☐ Other

☐ Specialist consult details (if the prescriber submitting the request is not a specialist)

Name(s) of the specialist(s) Date(s) of last visit or consult

Contact information

For mid-level practitioners (e.g., nurse practitioners, physician assistants), please provide the name and specialty of the collaborating physician, if applicable.

Please document member custody status.

☐ Parent/Guardian ☐ Department of Children and Families (DCF)

over

Please document member placement status.

☐ Home with Parent/Guardian ☐ Foster Care ☐ Residential Treatment Facility

☐ Uncertain ☐ Other

Please document agency involvement.

☐ DCF ☐ Department of Mental Health (DMH)

☐ Department of Developmental Services (DDS) ☐ Department of Youth Services (DYS)

Is the member/family currently receiving appropriate psychotherapeutic and/or community based services for the targeted clinical mental health related concerns (e.g., Applied Behavioral Analysis, Children's Behavioral Health Initiative, school interventions, specialized placement)?

☐ Yes. Please document details of interventions below, if applicable. ☐ No

Psychiatric care provided is coordinated with other psychotherapeutic and community based services. ☐ Yes ☐ No

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer this member care coordination services. Please describe which additional behavioral health services would be beneficial. *Please inform the member, parent, or legal guardian to expect outreach from a MassHealth representative of care coordination services.*

** Sample informed consent form available on the MassHealth PBHMI Information webpage. For additional information go to: https://www.mass.gov/info-details/pediatric-behavioral-health-medication-initiative-pbhmi-information*

Please complete for members who have been on one of the following for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation): a polypharmacy regimen, members < six years of age who have been on an applicable behavioral health medication, and members < ten years of age who have been on an antipsychotic.

Have previous efforts to reduce or simplify the regimen in the past 24 months resulted in symptom exacerbation? ☐ Yes ☐ No

The family or caregiver does not support the regimen change at this time due to risk of exacerbation. ☐ Yes ☐ No

Is there another significant barrier for therapy discontinuation? ☐ Yes ☐ No

If yes, please explain.

Section II. Polypharmacy within the same medication class (e.g., antidepressants, benzodiazepines, cerebral stimulants, mood stabilizers [agents considered to be used only for seizure diagnoses are not included]). Complete this section for all members < 18 years of age if request will result in polypharmacy within the same medication class.

Please document if monotherapy trials (include drug name, dates/duration of use, and outcome) were tried before prescribing polypharmacy with two or more agents within the same medication class for this member.**

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

over

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Other(s)

Please document clinical rationale for polypharmacy within the same medication class for this member.

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on an antidepressant or mood stabilizer polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?

☐ Yes. Please complete the applicable question in Section I. ☐ No

**Attach a letter with additional information regarding medication trials as applicable.*

Section III. Antipsychotic Polypharmacy. Complete this section for all members < 18 years of age if request will result in prescription of two or more antipsychotics for ≥ 60 days within a 90-day period.

Please select the stage of treatment and clinical rationale for antipsychotic polypharmacy.

☐ **Acute stage** (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects)

☐ Member experienced an inadequate response or adverse reaction to two monotherapy trials with antipsychotics.

Drug name 1 Dates/Duration of use

Drug name 2 Dates/Duration of use

☐ Member is transitioning from one antipsychotic to the other.

☐ Other, please explain.

☐ **Maintenance stage** (response to antipsychotic treatment with goal of remission or recovery)

1. Is the regimen effective, therapy benefits outweigh risks, and appropriate monitoring is in place?
   ☐ Yes ☐ No
2. Has the member been on an antipsychotic polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?
   ☐ Yes. Please complete the applicable question in Section I. ☐ No

☐ **Discontinuation stage** (clinically indicated that the antipsychotic regimen can likely be successfully tapered)

☐ Member is transitioning from one antipsychotic to the other.

☐ Member is tapering antipsychotic. Please describe taper plan including duration.

over

Section IV. Behavioral Health Medication (e.g., antidepressant, armodafinil, atomoxetine, benzodiazepine, buspirone, donepezil, memantine, meprobamate, modafinil, mood stabilizer [agents considered to be used only for seizure diagnoses are not included], naltrexone, prazosin, or viloxazine) for members < six years of age.

Please document any previous medication trial(s). Include drug name, dates/duration of use, and outcome.**

Please document clinical rationale for use of an antidepressant, armodafinil, atomoxetine, benzodiazepine, buspirone, donepezil, memantine, meprobamate, modafinil, mood stabilizer, naltrexone, prazosin, or viloxazine for this member < six years of age.

Has the member been on the requested agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

***Attach a letter with additional information regarding medication trials as applicable.*

Section V. Antipsychotic Request for Members < ten years of age.

Please select the stage of treatment and clinical rationale for use of an antipsychotic for this member < ten years of age.

☐ **Acute stage** (initiation of antipsychotic treatment likely with subsequent dose adjustments to maximize response and minimize side effects)

☐ **Maintenance stage** (response to antipsychotic treatment with goal of remission or recovery)

1. Is the regimen effective, therapy benefits outweigh risks, and appropriate monitoring is in place?
   ☐ Yes ☐ No
2. Has the member been on an antipsychotic agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)?
   ☐ Yes. Please complete the applicable question in Section I. ☐ No

☐ **Discontinuation stage** (clinically indicated that the antipsychotic regimen can likely be successfully tapered)

☐ Member is transitioning from one antipsychotic to the other.

☐ Member is tapering antipsychotic. Please describe taper plan including duration.

Section VI. Alpha$_2$ Agonist or Cerebral Stimulant Request for Members < three years of age.

Please document any previous medication trial(s). Include drug name, dates/duration of use, and outcome. For requests for an amphetamine product, include drug name, dates/duration of use, and outcome to a trial with a methylphenidate product.**

Please document clinical rationale for use of an alpha2 agonist and/or cerebral stimulant for this member < three years of age.

***Attach a letter with additional information regarding medication trials as applicable.*

over

Section VII. Hypnotic Request for Members < six years of age.

Please document if member has other behavioral health comorbidities (e.g., anxiety, depression, ADHD).

Please document medication trials with melatonin and/or clonidine, if clinically appropriate. Include drug name, dates/duration of use, and outcome.**

Please document behavioral interventions (e.g., bedtime routine, extinction, fading, strategic napping, positive reinforcement, regular sleep-wake cycles, sleep restrictions, relaxation techniques).

Please document clinical rationale for the use of a hypnotic agent for this member < six years of age.

Has the member been on the requested hypnotic agent for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

***Attach a letter with additional information regarding medication trials as applicable.*

Section VIII. Multiple Behavioral Health Medications.

Complete this section for all members < 18 years of age if request will result in prescriptions of four or more behavioral health medications within a 45-day period if one of the following is included: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant.

Also complete this section for all members < 18 years of age if request will result in prescriptions of five or more behavioral health medications within a 45-day period. For a complete list of all behavioral health medications, please refer to the MassHealth Pediatric Behavioral Health Medication Initiative.

Please document monotherapy trials (include drug name, dates/duration of use, and outcome) tried before prescribing a polypharmacy regimen for this member.**

Please document clinical rationale for use of multiple behavioral health medications for this member < 18 years of age.

Please document the treatment plans for medication regimen simplification (e.g., dose consolidation, frequency reduction) or medical necessity for continuation of a complex medication regimen.

Has the member been on the requested polypharmacy regimen for the past 12 months with no adjustments (i.e., dose decrease, attempted discontinuation)? ☐ Yes. Please complete the applicable question in Section I. ☐ No

***Attach a letter with additional information regarding medication trials as applicable.*

over

Section IX. Please complete for all requests for non-preferred drug products if one or more preferred drug products have been designated for this class of drugs.

If one or more preferred drug products have been designated for this class of drugs, and if you are requesting PA for a non-preferred drug product, please provide medical necessity for prescribing the non-preferred drug product rather than the preferred drug product.

Section X. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

* *Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Pediculicides and Scabicides
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ crotamiton lotion ☐ lindane shampoo ☐ malathion ☐ spinosad

Dose, frequency, and duration of medication requested

Indication or ICD-10 code, if applicable

☐ Crab lice ☐ Head lice ☐ Scabies ☐ Other (please indicate)

Section I. Please complete for lindane shampoo requests.

1. Has the member had a trial with a permethrin or piperonyl butoxide/pyrethrins product?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   ☐ No. Please describe clinical rationale for not using permethrin and piperonyl butoxide/pyrethrins for this member.
2. Has the member had a trial with malathion?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.
   ☐ No. Please describe clinical rationale for not using malathion for this member.

* *Please attach a letter documenting additional trials as necessary.*

Section II. Please complete for crotamiton lotion requests.

1. Has the member had a trial with permethrin 5%?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*
   Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using permethrin 5% for this member.

2. Has the member had a trial with oral ivermectin?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   ☐ No. Please describe clinical rationale for not using oral ivermectin for this member.

3. Has the member had a trial with crotamiton cream?
   ☐ Yes. Please list dates/duration of trials, and outcomes below. *

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe clinical rationale for not using crotamiton cream for this member.

** Please attach a letter documenting additional trials as necessary.*

Section III. Please complete for malathion, and spinosad requests.

Has the member had a trial with permethrin or piperonyl butoxide/pyrethrins?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using permethrin and piperonyl butoxide/pyrethrins for this member.

** Please attach a letter documenting additional trials as necessary.*

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

over

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details. _____
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

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Member Information

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Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
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over

Progesterone Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested (Check all that apply. Where applicable, the brand name is provided in brackets for reference.)

☐ Crinone 4% (progesterone gel)
☐ Crinone 8% (progesterone gel)
☐ Endometrin (progesterone vaginal insert)
☐ hydroxyprogesterone caproate injection

☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Frequency and duration of therapy requested _____

Drug NDC (if known) or service code _____

Indication (Check all that apply, or ICD-10 code, if applicable) _____

☐ Amenorrhea
  ☐ Primary ☐ Secondary
☐ Progestin challenge for the diagnosis of secondary amenorrhea
☐ Other (Please indicate.) _____

Please note: MassHealth does not pay for any drug when used to promote fertility as described in 130 CMR 406.413(B) "Limitations on Coverage of Drugs-Drug Exclusion." For additional information go to: www.mass.gov/regulations/130-CMR-406000-pharmacy-services.

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Section I. Please complete for all requests, if applicable.

1. Is the member currently pregnant with a singleton gestation? ☐ Yes ☐ No. Please explain.
   _____
   _____
2. Please indicate the current gestational week. _____
3. Was there a prior spontaneous preterm delivery with a singleton gestation? ☐ Yes ☐ No. Please explain.
   _____
   _____
4. Please indicate the gestational week(s) for the member's prior preterm delivery, if applicable. _____

Section II. Please complete for Crinone 4% and 8% gel requests for progestin challenge for the diagnosis of secondary amenorrhea.

1. Has the member experienced an adverse reaction to oral progesterone (micronized), medroxyprogesterone, or norethindrone?

   ☐ Yes. Name _____ Please describe trial below.

   Dose and frequency _____ Dates of Use _____ Outcome _____

   ☐ No. Explain why oral progesterone (micronized), medroxyprogesterone, or norethindrone have not been tried.

   _____

2. For Crinone 8% gel requests, has the member had a trial with Crinone 4% gel?

   ☐ Yes. Please list the dates/duration of use and outcomes below.

   Dates/duration _____ Outcome _____

   ☐ No. Please explain. _____

Section III. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

   _____

   _____

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen? ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

   _____

   _____

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name _____ Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

   Briefly describe details of adverse reaction or inadequate response.

   _____

   _____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details. _____

   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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over

Prostate Cancer Agents
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ abiraterone 250 mg, 500 mg
☐ Akeega (niraparib/abiraterone)
☐ Erleada (apalutamide)
☐ Jevtana (cabazitaxel) [MB]
☐ Nubeqa (darolutamide)
☐ Provenge (sipuleucel-T) [MB]
☐ Xtandi (enzalutamide)
☐ Yonsa (abiraterone 125 mg)

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose of medication requested **Frequency of medication requested**

Duration/Cycles of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Prostate cancer
☐ Other
☐ Metastatic ☐ Non-metastatic
☐ Castration-resistant ☐ Castration-sensitive
☐ Hormone-sensitive

Please indicate prescriber specialty. ☐ Oncology ☐ Urology ☐ Other

Section I. Please complete for Jevtana requests.

1. Has the member had an inadequate response or adverse reaction to a docetaxel containing regimen?
   ☐ Yes ☐ No
2. Please list previous regimen(s).
   Regimen Dates of use
   Regimen Dates of use
3. Will the requested medication be used in combination with prednisone? ☐ Yes ☐ No

Section II. Please complete for Provenge requests.

1. Does the member have an Eastern Cooperative Oncology Group (ECOG) performance score between 0-1?
   ☐ Yes ☐ No

   Please list ECOG performance score
2. Does the member have an estimated life expectancy > 6 months? ☐ Yes ☐ No
3. Does the member have hepatic metastases? ☐ Yes ☐ No
4. Does the member currently have symptoms? ☐ Yes ☐ No

   If yes, are the symptoms minimal? ☐ Yes ☐ No (please explain)

Section III. Please complete for abiraterone 250 mg and 500 mg, Erleada, Nubeqa, Xtandi, and Yonsa requests.

1. Will the requested medication be used in combination with a gonadotropin-releasing hormone (GnRH) analog?

   ☐ Yes. Drug name Dose and frequency ☐ No
2. Has the member had a bilateral orchiectomy? ☐ Yes ☐ No
3. For abiraterone 250 mg and 500 mg, does the member have metastatic high-risk castration-sensitive prostate cancer? ☐ Yes ☐ No

   If yes, will the requested medication be used in combination with prednisone? ☐ Yes ☐ No
4. For abiraterone 500 mg tablet, please provide medical necessity for use instead of abiraterone 250 mg tablet.
5. For Erleada and Xtandi for metastatic castration-sensitive prostate cancer, has the member tried abiraterone?
   ☐ Yes. Please list the dates/duration of use, dose and frequency, and outcome below.

   Dates of use Dose and frequency

   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Explain why not.
6. For Xtandi for metastatic castration-resistant prostate cancer, will the requested medication be used as monotherapy? ☐ Yes ☐ No

   If no, will the requested medication be used with Talzenna? ☐ Yes ☐ No
7. For Erleada and Nubeqa for non-metastatic castration-resistant prostate cancer, has the member tried Xtandi?
   ☐ Yes. Please list the dates/duration of use, dose and frequency, and outcome below.

   Dates of use Dose and frequency

   Did member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Explain why not.
8. For Nubeqa for metastatic hormone-sensitive prostate cancer or metastatic castration-sensitive prostate cancer, will the requested medication be used in combination with docetaxel? ☐ Yes ☐ No
9. For Yonsa, will the requested medication be used in combination with methylprednisolone? ☐ Yes ☐ No

over

Section IV. Please complete for Akeega requests.

1. Does the member have deleterious or suspected deleterious germline or somatic BRCA gene mutation?
   ☐ Yes ☐ No
2. Will the requested medication be used in combination with prednisone? ☐ Yes ☐ No

Section V. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen? ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

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Start date End date

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Is this a request for recertification? ☐ Yes ☐ No

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Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

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MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Proton Pump Inhibitor
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Aciphex Sprinkle (rabeprazole delayed release capsule)
- ☐ esomeprazole magnesium capsule > 1 unit/day
- ☐ esomeprazole magnesium 2.5 mg, 5 mg suspension
- ☐ esomeprazole sodium IV
- ☐ First-Omeprazole (omeprazole suspension compounding kit)
- ☐ Konvomep (omeprazole/sodium bicarbonate suspension)
- ☐ lansoprazole capsule > 1 unit/day
- ☐ lansoprazole orally disintegrating tablet (≥ 2 years of age)
- ☐ omeprazole 10 mg > 1 unit/day
- ☐ omeprazole 20 mg > 4 units/day
- ☐ omeprazole 40 mg > 2 units/day
- ☐ omeprazole/sodium bicarbonate powder for oral suspension
- ☐ pantoprazole tablet > 4 units/day
- ☐ Prilosec (omeprazole suspension)
- ☐ pantoprazole 40 mg suspension
- ☐ rabeprazole delayed-release tablet > 1 unit/day

Dose and frequency of requested agent

Intended duration of therapy

Indication (Check all that apply or include ICD-10 code, if applicable)

- ☐ **GERD**
  - ☐ Moderate-severe erosive esophagitis
  - ☐ Uncomplicated nonerosive esophagitis
  - ☐ Barrett's esophagus
  - ☐ GERD in child with one of the following conditions
    - ☐ Severe chronic respiratory disease (specify)
    - ☐ Neurologic disability (specify)
    - ☐ Other (specify)
- ☐ **Condition associated with extraesophageal symptoms secondary to gastric reflux**
  - ☐ Noncardiac chest pain
  - ☐ Asthma
  - ☐ Idiopathic hoarseness
  - ☐ Chronic laryngitis
  - ☐ Other (explain)
- ☐ **Duodenal ulcer**
  - ☐ Helicobacter pylori
  - ☐ Drug-induced
  - ☐ Treatment. List causative agent(s).
  - ☐ Prevention. List risk factor(s).
  - ☐ Other cause (specify)
- ☐ **Gastric ulcer**
  - ☐ Positive
  - ☐ Negative

☐ **Pathological hypersecretory syndromes**
- ☐ Zollinger-Ellison syndrome
- ☐ MEN Type I
- ☐ Other

☐ Other (explain)

Diagnostic studies performed (include dates of studies). Describe any diagnostic studies performed, including dates of studies.

Section I. Please complete for requests for Aciphex Sprinkle, esomeprazole magnesium 2.5 mg and 5 mg suspension, lansoprazole orally disintegrating tablet, Prilosec suspension, and pantoprazole 40 mg suspension.

Has the member had a trial with esomeprazole magnesium capsule, lansoprazole capsule, omeprazole, pantoprazole, or rabeprazole tablet?

☐ Yes. Please list the specific drug name, dates/duration of use, and outcomes below.

Drug name, dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

Drug name, dose and frequency Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please describe clinical rationale why these trials are not appropriate for this member.

Section II. Please complete for requests for omeprazole 20 mg capsules and pantoprazole tablets at quantities > 4 units/day, omeprazole 40 mg capsules > 2 units/day, and any other oral proton pump inhibitor at quantities > 1 unit/day.

Please describe medical necessity for use above the established quantity limits.

Section III. Please complete for requests for esomeprazole sodium IV and First-Omeprazole.

1. Please describe medical necessity for use of the requested formulation.
2. For esomeprazole sodium IV, has the member had a trial with pantoprazole IV?
   ☐ Yes. Please list dates/duration of use and outcomes below.

   Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

over

☐ No. Please describe clinical rationale why pantoprazole IV is not appropriate for this member.

Section IV. Please complete for requests for Konvomep and omeprazole/sodium bicarbonate powder for oral suspension.

1. Has the member had a trial with esomeprazole suspension, lansoprazole orally disintegrating tablet, omeprazole capsule, or pantoprazole suspension?
   ☐ Yes. Please list the specific drug name, dates/duration of use, and outcomes below.

   Drug name, dose, and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   Drug name, dose, and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction, inadequate response, or other.

   Drug name, dose, and frequency Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please describe clinical rationale why these trials are not appropriate for this member.
2. Please describe medical necessity for use of the requested formulation.

Section V. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

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Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.
☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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Pulmonary Hypertension
Prior Authorization Request

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Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist**.

Medication information

Medication requested (Check one or all that apply. Where applicable, the brand name is provided in brackets for reference.)

- ☐ Adempas (riociguat)
- ☐ ambrisentan
- ☐ bosentan
- ☐ epoprostenol [Veletri]
- ☐ Liqrev (sildenafil oral suspension)
- ☐ Opsumit (macitentan)
- ☐ Opsynvi (macitentan/tadalafil)
- ☐ Orenitram (treprostinil extended-release tablet)
- ☐ sildenafil 20 mg tablet
- ☐ sildenafil oral suspension [Revatio]
- ☐ tadalafil tablet
- ☐ Tadliq (tadalafil suspension)
- ☐ treprostinil injection
- ☐ Tyvaso (treprostinil inhalation solution)
- ☐ Tyvaso DPI (treprostinil inhalation powder)
- ☐ Uptravi (selexipag)
- ☐ Ventavis (iloprost inhalation)
- ☐ Winrevair (sotatercept-csrk)
- ☐ Other* _____

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose, frequency, and duration of medication requested _____

Is the member stabilized on the requested medication?

☐ Yes. Please provide start date. _____ ☐ No

Section I. Please complete for all requests.

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Chronic thromboembolic pulmonary hypertension (CTEPH)
- ☐ Pulmonary arterial hypertension (PAH)
- ☐ Pulmonary hypertension associated with interstitial lung disease (PH-ILD)
- ☐ Other (Please indicate.) _____

Please indicate prescriber specialty below.

☐ Cardiology ☐ Pulmonology ☐ Other (Please indicate.) _____

Please attach copies of medical records and/or office notes from cardiologist or pulmonologist regarding the diagnosis.

Section II. Please also complete for tadalafil tablet and Tadliq requests.

1. Has the member tried sildenafil 20 mg tablet?
   ☐ Yes. Please provide the following information.*

   Dates/duration of use _____

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Does the member have a contraindication to sildenafil? Please explain.

2. Is the member treatment naïve? ☐ Yes ☐ No
   If yes, will the requested agent be used in combination with ambrisentan? ☐ Yes ☐ No
3. Will the requested agent be administered concurrently with Adempas? ☐ Yes. Please explain below. ☐ No
4. For Tadliq, please provide medical necessity for the use of the requested formulation instead of tadalafil tablet.

Section III. Please also complete for Adempas requests.

1. Will Adempas be administered concurrently with a phosphodiesterase-5 inhibitor (sildenafil or tadalafil)?
   ☐ Yes. Please explain below. ☐ No
2. For members with CTEPH, please describe surgical history and/or prognosis.
3. For members with pulmonary arterial hypertension, has the member tried sildenafil or tadalafil?
   ☐ Yes. Please provide the following information.*
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   ☐ No. Does the member have a contraindication to sildenafil and tadalafil? Please explain.

Section IV. Please also complete for Orenitram, treprostinil injection, Tyvaso, Tyvaso DPI, and Ventavis for PAH requests.

Has the member tried epoprostenol (Veletri) or Flolan?
☐ Yes. Please provide the following information.*
Dates/duration of use
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.
☐ No. Does the member have a contraindication to epoprostenol (Veletri) or Flolan? Please explain.

Section V. Please also complete for Tyvaso DPI for PH-ILD requests.

Please attach medical records documenting inadequate response, adverse reaction, or contraindication to Tyvaso inhalation solution.

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Section VI. Please also complete for epoprostenol (Veletri) requests.

Has the member tried Flolan?

☐ Yes. Please provide the following information.*

Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

☐ No. Does the member have a contraindication to Flolan? Please explain.

Section VII. Please also complete for Liqrev, sildenafil 20 mg tablet and oral suspension [Revatio] requests.

1. Will sildenafil be administered concurrently with Adempas? ☐ Yes. Please explain below. ☐ No
2. For Liqrev and sildenafil oral suspension [Revatio], please provide medical necessity for the use of the requested formulation instead of sildenafil tablet.
3. For Liqrev, please provide medical necessity for the use of the requested formulation instead of sildenafil oral suspension [Revatio].

* Please attach a letter documenting additional trials as necessary.

Section VIII. Please also complete for bosentan for suspension requests.

Member's current weight Date

Section IX. Please also complete for Uptravi vial requests.

1. Is the member stabilized on Uptravi tablets?

   ☐ Yes. Please provide start date. ☐ No
2. Is the member temporarily unable to take oral medications?

   ☐ Yes. Please explain.

   ☐ No

Section X. Please also complete for Opsynvi requests.

1. Please provide medical necessity for the use of the combination product instead of the commercially available separate agents.

5. Will the requested agent be administered concurrently with Adempas? ☐ Yes. Please explain below. ☐ No

Section XI. Please also complete for Winrevair requests.

1. Member's current weight Date
2. Please document member's current WHO functional class. ☐ I ☐ II ☐ III ☐ IV

over

3. Is the member stable on background therapy for PAH? ☐ Yes. ☐ No.
4. For recertification requests, please attach medical records documenting a positive response to therapy.

Section XII. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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Rezdiffra
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Dose, frequency, and duration requested

Drug NDC (if known) or service code

Indication or ICD-10 code, if applicable

☐ Nonalcoholic steatohepatitis (NASH) or metabolic dysfunction-associated steatohepatitis (MASH), with moderate to advanced liver fibrosis

☐ Other

Is the prescriber a gastroenterologist or hepatologist?
☐ Yes
☐ No. Please attach consultation notes from a gastroenterologist or hepatologist addressing the use of the requested agent.

Section I. Please complete for all requests.

1. Please provide medical records documenting the results from liver biopsy or non-invasive testing (NIT) supporting diagnosis.
2. Please provide fibrosis stage (i.e., Metavir Score)
3. Please document member's current weight. Date
4. Has the member been counseled to continue a reduced-calorie diet and increased physical activity? ☐ Yes ☐ No.
5. Has the member been counseled to abstain from alcohol use? ☐ Yes ☐ No.
6. For recertification requests, please attach medical records documenting positive response to therapy (e.g., laboratory or imaging testing).

Section II. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

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Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Skysona
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Dose, frequency, and duration requested

Drug NDC (if known) or service code

Indication or ICD-10 code, if applicable

☐ Cerebral adrenoleukodystrophy (CALD)

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans(ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.

Please indicate prescriber specialty below.

☐ Neurologist ☐ Other

If applicable, please also complete section for professionally administered medications at end of form.

Section I. Please complete for all requests.

1. Please provide anticipated dates and dosing for the following as applicable.

   Apheresis Admission Infusion Dose Discharge
2. Does the member have elevated very long chain fatty acids (VLCFAs)? ☐ Yes ☐ No
3. Please provide medical records documenting the results from genetic testing showing mutations in the ABCD1 gene.
4. Please provide the following scores.

   Neurologic Function Score (NFS)

   Loes score
5. Did the member have gadolinium enhancement on brain magnetic resonance imaging (MRI)? ☐ Yes ☐ No
6. Has the member had previous allogeneic transplant or gene therapy? ☐ Yes. Please describe. ☐ No
7. Outreach for both short- and long-term monitoring for efficacy and durability of response will be conducted by MassHealth. The applicable information [including but not limited to medical records confirming the dates of treatment and documenting the initial response to therapy] will be provided to MassHealth upon request. ☐ Yes ☐ No

Section II. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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T-cell Immunotherapies
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Abecma (idecabtagene vicleucel) [MB]
- ☐ Amtagvi (lifileucel) [MB]
- ☐ Breyanzi (lisocabtagene maraleucel) [MB]
- ☐ Carvykti (ciltacabtagene autoleucel) [MB]
- ☐ Columvi (glofitamab-gxbm) [MB]
- ☐ Elrexfio (elranatamab-bcmm) [MB]
- ☐ Epkinly (epcoritamab-bysp) [MB]
- ☐ Kymriah (tisagenlecleucel) [MB]
- ☐ Lunsumio (mosunetuzumab-axgb) [MB]
- ☐ Talvey (talquetamab-tgvs) [MB]
- ☐ Tecartus (brexucabtagene autoleucel) [MB]
- ☐ Tecvayli (teclistamab-cqyv) [MB]
- ☐ Yescarta (axicabtagene ciloleucel) [MB]

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Dose, frequency, and duration of medication requested

Indication (Check all that apply or include ICD-10 code, if applicable.)

[‡] **Abecma, Carvykti, Elrexfio, Talvey, and Tecvayli requests only**
[¶] **Amgtagvi requests only**
[††] **Breyanzi requests only**
[§§] **Columvi requests only**
[**] **Epkinly requests only**
[*] **Kymriah requests only**
[‖] **Lunsumio requests only**
[†] **Tecartus requests only**
[§] **Yescarta requests only**

- ☐ B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse [*]
- ☐ Large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy [§]
- ☐ Relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy [* § ‖]
- ☐ Relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), high grade B-cell lymphoma, and DLBCL arising from FL[*]
- ☐ Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) [†]
- ☐ Relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL NOS, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from FL [§]
- ☐ Relapsed or refractory DLBCL NOS, DLBCL arising from indolent lymphoma, DLBCL arising from high-grade B-cell lymphoma [**]
- ☐ Relapsed or refractory large B-cell lymphoma, including DLBCL NOS (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and FL grade 3B [††]
  - ☐ Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy

☐ Relapsed or refractory DLBCL, not otherwise specified or LBCL arising from follicular lymphoma §§

☐ Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation [HSCT] due to comorbidities or age

☐ Relapsed or refractory mantle cell lymphoma (MCL)†

☐ Relapse or refractory disease after two or more lines of systemic therapy

☐ Relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody ‡ ±

☐ Unresectable or metastatic melanoma¶

Please indicate prescriber specialty below.

☐ Hematology ☐ Oncology ☐ Other

Section I. Please complete for all requests.

1. Member's current weight Date
2. Please indicate billing preference. ☐ Prescriber in-office ☐ Hospital outpatient
   If applicable, please also complete section for professionally administered medications at end of form.
   Drug NDC (if known) or service code
3. Please provide anticipated dates for the following as applicable.
   Treatment date Leukapheresis Admission Infusion Discharge
4. Please provide the infusion setting. ☐ Inpatient ☐ Outpatient
5. Will the infusion take place in a health care facility that has been certified pursuant to the Risk Evaluation and Mitigation Strategy (REMS) program specific to the treatment being provided? ☐ Yes ☐ No
6. Please list any other prior trials including the drug names, dates/duration of use, and outcomes below. Please note, Abecma, Carvykti, Elrexfio, Talvey, and Tecvayli are FDA-approved for use after four or more lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. *

   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.

   Drug Dates/duration ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
7. Outreach for both short- and long-term monitoring for efficacy and durability of response will be conducted by MassHealth. The applicable information [including but not limited to: medical records, dates of procedures, infusions, and admissions; adverse reactions experienced; agents used to treat adverse reactions; response to therapy (e.g. complete blood count, bone marrow blasts, peripheral blood blasts, platelets, absolute neutrophil counts)] will be provided to MassHealth upon request. ☐ Yes ☐ No

over

Section II. Please also complete for Kymriah requests for a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.

1. Please indicate Philadelphia chromosome type. ☐ Positive ☐ Negative
   If positive, has the member failed two kinase inhibitors? ☐ Yes. Please provide details below.* ☐ No
   Drug _____ Dates/duration _____ Outcome _____
   Drug _____ Dates/duration _____ Outcome _____
2. Does the member have refractory disease? ☐ Yes ☐ No
3. Please provide the number of relapses. _____

Section III. Please also complete for Tecartus requests for a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

1. Please indicate Philadelphia chromosome type. ☐ Positive ☐ Negative
   If positive, has the member failed one tyrosine kinase inhibitor? ☐ Yes. Please provide details below.* ☐ No
   Drug _____ Dates/duration _____ Outcome _____
2. Does the member have primary refractory disease? ☐ Yes ☐ No
3. Please provide the number of relapses. _____ Dates/duration _____
4. Did the member receive an allogeneic stem cell transplant? ☐ Yes ☐ No Date _____

**Attach a letter with additional information regarding medication trials as applicable.*

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
   _____
   _____
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
   _____
   _____
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   _____
   _____

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4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

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Targeted Immunomodulators
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Anti-TNFs

- ☐ Abrilada (adalimumab-afzb)
- ☐ adalimumab-aacf, unbranded
- ☐ adalimumab-aaty, unbranded
- ☐ adalimumab-adaz, unbranded
- ☐ adalimumab-adbm, unbranded
- ☐ adalimumab-fkjp, unbranded
- ☐ adalimumab-ryvk, unbranded
- ☐ Amjevita (adalimumab-atto)
- ☐ Avsola (infliximab-axxq)
- ☐ Cimzia (certolizumab)
- ☐ Cyltezo (adalimumab-adbm)
- ☐ Enbrel (etanercept)
- ☐ Hadlima (adalimumab-bwwd)
- ☐ Hulio (adalimumab-fkjp)
- ☐ Humira (adalimumab)
- ☐ Hyrimoz (adalimumab-adaz)
- ☐ Idacio (adalimumab-aacf)
- ☐ Inflectra (infliximab-dyyb)
- ☐ infliximab, unbranded
- ☐ Remicade (infliximab)
- ☐ Renflexis (infliximab-abda)
- ☐ Simlandi (adalimumab-ryvk)
- ☐ Simponi (golimumab)
- ☐ Simponi Aria (golimumab for infusion)
- ☐ Yuflyma (adalimumab-aaty)
- ☐ Yusimry (adalimumab-aqvh)
- ☐ Zymfentra (infliximab-dyyb)

Interleukin Antagonists

- ☐ Actemra (tocilizumab auto-injection, prefilled syringe)
- ☐ Actemra (tocilizumab vial) [MB]
- ☐ Adbry (tralokinumab-ldrm)
- ☐ Arcalyst (rilonacept)
- ☐ Bimzelx (bimekizumab-bkzx)
- ☐ Cosentyx (secukinumab auto-injection, prefilled syringe)
- ☐ Cosentyx (secukinumab vial) [MB]
- ☐ Ilaris (canakinumab)
- ☐ Ilumya (tildrakizumab-asmn)
- ☐ Kevzara (sarilumab)
- ☐ Kineret (anakinra)
- ☐ Omvoh (mirikizumab-mrkz)
- ☐ Siliq (brodalumab)
- ☐ Skyrizi (risankizumab-rzaa)
- ☐ Spevigo (spesolimab-sbzo)
- ☐ Stelara (ustekinumab 45 mg/0.5 mL prefilled syringe, 90 mg/mL prefilled syringe, 45 mg/0.5 mL vial)
- ☐ Stelara (ustekinumab 130 mg/26 mL vial) [MB]
- ☐ Taltz (ixekizumab)
- ☐ Tremfya (guselkumab)

Oral Janus Kinase Inhibitors

- ☐ Cibinqo (abrocitinib)
- ☐ Litfulo (ritlecitinib)
- ☐ Olumiant (baricitinib)
- ☐ Rinvoq (upadacitinib)
- ☐ Xeljanz (tofacitinib)
- ☐ Xeljanz XR (tofacitinib extended-release)

Miscellaneous Agents

- ☐ Entyvio (vedolizumab)
- ☐ Orencia (abatacept auto-injection, prefilled syringe)
- ☐ Orencia (abatacept vial) [MB]
- ☐ Otezla (apremilast)
- ☐ Sotyktu (deucravacitinib)
- ☐ Velsipity (etrasimod)
- ☐ Zeposia (ozanimod)

Dose, frequency, and duration of medication requested

[MB] This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA and criteria, if applicable.

Please complete the following for all requests.

1. Member's current weight
2. Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient

If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code

3. Is the member stabilized on the requested medication?

☐ Yes. Please provide start date. ☐ No

4. Please indicate prescriber specialty below.

☐ Allergy/Immunology ☐ Dermatology ☐ Gastroenterology ☐ Rheumatology ☐ Other

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Acute graft versus host disease (aGVHD) prophylaxis
- ☐ Adult-onset Still's disease (AOSD)
- ☐ Alopecia areata
- ☐ Ankylosing spondylitis (AS)
- ☐ Atopic dermatitis
- ☐ Crohn's disease
  - ☐ Fistulizing Crohn's disease
- ☐ Cytokine release syndrome
- ☐ Deficiency of interleukin-1 receptor antagonist (DIRA)
- ☐ Enthesitis-related arthritis (ERA)
- ☐ Familial cold autoinflammatory syndrome (FCAS)
- ☐ Familial Mediterranean fever (FMF)
- ☐ Giant cell arteritis (GCA)
- ☐ Generalized Pustular Psoriasis
- ☐ Hidradenitis suppurativa (HS) (Hurley Stage II or III)
- ☐ Hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD)
- ☐ Juvenile idiopathic arthritis (JIA)
  - ☐ Polyarticular ☐ Systemic
- ☐ Muckle-Wells syndrome (MWS)
- ☐ Neonatal-onset multisystem inflammatory disease (NOMID)
- ☐ Non-infectious uveitis
- ☐ Non-radiographic axial spondyloarthritis (nr-AxSpA)
- ☐ Oral ulcers associated with Behcet's disease
- ☐ Plaque psoriasis (PsO)
- ☐ Polymyalgia rheumatica (PMR)
- ☐ Psoriatic arthritis (PsA)
- ☐ Recurrent pericarditis
- ☐ Rheumatoid arthritis (RA)
- ☐ Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
- ☐ Tumor necrosis factor receptor associated periodic syndrome (TRAPS)
- ☐ Ulcerative colitis (UC)
- ☐ Other

Please specify severity of indication below.

☐ Mild ☐ Mild-moderate ☐ Moderate ☐ Moderate-severe ☐ Severe

Section I. Please complete for all requests, except for a diagnosis of aGVHD prophylaxis, alopecia areata, atopic dermatitis, AOSD, cytokine release syndrome, DIRA, FCAS, FMF, GCA, Generalized Pustular Psoriasis, HIDS/MKD, HS (Hurley Stage II or III), MWS, NOMID, non-infectious uveitis, nr-AxSpA, oral ulcers associated with Behcet's disease, PMR, SSc-ILD, or TRAPS.

Has the member tried traditional or biologic disease modifying antirheumatic drugs (DMARDs)?‡

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XIX below.*

☐ No. Please explain why not.

‡ *For requests for Cimzia, all infliximab products, and Simponi, please provide clinical rationale for use instead of Enbrel and Humira, if applicable. For requests for Remicade, please provide clinical rationale for use instead of unbranded infliximab.*

For requests for Inflectra, Remicade, or Renflexis, please provide clinical rationale for use instead of unbranded infliximab and Avsola.

For requests for all adalimumab products (except Humira), please also complete section XIV.

For requests for Olumiant or Rinvoq, please document a trial with Xeljanz or Xeljanz XR, or provide clinical rationale for use of the requested agent instead of both Xeljanz and Xeljanz XR, if applicable.

over

For requests for Bimzelx, Cosentyx, Ilumya, Siliq, Skyrizi, and Tremfya, please document a trial with Stelara, or provide clinical rationale for use of the requested agent instead of Stelara and Taltz, if applicable.
For requests for Stelara and Taltz for a diagnosis of PsA, a trial with a traditional or biologic DMARD is not required.
For requests for Stelara for a diagnosis of UC, a trial with a traditional or biologic DMARD is not required.

Section II. Please also complete for treatment of PsO with any adalimumab product, Avsola, Bimzelx, Cimzia, Cosentyx, Enbrel, Ilumya, Inflectra, Otezla, Remicade, Renflexis, Siliq, Skyrizi, Stelara, Taltz, Tremfya, or unbranded infliximab.

Has the member tried other therapies to treat this condition including topical agents, systemic agents, and phototherapy?

☐ Yes. Please list the names of the therapies, dates/duration of trials, and outcomes in Section XIX below.*

☐ No. Please explain why not.

Section III. Please also complete for treatment of AS with anti-TNFs, Cosentyx, Rinvoq, Taltz, Xeljanz, and Xeljanz XR, and for treatment of nr-AxSpA with Cimzia, Cosentyx, Rinvoq, and Taltz.

1. Has the member tried two nonsteroidal anti-inflammatory drugs (NSAIDs)?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XIX below.*
   ☐ No. Please explain why not.
2. If the request is for Cosentyx, Rinvoq, Xeljanz, or Xeljanz XR for the treatment of AS, has the member tried one anti-TNF agent that is FDA-approved for AS?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XIX below.*
   ☐ No. Please explain why not.
3. If the request is for Cosentyx for the treatment of AS, has the member tried Taltz?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*
   ☐ No. Please explain why not.
4. If the request is for Cosentyx or Rinvoq for the treatment of nr-AxSpA, has the member tried one anti-TNF agent?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XIX below.*
   ☐ No. Please explain why not.
5. If the request is for Cosentyx or Rinvoq for the treatment of nr-AxSpA, has the member tried Taltz?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*
   ☐ No. Please explain why not.

Section IV. Please complete for treatment of cytokine release syndrome with Actemra IV.

Please provide anticipated date of administration with concurrent CAR T-cell therapy.

Section V. Please complete for treatment of non-infectious uveitis with Humira and for treatment of GCA with Actemra.

Has the member tried other medications to treat this condition including glucocorticoid therapy for Actemra, or glucocorticoid and immunosuppressive therapy for Humira?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes in Section XIX below.*

☐ No. Please explain why not.

over

Section VI. Please complete for treatment of SSc-ILD with Actemra SC.

Has the member tried cyclophosphamide or mycophenolate?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes in Section XIX below.*

☐ No. Please explain why not.

Section VII. Please complete for treatment of DIRA with Arcalyst and Kineret.

1. Has the diagnosis been confirmed through genetic testing? ☐ Yes. ☐ No.
2. If the request is for Arcalyst, has the member tried Kineret?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*

   ☐ No. Please explain why not.

Section VIII. Please complete for treatment FCAS and MWS with Arcalyst and Ilaris and for treatment of FMF, HIDS/MKD, and TRAPS with Ilaris.

1. Has the diagnosis been confirmed through genetic testing? ☐ Yes. ☐ No.
   If no, does the member have evidence of symptoms indicative of the disease?

   ☐ Yes. Please explain. ☐ No
2. If the request is for treatment of FCAS and MWS with Arcalyst, has the member tried Ilaris?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*

   ☐ No. Please explain why not.
3. If the request is for treatment of FMF with Ilaris, has the member tried colchicine?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*

   ☐ No. Please explain why not.

Section IX. Please complete for treatment of AOSD and systemic JIA with Ilaris, and for treatment of recurrent pericarditis with Arcalyst.

1. Has the member tried other medications to treat this condition, including corticosteroids and Kineret?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes in Section XIX below.*

   ☐ No. Please explain why not.
2. If the request is for treatment of recurrent pericarditis with Arcalyst, has the member tried colchicine and NSAIDs or aspirin?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*

   ☐ No. Please explain why not.

Section X. Please complete for aGVHD prophylaxis with Orencia.

1. Will the requested agent be used in combination with a calcineurin inhibitor?
   ☐ Yes. Please list drug name, dose, and frequency below.

   Drug name Dose and frequency

   ☐ No. Please explain why not.
2. Will the requested agent be used in combination with methotrexate?

   ☐ Yes. Please list dose and frequency.

   ☐ No. Please explain why not.

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Section XI. Please complete for treatment of atopic dermatitis with Adbry, Cibinqo, and Rinvoq.

1. Has the member tried a superpotent or potent topical corticosteroid to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*
   ☐ No. Please explain why not.
2. Has the member tried topical tacrolimus or Eucrisa to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*
   ☐ No. Please explain why not.
3. For Cibinqo and Rinvoq, has the member tried Dupixent to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*
   ☐ No. Please explain why not.

Section XII. Please complete for treatment of alopecia areata with Litfulo and Olumiant.

Has the member tried other medications to treat this condition, including a topical corticosteroid, an intralesional corticosteroid, and Xeljanz or Xeljanz XR?

☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XIX below.*

☐ No. Please explain why not.

Section XIII. Please complete for treatment of polymyalgia rheumatica with Kevzara.

1. Has the member tried a systemic corticosteroid to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*
   ☐ No. Please explain why not.
2. Has the member tried methotrexate to treat this condition?
   ☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*
   ☐ No. Please explain why not.

Section XIV. Please also complete for Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry, and unbranded adalimumab generic requests.

Has the member had a trial with Humira?

☐ Yes. Please attach medical records documenting an inadequate response or adverse reaction to Humira.

☐ No. Please document clinical rationale for use of the requested agent instead of Humira.

Section XV. Please also complete for Velsipity and Zeposia.

Has the member had a trial with Entyvio?

☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*

☐ No. Please explain why not.

Section XVI. Please also complete for Spevigo.

1. Member's current weight _____ Date _____
2. For Spevigo prefilled syringe, has the member tried a biologic DMARD?
   ☐ Yes. Please list the drug names, dates/duration of trials, and outcomes in Section XIX below.
   ☐ No. Please explain why not.
3. For Spevigo prefilled syringe, has the member had a positive response to treatment for an acute pustular psoriasis flare using Spevigo vial? ☐ Yes ☐ No

over

Section XVII. Please also complete for Zymfentra.

1. Please document the medical necessity for the subcutaneous formulation instead of an intravenous infliximab formulation.
2. Is the member currently stable on an infliximab product?
   - ☐ Yes. Please provide start date.
   - ☐ No. Please explain why not.

Section XVIII. Please also complete for Omvoh.

Has the member had a trial with Stelara?

☐ Yes. Please list the drug name, dates/duration of trial, and outcome in Section XIX below.*

☐ No. Please explain why not.

Section XIX. Please complete for all requests as needed.

Please provide the following information regarding previous trials.*

Drug name/Therapy Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

Drug name/Therapy Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

Drug name/Therapy Dates/duration of use

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Briefly describe details of adverse reaction or inadequate response.

Drug name/Therapy Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

Drug name/Therapy Dates/duration of use

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

** Please attach a letter documenting additional trials as necessary.*

Section XX. Please complete for requests for quantities above quantity limits.

Please describe the clinical rationale for exceeding the quantity limit.

over

Section XXI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Thrombocytopenic Agents
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

- ☐ Alvaiz (eltrombopag choline)
- ☐ Cablivi (caplacizumab-yhdp)
- ☐ Doptelet (avatrombopag)
- ☐ Mulpleta (lusutrombopag)
- ☐ Nplate (romiplostim) [MB]
- ☐ Promacta (eltrombopag olamine)
- ☐ Tavalisse (fostamatinib)

Dose and frequency _____ **Duration of therapy** _____

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Drug NDC (if known) or service code _____

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Indication (Check all that apply or include ICD-10 code, if applicable.)

- ☐ Acquired thrombotic thrombocytopenic purpura (aTTP)
- ☐ Chronic, relapsed, or refractory immune thrombocytopenia (ITP)
- ☐ Hematopoietic Syndrome of Acute Radiation Syndrome (HS-ARS)/Acute exposure to myelosuppressive doses of radiation
- ☐ Severe aplastic anemia
- ☐ Thrombocytopenia due to chronic liver disease (CLD)
- ☐ Thrombocytopenia in the setting of hepatitis C
- ☐ Other _____

Section I. Please complete for Doptelet and Mulpleta requests for thrombocytopenia due to chronic liver disease.

1. Is a procedure planned? ☐ Yes. Please provide anticipated date of procedure. _____ ☐ No
2. Please provide date and results of most recent platelet count (including laboratory reference ranges).
   _____
3. For Mulpleta requests, has the member had a trial with Doptelet?
   ☐ Yes. Please list the dates/duration of use and outcomes below.
   Dates/duration of use _____ ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   _____

☐ No. Please explain why not.

Section II. Please complete for Alvaiz, Doptelet, Nplate, Promacta, and Tavalisse requests for chronic, relapsed or refractory ITP.

1. Please provide date and results of most recent platelet count (including laboratory reference ranges). For platelet count > 30,000 cells/mcL, describe medical necessity for platelet elevation.
2. Has the member had a trial with a corticosteroid or immunoglobulin therapy?
   ☐ Yes. Please list the drug name, dates/duration of use, and outcomes below.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please explain why not.
3. Has the member had a splenectomy? ☐ Yes ☐ No
4. For Alvaiz, please describe medical necessity for use instead of Promacta.
5. For Doptelet, Nplate, and Tavalisse requests, has the member had a trial with eltrombopag?
   ☐ Yes. Please list the dates/duration of use and outcomes below.
   Dates/duration of use ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, or other.
   ☐ No. Please explain why not.

Section III. Please complete for Alvaiz and Promacta requests for thrombocytopenia in the setting of hepatitis C.

1. Please provide date and results of most recent platelet count (including laboratory reference ranges).
2. Is the member currently on interferon therapy? ☐ Yes. Please provide start date. ☐ No
3. For members not currently on interferon therapy, does the treatment plan include initiation of therapy with interferon? ☐ Yes ☐ No
4. For Alvaiz, please describe medical necessity for use instead of Promacta.

Section IV. Please complete for Alvaiz and Promacta requests for severe aplastic anemia.

1. Please provide date and results of most recent platelet count (including laboratory reference ranges).
2. Has the member had a trial with anti-thymocyte globulin (ATG)?
   ☐ Yes. Please list the dates/duration of use and outcomes below.
   Dates/duration of use ☐ Adverse reaction ☐ Inadequate response ☐ Other

over

Briefly describe details of adverse reaction, inadequate response, or other.

☐ No. Please explain why not.

3. Has the member had a trial with cyclosporine?
   ☐ Yes. Please list the dates/duration of use and outcomes below.

   Dates/duration of use ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other.

   ☐ No. Please explain why not.
4. For Alvaiz, please describe medical necessity for use instead of Promacta.
5. For use of Promacta in combination with ATG and cyclosporine, please provide clinical rationale.

Section V. Please complete for Cablivi requests.

Will the member be taking the requested medication concurrently with immunosuppressive therapy?

☐ Yes. Please list the drug name and dates/duration of use.

Drug name Dates/duration of use

☐ No. Please explain why not.

Section VI. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No

   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?

   ☐ Yes ☐ No

   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?

   ☐ Yes ☐ No

   If yes, please provide details for the previous trial.

   Drug name Dates/duration of use

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response

over

Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

☐ Yes. Please provide details.

☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Topical Anesthetics
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ lidocaine 5% patch > 3 patches/day

Dose/frequency _____ patch/patches every 12 hours/24 hours (with 12 hours off)

☐ Other _____

☐ lidocaine 4%patch > 4 patches/day. Dose/frequency _____

☐ Qutenza (capsaicin high dose patch) [MB] Dose/frequency _____

☐ Ztlido (lidocaine 1.8% patch) Dose/frequency _____

Number of patches requested/30 days _____

[MB] *This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, PA does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for PA requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for PA status and criteria, if applicable.*

Please indicate billing preference. ☐ Pharmacy ☐ Prescriber in-office ☐ Hospital outpatient
If applicable, please also complete section for professionally administered medications at end of form.

Indication (Check all that apply or include ICD-10 code, if applicable.)

☐ Dermatological procedure requiring local analgesia. Please describe. _____
☐ Diabetic peripheral neuropathy
☐ Neurologic pain
☐ Post herpetic neuralgia
☐ Other _____

If other, does the type of pain being treated have a neuropathic component? ☐ Yes ☐ No

Please list all other medications currently prescribed for the member for this indication.

_____

_____

Section I. Please complete for requests for lidocaine patch and Ztlido exceeding quantity limits.

Please describe the medical necessity for using the requested agent above the quantity limit.

Section II. Please also complete for Ztlido requests.

Has the member had a trial with lidocaine 4% patches and lidocaine 5% patches?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using lidocaine 4% patches and lidocaine 5% patches in this member.

** Please attach a letter documenting additional trials as necessary.*

Section III. Please complete for Qutenza requests.

For requests for postherpetic neuralgia, please complete questions 1 and 2. For requests for diabetic peripheral neuropathy, please complete all of the following questions.

1. Has the member had a trial with lidocaine patch and a topical capsaicin agent?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

☐ No. Please describe clinical rationale for not using lidocaine patch and a topical capsaicin agent in this member.

2. Has the member had a trial with a tricyclic antidepressant and an anticonvulsant (gabapentin or pregabalin)?

☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

Drug name Dates/duration of use Dose and frequency

Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

Drug name _____ Dates/duration of use _____ Dose and frequency _____
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

_____

over

☐ No. Please describe medical necessity for transdermal formulation.

_____

3. Has the member had a trial with venlafaxine or duloxetine?
   ☐ Yes. Please list the drug name, dates/duration of trials, and outcomes below.*

   Drug name _____ Dates/duration of use _____ Dose and frequency _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other
   Briefly describe details of adverse reaction, inadequate response, contraindication, or other.

   _____

   ☐ No. Please describe medical necessity for transdermal formulation.

   _____

** Please attach a letter documenting additional trials as necessary.*

Section IV. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

   _____

   _____

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

   _____

   _____

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name _____ Dates/duration of use _____
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

   _____

   _____

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?

   ☐ Yes. Please provide details. _____
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
☐ **MassHealth Drug Utilization Review Program** Pharmacy: Fax: (877) 208-7428 - Tel: (800) 745-7318
MassHealth Managed Care Organization (MCO) and Accountable Care Partnership Plans (ACPP)
☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
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☐ **Tufts Health Plan** Online Prior Authorization: point32health.promptpa.com Pharmacy: Fax: (617) 673-0939 - Tel: (888) 257-1985
☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Topical Corticosteroids
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

Class I Superpotent products (See Sections I., II., and III.)

- ☐ diflorasone: ointment
- ☐ halobetasol: foam
- ☐ halobetasol (Bryhali, Ultravate): lotion

Class II Potent products (See Sections I., II., and III.)

- ☐ desoximetasone (Topicort): ointment (0.25%), spray (0.25%), gel (0.05%)
- ☐ diflorasone (Apexicon-E): cream
- ☐ halcinonide (Halog): cream, solution

Class III Upper Mid-Strength Potent products (See Sections I., II., and III.)

- ☐ amcinonide: cream
- ☐ desoximetasone (Topicort): cream (0.05%), ointment (0.05%)
- ☐ diflorasone: cream

Class IV Mid-Strength Potent products (See Sections I., II., and III.)

- ☐ clocortolone: cream
- ☐ fluocinolone (Synalar): ointment-kit
- ☐ flurandrenolide: ointment
- ☐ triamcinolone: ointment (0.05%), spray

Class V Lower Mid-Strength Potent products (See Sections I., II., and III.)

- ☐ fluocinolone (Synalar): cream-kit
- ☐ flurandrenolide: cream, lotion
- ☐ fluticasone propionate: lotion
- ☐ hydrocortisone butyrate: lotion
- ☐ hydrocortisone butyrate/emollient (Locoid Lipocream): cream

Class VI Mild Potent products (See Sections I., II., and III.)

- ☐ fluocinolone (Synalar): solution-kit

Class VII Least Potent products (See Sections I., II., and III.)

- ☐ hydrocortisone: solution

Combination products

- ☐ betamethasone/calcipotriene (Taclonex): ointment, scalp suspension
- ☐ halobetasol/tazarotene (Duobrii): lotion
- ☐ neomycin/fluocinolone: cream, cream-kit

Strength and formulation requested

Frequency and duration of therapy **Drug NDC (if known)**

Indication(s) or ICD-10 code(s), if applicable

Section I. Please complete for all requests, excluding combination products.

Has the member had a trial with all topical corticosteroids of the same formulation and potency range that are available without prior authorization?

☐ Yes. Please list the specific drug name, dates/duration of use, and outcomes below*.

Drug name, strength, and formulation ____ Dates/duration of use ____
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

Drug name, strength, and formulation ____ Dates/duration of use ____
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

Drug name, strength, and formulation ____ Dates/duration of use ____
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

Drug name, strength, and formulation ____ Dates/duration of use ____
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

Drug name, strength, and formulation ____ Dates/duration of use ____
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please explain contraindication or clinical rationale for not using other topical corticosteroid(s) that are available without prior authorization in this member.

Section II. Please complete for foam and shampoo formulations in scalp-related conditions.

Has the member had a trial with one topical corticosteroid of a similar formulation and similar or greater potency range that is available without prior authorization?

☐ Yes. Please list the specific drug name, dates/duration of use, and outcomes below*.

Drug name, strength, and formulation ____ Dates/duration of use ____
Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
Briefly describe details of adverse reaction or inadequate response.

☐ No. Please explain contraindication or clinical rationale for not using other topical corticosteroid(s) that are available without prior authorization for this member.

over

Section III. Please complete for foam, gel, kit, shampoo, solution, and spray formulations.

Explain medical necessity for the requested formulation.

Section IV. Please complete for combination products.

1. Provide medical necessity for the combination product instead of the individual agents.
2. For Duobrii, has the member had a trial with one superpotent or potent topical corticosteroid?
   ☐ Yes. Please list the specific drug name, dates/duration of use, and outcomes below.*
   Drug name, strength, and formulation Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
   ☐ No

**Attach a letter with additional information regarding medication trials as applicable*.

Section V. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

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Printed name of prescribing provider Date

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Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

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Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

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☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
☐ **Health New England** Online Prior Authorization: go.covermymeds.com/OptumRx Pharmacy: Fax: (800) 550-9246 - Tel: (800) 918-7545
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☐ **WellSense Health Plan** Online Prior Authorization: wellsense.org/providers/ma/pharmacy/prior-authorizations Pharmacy: Fax: (833) 951-1680 - Tel: (877) 417-1822

over

Topical Vitamin D Analogues
Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested and tube size

- ☐ calcipotriene cream (quantity > 60 grams/30 days)
  - ☐ 60 gram tube ☐ 120 gram tube
- ☐ calcipotriene foam
  - ☐ 60 gram tube ☐ 120 gram tube
- ☐ calcipotriene ointment (quantity > 60 grams/30 days)
  - ☐ 60 gram tube ☐ 120 gram tube
- ☐ calcitriol ointment
  - ☐ 100 gram tube
- ☐ Other*

Frequency of application

Indication (Check all that apply, or ICD-10 code, if applicable)

- ☐ Plaque psoriasis
- ☐ Other (Please indicate.)

Drug NDC (if known) or service code

** If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Section I. Please complete for requests for calcitriol ointment and calcipotriene foam.

1. Has the member had a trial with a topical corticosteroid?
   - ☐ Yes. Please list the drug name, dates/duration of use, and outcome of trial as noted below.*

     Drug name Dates/duration of use

     Did the member experience any of the following outcomes? ☐ Adverse reaction ☐ Inadequate response

     Briefly describe details of adverse reaction or inadequate response.
   - ☐ No. Does the member have a contraindication to topical corticosteroids? Please explain.
2. Has the member had a trial with calcipotriene cream, ointment, or scalp solution?
   - ☐ Yes. Please list the drug name, dates/duration of use, and outcome of trial as noted below.*

     Drug name Dates/duration of use

     Did the member experience any of the following outcomes? ☐ Adverse reaction ☐ Inadequate response

Briefly describe details of adverse reaction or inadequate response.

☐ No. Does the member have a contraindication to calcipotriene cream, ointment, and scalp solution?
Please explain.

** Please attach a letter documenting additional trials as necessary.*

Section II. Please complete for requests for quantities exceeding established quantity limits.

Please describe the clinical rationale for exceeding the quantity limit.

Section III. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.
2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.
3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.
4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

Prior Authorization Request Administrative Information

Member Information

Last name _____ First name _____ MI _____

Member ID _____ Date of birth _____

Sex assigned at birth ☐ Female ☐ Male ☐ "X" or Intersex

Current gender ☐ Female ☐ Male ☐ Transgender male ☐ Transgender female ☐ Other _____

Place of residence ☐ Home ☐ Nursing facility ☐ Other _____

Race _____ Ethnicity _____

Preferred spoken language _____ Preferred written language _____

MassHealth does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, creed, sexual orientation, or sex (including gender identity and gender stereotyping).

Plan Contact Information

Please indicate the member's MassHealth Plan and fax or submit this completed and signed form according to the Plan's contact information below.

MassHealth Fee-For-Service (FFS) Plan, Primary Care Clinician (PCC) Plan, Primary Care Accountable Care Organization (PCACO) Plan, Children's Medical Security Plan, and Health Safety Net Plan
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☐ **Fallon Health** Online Prior Authorization: go.covermymeds.com/OptumRx Online Prior Authorization: providerportal.surescripts.net/ProviderPortal/optum Pharmacy: Fax: (844) 403-1029 - Tel: (844) 720-0033
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☐ **Mass General Brigham Health Plan** Online Prior Authorization (Non-Specialty Drugs): go.covermymeds.com/OptumRx Online Prior Authorization (Specialty/Medical Drugs): provider.massgeneralbrighamhealthplan.org Pharmacy: Fax: (844) 403-1029 - Tel: (800) 711-4555
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over

Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors Prior Authorization Request

MassHealth reviews requests for prior authorization (PA) on the basis of medical necessity only. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including current member eligibility, other insurance, and program restrictions. MassHealth will notify the requesting provider and member of its decision. Keep a copy of this form for your records. If faxing this form, please use black ink.

Additional information about these agents, including PA requirements and preferred products, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Medication information

Medication requested

☐ Austedo (deutetrabenazine)

☐ Austedo XR (deutetrabenazine extended-release)

☐ Ingrezza (valbenazine)

☐ tetrabenazine

☐ Other* _____

**If request is for a non-preferred brand name or generic product, please attach supporting documentation (e.g., copies of medical records and/or office notes regarding adverse reaction or inadequate response to the preferred product).*

Dose, frequency, and duration of requested medication _____

Drug NDC (if known) or service code _____

Indication (Check all that apply, or ICD-10 code if applicable.) _____

☐ chorea associated with Huntington's disease

☐ tardive dyskinesia

☐ persistent, disabling, or intrusive

☐ Other (Please describe.) _____

Is this member a referral candidate for care coordination? ☐ Yes ☐ No

If yes, MassHealth will offer care coordination services to this member. Please describe which additional behavioral health services would be beneficial. _____

Section I. Please complete for Austedo, Austedo XR, and Ingrezza requests.

1. For Huntington's disease, has the member had a trial with tetrabenazine?

   ☐ Yes. Please list the dates/duration of trial and outcomes. Dates/duration of use _____

   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response ☐ Other

   Briefly describe details of adverse reaction, inadequate response, or other. _____

   ☐ No. Please explain why not. _____

2. For Austedo and Austedo XR, doses > 36 mg/day, has the member been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer? ☐ Yes. ☐ No.

Section II. Please complete for tetrabenazine requests > 50 mg/day.

Has the member been genotyped for the drug metabolizing enzyme CYP2D6 to determine that the member is not a poor metabolizer? ☐ Yes. ☐ No.

Section III. Please complete and provide documentation for exceptions to Step Therapy.

1. Is the alternative drug required under the step therapy protocol contraindicated, or will likely cause an adverse reaction in, or physical or mental harm to the member? ☐ Yes ☐ No
   If yes, briefly describe details of contraindication, adverse reaction, or harm.

2. Is the alternative drug required under the step therapy protocol expected to be ineffective based on the known clinical characteristics of the member and the known characteristics of the alternative drug regimen?
   ☐ Yes ☐ No
   If yes, briefly describe details of known clinical characteristics of member and alternative drug regimen.

3. Has the member previously tried the alternative drug required under the step therapy protocol, or another alternative drug in the same pharmacologic class or with the same mechanism of action, and such alternative drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event?
   ☐ Yes ☐ No
   If yes, please provide details for the previous trial.
   Drug name Dates/duration of use
   Did the member experience any of the following? ☐ Adverse reaction ☐ Inadequate response
   Briefly describe details of adverse reaction or inadequate response.

4. Is the member stable on the requested prescription drug prescribed by the health care provider, and switching drugs will likely cause an adverse reaction in or physical or mental harm to the member?
   ☐ Yes. Please provide details.
   ☐ No

Please continue to next page and complete Prescriber and Provider Information section.

over

Prior Authorization Request Prescriber and Provider Information

Prescriber Information

Last name* First name* MI

NPI* Individual MH Provider ID

DEA No. Office Contact Name

Address City State Zip

E-mail address

Telephone No.*

Fax No.* (Please provide fax number for PA response notification.)

** Required*

Please also complete for professionally administered medications, if applicable.

Start date End date

Servicing prescriber/facility name ☐ Same as prescribing provider

Servicing provider/facility address

Servicing provider NPI/tax ID No.

Name of billing provider

Billing provider NPI No.

Is this a request for recertification? ☐ Yes ☐ No

CPT code No. of visits J code No. of units

Prescribing provider's attestation, signature, and date

I certify under the pains and penalties of perjury that I am the prescribing provider identified in the Prescriber information section of this form. Any attached statement on my letterhead has been reviewed and signed by me. I certify that the medical necessity information (per 130 CMR 450.204) on this form is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

Prescribing provider's signature _____

Printed name of prescribing provider Date

(The form can either be signed by hand and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.)

MassHealth Concomitant Opioid and Benzodiazepine Initiative

BACKGROUND

The MassHealth Concomitant Opioid and Benzodiazepine Initiative (COBI) requires prior authorization for members using opioid and benzodiazepine medications concomitantly. This is due, in part, to the growing data supporting the significant risk associated with the concomitant use of these medications. As part of this initiative, prior authorization is required for any benzodiazepine in members who fill both ≥ 15 days supply of benzodiazepines and an opioid within the past 45 days. Effective with the March 2024 MassHealth Drug list update, PA is required for members who are newly starting opioid therapy and are stable on benzodiazepine therapy for ≥ 15 days supply within the past 45 days. Members can receive up to a combined total of 14 days supply of one or more opioid(s) within the past 45-day period without PA. Please note: In general, members that are residents of nursing homes or chronic care facilities, enrolled in hospice, or with a current diagnosis or cancer or sickle cell disease may be considered on a case-by-case basis for an exemption from COBI requirements.

The reference table below lists the opioid and benzodiazepine medications included in the Concomitant Opioid and Benzodiazepine Initiative. Further information on the prior authorization requirements, including approval criteria, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Concomitant Opioid and Benzodiazepine Initiative Medication List[1]	
Benzodiazepines	**Opioids**
alprazolam	buprenorphine[3]
chlordiazepoxide	butorphanol
chlordiazepoxide/clidinium	codeine
clonazepam	dihydrocodeine
clorazepate	fentanyl
diazepam[2]	hydrocodone
estazolam	hydromorphone
flurazepam	levorphanol
lorazepam	meperidine
midazolam[2]	methadone
oxazepam	morphine
quazepam	oxycodone
temazepam	oxymorphone
triazolam	opioid powders
	tapentadol
	tramadol

[1]Injectable benzodiazepine formulations are excluded from the Concomitant Opioid and Benzodiazepine Initiative requirements.

[2]Nasal and rectal diazepam and nasal midazolam formulations are excluded from the Concomitant Opioid and Benzodiazepine Initiative requirements.

[3]Buprenorphine formulations used in the treatment of substance use disorder are not included in the Concomitant Opioid and Benzodiazepine Initiative.

Q&A ABOUT THE MASSHEALTH CONCOMITANT OPIOID AND BENZODIAZEPINE INITIATIVE

What is the goal of this initiative?

The MassHealth Concomitant Opioid and Benzodiazepine Initiative focuses on safe prescribing practices for regimens incorporating both opioid and benzodiazepine medications in MassHealth members. The initiative includes prior authorization requirements for both opioids and benzodiazepines when used concomitantly.

What types of medications will be affected by this initiative?

This initiative targets both opioid and benzodiazepine medications. A comprehensive medication list and additional information about the MassHealth Concomitant Opioid and Benzodiazepine Initiative, including prior authorization requirements, are available on the MassHealth Drug List webpage at www.mass.gov/druglist.

Who will be affected by the MassHealth Concomitant Opioid and Benzodiazepine Initiative?

Currently the initiative impacts MassHealth members enrolled in the fee-for-service, Primary Care Clinician Plan, and Primary Care Accountable Care Organizations. Corresponding policies are in place or in development by MassHealth Managed Care Organizations and Accountable Care Partnership Plans.

When will the prior authorization requirements for the MassHealth Concomitant Opioid and Benzodiazepine Initiative take effect?

Polypharmacy within the same medication class currently exists and information can be found on the MassHealth Drug List website. The anticipated start date for this initiative will be November 25, 2019.

Will prescriptions written prior to the start of this initiative be grandfathered?

No. The initiative will take effect on November 25, 2019, with claims for benzodiazepine medications rejecting as early as January 2020. The pharmacy will be notified regarding the need for prior authorization as well as the availability of emergency supplies if required.

How will prescribers know what information needs to be submitted for a prior authorization?

The Benzodiazepines and Other Antianxiety Agents Prior Authorization form and the Opioids/Acetaminophen Analgesic Prior Authorization form have been updated with additional information about the MassHealth Concomitant Opioid and Benzodiazepine Initiative. Prior authorization requirements are available on the MassHealth Drug List webpage at www.mass.gov/druglist.

Is there a specific prior authorization form for the MassHealth Concomitant Opioid and Benzodiazepine Initiative?

No. The Benzodiazepines and Other Antianxiety Agents Prior Authorization form and the Opioids/Acetaminophen Analgesic Prior Authorization form are available on the MassHealth Drug List webpage at www.mass.gov/druglist.

Will a prior authorization request need to be submitted for each opioid and benzodiazepine medication?

No. Questions addressed in the Benzodiazepines and Other Antianxiety Agents Prior Authorization form and the Opioids/Acetaminophen Analgesic Prior Authorization form will allow documentation of the full Opioid and Benzodiazepine regimen, to include name, dose, frequency and indication. Additionally, questions regarding clinical rationale and tapering of agents will also be included.

Are any resources available to aid prescribers in determining which members will be affected by this initiative?

The MassHealth Drug Utilization Review (DUR) Program can provide prescribers with a list of members for whom the prescriber has (a) provided treatment and (b) may be affected by this initiative. Prescribers may request this list by contacting the DUR program at (800) 745-7318.

Are there any prescriber restrictions for prior authorization requests for this initiative?

All enrolled prescribers may submit prior authorization requests on behalf of the member.

Will a prior authorization request need to be submitted when a medication changes in the opioid and benzodiazepine regimen?

Prior authorization may be required for members with a change in therapy. Dose changes may require resubmission of prior authorization in members who also fall under the high dose opioid criteria, benzodiazepine polypharmacy criteria or in situations where the medication itself requires prior authorization. Prescribers who need to cross taper or titrate medications should clearly document the plan so that DUR can facilitate those changes. Prescribers are encouraged to submit prior authorization requests prior to implementing medication changes to avoid disruption in therapy.

If there is more than one prescriber involved in the medication regimen, which prescriber would be responsible for submitting the prior authorization request on behalf of the member?

Coordination of care between prescribers is strongly encouraged to ensure safe and effective prescribing practices. Any enrolled prescriber involved in the member's care may submit the prior authorization request. The prescriber who submits the prior authorization request is encouraged to coordinate with all other prescribers for the member and clearly document the diagnoses and corresponding treatment plan, including all current medications, on the prior authorization request.

Will member care be disrupted if the prior authorization request has not been submitted or processed before the prescription is filled?

Emergency supplies of medications will be available to avoid disruption in therapy. The prescriber, member, and/or member's caregiver may request an emergency supply of medication at the member's pharmacy. Emergency supplies of medications are available for any clinically appropriate duration of therapy, with a minimum of 72 hours. There is no limit to the number of subsequent emergency supplies of medications, if such supplies are medically necessary.

What is the approval duration for prior authorization requests submitted under the MassHealth Concomitant Opioid and Benzodiazepine Initiative?

The duration of a prior authorization approval and of a recertification may be up to 12 months, depending on the clinical situation.

What is a provisional prior authorization approval?

A prior authorization request may be approved provisionally for a duration of up to 6 months depending on the clinical situation. Prior authorization requests may be approved provisionally to avoid disruption in therapy when clinical documentation is required from a prescriber or during a documented taper plan. In circumstances where additional clinical documentation is required, prescribers will be notified via fax and/or telephone.

Who can answer additional questions?

For Pharmacists and Prescribers

If you have questions about a specific member or claim affected by the MassHealth Concomitant Opioid and Benzodiazepine Initiative, please contact the Drug Utilization Review Program at (800) 745-7318.

For MassHealth Members

If you have questions about the MassHealth Concomitant Opioid and Benzodiazepine Initiative, please call MassHealth Customer Service at (800) 841-2900 (TTY: (800) 497-4648).

MassHealth Opioid and Pain Initiative

A. Opioid Analgesics that Require Prior Authorization (PA) for All Dosage Forms and Strengths

Note: See Section B below for information regarding agents with additional restrictions such as age, dose, monotherapy, and/or quantity limits.

dihydrocodeine/acetaminophen/caffeine – **PA**
fentanyl buccal tablet – **PA**
fentanyl transmucosal system – **PA**
meperidine – **PA**
Olinvyk (oliceridine) [MB] – **PA**
opioid powders – **PA**
Nucynta (tapentadol immediate-release) – **PA**
Nucynta ER (tapentadol extended-release) – **PA**

[MB] This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy. If listed, prior authorization does not apply through the hospital outpatient and inpatient settings. Please refer to 130 CMR 433.408 for prior authorization requirements for other health care professionals. Notwithstanding the above, this drug may be an exception to the unified pharmacy policy; please refer to respective MassHealth Accountable Care Partnership Plans (ACPPs) and Managed Care Organizations (MCOs) for prior authorization status and criteria, if applicable.

B. Opioid Analgesics with Age, High Dose, High Dose Short-Acting Monotherapy, and/or Quantity Limit Restrictions that Require PA

Note: Some medications in the table below (notated with an asterisk) require PA for all dosage forms and strengths. Additional information is required for opioid requests that exceed age, dose, or quantity limits, or for use of a high-dose short-acting opioid as monotherapy. Please provide medical records and complete the appropriate section of the Opioids/Acetaminophen Analgesic Prior Authorization Request form when requesting PA for ages, quantities, or doses outside of the limits listed below, or for use of a high-dose short-acting opioid without a long-acting opioid agent. Certain exemptions may apply to high-dose criteria (e.g., diagnosis of sickle cell disease, active cancer pain, palliative care, hospice).

The accumulated high dose threshold is 120 mg of morphine or morphine equivalent (MME) per day for an individual agent, and 180 MME per day for the entire regimen. All buprenorphine formulations are excluded from the opioid accumulator.

Long-acting		
Drug	**Age/Dose Limit**	**Quantity Limit**
Belbuca (buprenorphine buccal film)*	> 1,800 mcg/day	> 2 films/day
Butrans (buprenorphine transdermal system)‡	> 20 mcg/hr (i.e. one 20 mcg/hr patch every 7 days)	> 4 patches/28 days
Conzip (tramadol extended-release capsule)*‡	< 12 years > 300 mg/day	> 1 capsule/day
Dolophine, Methadose (methadone)*†‡	> 25 mg/day	N/A
fentanyl transdermal system‡[2]	> 50 mcg/hr (i.e. one 50 mcg/hr patch every 72 hours)	> 10 patches/30 days
hydrocodone extended-release*‡	> 80 mg/day	> 2 capsules/day
hydromorphone extended-release*‡	> 24 mg/day	> 1 tablet/day
Hysingla ER (hydrocodone extended-release)*‡	> 80 mg/day	> 1 tablet/day
levorphanol*‡	> 4 mg/day	> 2 tablets/day
morphine extended-release capsule*‡	> 120 mg/day	> 1 capsule/day
MS Contin (morphine controlled-release)‡	> 120 mg/day	N/A
Oxycontin (oxycodone extended-release tablet)*‡	> 80 mg/day	> 3 tablets/day
oxymorphone extended-release*	> 40 mg/day	> 2 tablets/day
tramadol extended-release tablet*‡	< 12 years > 300 mg/day	> 1 tablet/day
Xtampza (oxycodone extended-release capsule)*	> 72 mg/day	> 2 capsules/day

* Both brand and generic (if available) require PA, even within dose and quantity limits; PA criteria available at www.mass.gov/druglist.
† Dose limits apply to both oral and injectable formulation.
‡ Available generically
[2] Fentanyl transdermal system 37.5, 62.5, and 87.5 mcg/hr require PA, even within dose and quantity limits.

Short-acting	
Drug	**Age/Dose/Quantity Limit**
acetaminophen products‡	> 4 grams/day
acetaminophen with codeine products‡[1]	< 12 years > 4 grams acetaminophen/day > 360 mg codeine/day
benzhydrocodone/acetaminophen*‡[1]	> 65.28 mg benzhydrocodone/day > 4 grams acetaminophen/day
butorphanol nasal spray*‡	> 2 canisters/30 days
codeine products‡[1]	< 12 years > 360 mg/day
Dilaudid (hydromorphone)†‡[1]	> 24 mg/day
hydrocodone/acetaminophen‡[1]	> 80 mg hydrocodone/day > 4 grams acetaminophen/day
hydrocodone/acetaminophen 300 mg*‡[1]	> 80 mg hydrocodone/day > 4 grams acetaminophen/day
hydrocodone 5 mg, 10 mg/ibuprofen*‡[1]	> 80 mg hydrocodone/day > 3.2 grams ibuprofen/day
hydrocodone 7.5 mg/ibuprofen‡[1]	> 80 mg hydrocodone/day > 3.2 grams ibuprofen/day
morphine immediate-release†‡[1]	> 120 mg/day
oxymorphone immediate-release*†‡[1]	> 40 mg/day
oxycodone/acetaminophen 300 mg*‡[1]	> 80 mg oxycodone/day > 4 grams acetaminophen/day
oxycodone/aspirin‡	> 80 mg oxycodone/day > 4 grams aspirin/day
oxycodone immediate-release‡[1]	> 80 mg/day
Percocet (oxycodone/acetaminophen)‡[1]	> 80 mg oxycodone/day > 4 grams acetaminophen/day
Seglentis (celecoxib/tramadol)*[1]	< 12 years > 400 mg tramadol/day
tramadol 100 mg*‡[1]	< 12 years > 400 mg/day
tramadol solution*‡[1]	< 12 years > 400 mg/day
Ultracet (tramadol/acetaminophen)*‡[1]	< 12 years > 400 mg tramadol/day > 4 grams acetaminophen/day
Ultram (tramadol 50 mg)‡[1]	< 12 years > 400 mg/day

* Both brand and generic (if available) require PA, even within dose and quantity limits; PA criteria available at www.mass.gov/druglist.
† Dose limits apply to both oral and injectable formulation.
‡ Available generically
[1] High dose short-acting monotherapy limits apply.

C. Duplicate Opioid Therapy

PA is required for members taking ≥ two long-acting opioids for > two months.

PA is required for members taking ≥ two short-acting opioids for > two months.

over

D. Concurrent Therapy with Opioid Dependence Agents

For members determined to be stable on any opioid dependence therapy:

- PA is required for any long-acting opioid.
- PA is required for any short-acting opioid for > seven days supply.
- PA is required for any short-acting opioid(s) for > seven days of therapy within the last 30 days.

E. Opioid First-Fill Seven-Day Supply Restriction

In general, members who have not filled an opioid prescription recently or who are naïve to opioids will be limited to a seven-day supply for their first fill. Seven-day supply opioid restrictions do not apply to members who already take opioids. Certain exemptions may apply to seven-day supply opioid restrictions.

F. Concomitant Opioid and Benzodiazepine Initiative

Effective with the March 2024 MassHealth Drug list update, PA is required for members who are newly starting opioid therapy and are stable on benzodiazepine therapy for ≥ 15 days supply within the past 45 days. Members can receive up to a combined total of 14 days supply of one or more opioid(s) within the past 45-day period without PA. Please note: In general, members that are residents of nursing homes or chronic care facilities, enrolled in hospice, or with a current diagnosis or cancer or sickle cell disease may be considered on a case-by-case basis for an exemption from COBI requirements.

A comprehensive medication list and additional information about the MassHealth Concomitant Opioid and Benzodiazepine Initiative, including prior authorization requirements, are available on the MassHealth Drug List webpage at **www.mass.gov/druglist.** Please refer to the Concomitant Opioid and Benzodiazepine Initiative for further information.

MassHealth Pediatric Behavioral Health Medication Initiative

BACKGROUND

The Pediatric Behavioral Health Medication Initiative proactively requires prior authorization for pediatric members (generally members less than 18 years of age) for certain behavioral health medication classes and/or specific medication combinations (i.e., polypharmacy) that have limited evidence for safety and efficacy in the pediatric population.

As part of this initiative, the following situations will require a prior authorization:

1. **Behavioral health medication polypharmacy**: (i.e., alpha$_2$ agonists, antidepressants, antipsychotics, armodafinil, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil, hypnotic agents, memantine, meprobamate, modafinil, mood stabilizers [agents considered to be used only for seizure diagnoses are not included], naltrexone, prazosin, and viloxazine) filled within a 45-day period for members less than 18 years of age:
    - Pharmacy claims for 4 or more behavioral health medications **if one of the following is included**: an antipsychotic, a benzodiazepine, divalproex/valproate, lithium, or a tricyclic antidepressant
    - Pharmacy claims for 5 or more behavioral health medications (regardless of the medications included)
2. **Antipsychotic polypharmacy**: overlapping pharmacy claims for two or more antipsychotics for at least 60 days within a 90-day period for members less than 18 years of age;
3. **Antidepressant polypharmacy**: overlapping pharmacy claims for two or more antidepressants for at least 60 days within a 90-day period for members less than 18 years of age;
4. **Cerebral stimulant polypharmacy**: overlapping pharmacy claims for two or more cerebral stimulants (immediate-release and extended-release formulations of the same chemical entity are counted as one) for at least 60 days within a 90-day period for members less than 18 years of age;
5. **Mood stabilizer polypharmacy**: overlapping pharmacy claims for three or more mood stabilizers (agents considered to be used only for seizure diagnoses are not included) for at least 60 days within a 90-day period for members less than 18 years of age;
6. **Benzodiazepine polypharmacy**: overlapping pharmacy claims for two or more benzodiazepines (hypnotic benzodiazepine agents, clobazam, nasal and rectal diazepam, and nasal midazolam are not included) for at least 60 days within a 90-day period for members less than 18 years of age;
7. **Antipsychotic** pharmacy claim for members less than ten years of age;
8. **Antidepressant, armodafinil**, **atomoxetine, benzodiazepine, buspirone, donepezil, hypnotic, memantine, meprobamate, modafinil**, **mood stabilizer (agents considered to be used only for seizure diagnoses are not included), naltrexone, prazosin, or viloxazine** pharmacy claim for members less than six years of age;
9. **Alpha$_2$ agonist or cerebral stimulant** pharmacy claim for members less than three years of age.

The reference table below lists the behavioral health medications included in the Pediatric Behavioral Health Medication Initiative. Further information on the prior authorization requirements, including approval criteria, can be found within the MassHealth Drug List at **www.mass.gov/druglist.**

Pediatric Behavioral Health Medication Initiative Medication List[1]

Antidepressants

amitriptyline
amoxapine
bupropion
citalopram
clomipramine
desipramine
desvenlafaxine
dextromethorphan/bupropion
doxepin
duloxetine
escitalopram
esketamine
fluoxetine
fluvoxamine
imipramine
isocarboxazid
levomilnacipran
mirtazapine
nefazodone
nortriptyline
paroxetine
phenelzine
protriptyline
selegiline[2]
sertraline
tranylcypromine
trazodone
trimipramine
venlafaxine
vilazodone
vortioxetine
zuranolone

Antipsychotics

aripiprazole
asenapine
brexpiprazole
cariprazine
chlorpromazine
clozapine
fluphenazine
haloperidol
iloperidone
loxapine
lumateperone
lurasidone
molindone
olanzapine
olanzapine/fluoxetine
olanzapine/samidorphan
paliperidone
perphenazine
perphenazine/amitriptyline
pimozide
quetiapine
risperidone
thioridazine
thiothixene
trifluoperazine
ziprasidone

Mood Stabilizers

carbamazepine
divalproex
gabapentin
lamotrigine
lithium
oxcarbazepine
pregabalin
topiramate
valproic acid

Antianxiety Agents

alprazolam
buspirone
chlordiazepoxide
chlordiazepoxide/amitriptyline
clonazepam
clorazepate
diazepam[3]
lorazepam
meprobamate
midazolam[3]
oxazepam

Hypnotics

daridorexant
doxepin[4]
estazolam
eszopiclone
flurazepam
lemborexant
quazepam
suvorexant
temazepam
triazolam
zaleplon
zolpidem

Alpha$_2$ Agonists

clonidine
guanfacine

Stimulants

amphetamine
dexmethylphenidate
dextroamphetamine
dextroamphetamine/amphetamine
lisdexamfetamine
methamphetamine
methylphenidate
serdexmethylphenidate/dexmethylphenidate

Miscellaneous

armodafinil
atomoxetine
donepezil
memantine
modafinil
naltrexone[5]
prazosin
viloxazine

[1]Short-acting intramuscular injectable and intravenous formulations are excluded from the Pediatric Behavioral Health Medication Initiative requirements.

[2]Emsam (selegiline) is the only selegiline formulation included in the Pediatric Behavioral Health Medication Initiative.

[3]Nasal and rectal diazepam and nasal midazolam formulations are excluded from the Pediatric Behavioral Health Medication Initiative requirements.

[4]Doxepin tablet is classified as a hypnotic agent and the Pediatric Behavioral Health Medication Initiative requirements for antidepressants do not apply. Pediatric Behavioral Health Medication Initiative requirements for hypnotics apply.

[5]Vivitrol (naltrexone injection) is excluded from the Pediatric Behavioral Health Medication Initiative requirements.

10 Tips for a Good Night's Sleep

1. **Keep consistent bedtimes and wake times seven days a week** (even after a "bad" night).

2. You should stay in bed equal only to the number of hours of sleep you are achieving per night (for example, if you are getting six hours of sleep per night, you should plan bedtime and wake time as six hours apart). **Many insomniacs spend far too much time in bed**, attempting to "squeeze" out a few more minutes of sleep.

3. If you have difficulty getting to sleep within 20 minutes, **get out of bed** and do something relaxing and distracting. For many people, this is reading. **Do not do housework, bills, work, or anything that is too stimulating within two hours of bedtime or during a nighttime awakening**.

4. Although some people's insomnia is helped by a **nap** at midday, for most it **will interfere with falling asleep that night**.

5. **Avoid alcohol** within five hours of bedtime. Alcohol is a poor hypnotic and causes nighttime awakenings.

6. **Avoid caffeine** (coffee, tea, soda, chocolate) after noon. Even if it doesn't prevent you from falling asleep, it can cause shallow sleep or nighttime awakenings.

7. **Avoid** going to bed on either an **empty stomach or a full stomach**. A light snack may be of value.

8. **Bedrooms should be quiet, safe, and relaxing**. Clocks should face away from the bed, so as not to "count down" the minutes until morning.

9. **Daily exercise** will improve insomnia, although the effects may not be immediate.

10. **Schedule "worry time"** earlier in the day, so as to consider the day's problems and find some resolution **before** getting into bed.

John Winkelman, MD, PhD
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Assistant Professor of Psychiatry
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03/17

Certain MassHealth Outpatient Physician Administered Drugs to be Paid by Fee Schedule

This list identifies the current list of "**Fee Schedule Drugs**" for purposes of Section 5.C.14 of the Acute Hospital Request for Applications (the RFA). The list of Fee Schedule Drugs may be updated from time-to-time. Hospitals will be reimbursed for Fee Schedule Drugs in accordance with Section 5.C.14 of the RFA.

The Fee Schedule Drugs are listed sequentially by J-Code as follows:

- J2182 – Mepolizumab
- J2350 – Ocrelizumab
- J9022 – Atezolizumab
- J9047 – Carfilzomib
- J9173 – Durvalumab
- J9266 – Pegaspargase
- J9271 – Pembrolizumab
- J9299 – Nivolumab
- J9306 – Pertuzumab

Pharmacy Selection Form

Controlled Substance Management Program

Use this form to request a different primary pharmacy from the one that MassHealth assigned to you upon enrollment into the Controlled Substance Management Program (CSMP) or to request a different pharmacy after you have been enrolled. Until MassHealth notifies you that your request has been approved, you must continue to use your current (or MassHealth-assigned) primary pharmacy.

Reminder: You can request a change in your pharmacy no more than once per year, unless the primary pharmacy is unable to address due to a change in your residence, your medical condition, or the primary pharmacy's business practices.

To request a different pharmacy, fill out the information below, and mail or fax this form to:

MassHealth Drug Utilization Review
Program P.O. Box 2586
Worcester, MA 01613-2586
Fax: (877) 208-7428

Member Information

Your Name: _____ Your MassHealth ID Number: _____

Name and Address of Current Pharmacy

_____

_____

_____

Name and Address of New Pharmacy

_____

_____

_____

Reason for change in your primary pharmacy: _____

Effective Date

Please enter the requested effective date of the change in your primary pharmacy. Please allow four business days for mailing and processing. We will send you a letter confirming your selection. Until MassHealth notifies you that your request has been approved, you must continue to use your current (or MassHealth-assigned) primary pharmacy.

Requested Effective Date: _____

Member Authorization: I understand that I may not change my primary pharmacy again for at least one year from the date of signature below, unless for one of the reasons listed above.

_____

Your Signature Date

Controlled Substances Management Program (CSMP): Criteria for Member Enrollment

The MassHealth agency has established a Controlled Substance Management Program (CSMP) for MassHealth members who overutilize or improperly utilize prescribed drugs. Members in the CSMP are restricted to obtaining all prescribed drugs only from the provider that the MassHealth agency designates as the member's primary pharmacy.

Members who meet one of the following will be enrolled in the program.

- All of the following:
  - Member's average daily morphine equivalent dose is ≥ 90 milliequivalents in both three-month periods of the previous six-month period; **and**
  - These prescriptions were written by three or more prescribers or filled by three or more pharmacies.

- All of the following:
  - Member's average daily morphine equivalent dose is ≥ 90 milliequivalents in both three-month periods of the previous six-month period; **and**
  - These prescriptions were written by two or more prescribers or filled by two or more pharmacies; **and**
  - Member filled three or more prescriptions and/or refills for high-risk medications (i.e., benzodiazepine agents, gabapentin, or stimulant agents) in both three-month periods of the previous six-month period.

- All of the following:
  - Member's average daily morphine equivalent dose is ≥ 90 milliequivalents in both three-month periods of the previous six-month period; **and**
  - Member had six or more emergency department visits during the previous six-month period.

ENHANCED-SERVICES PHARMACY ATTESTATION

Commonwealth of Massachusetts | Executive Office of Health and Human Services | www.mass.gov/masshealth

SECTION I: Instructions

MassHealth will collect and maintain a copy of the Enhanced-Services Pharmacy Attestation for each of its participating pharmacies, signed by someone with actual authority to bind the pharmacy. Each pharmacy must complete this form and email it to Jessica.Robinson@mass.gov for review. Enhanced-services pharmacy attestation and enrollment will occur on an annual basis and will be effective through the end of the calendar year. MassHealth may use this information in connection with dispensing fee reimbursement designations.

Before completing this form, the individual signing must complete and submit the Independent Pharmacy and Entity-Owned Community Health Center Pharmacy Attestation; only independent pharmacies and entity-owned community health center pharmacies are eligible to enroll as enhanced-services pharmacies.

SECTION II: Pharmacy Information

Pharmacy Name		Pharmacy Tax ID
Pharmacy Street Address		
Pharmacy City	Pharmacy State	Pharmacy Zip Code

Pharmacy MassHealth Provider ID Site/Location (PID/SL) – Please include all PID/SLs associated with the pharmacy.

Pharmacy NPI(s) – Please include all NPIs associated with the pharmacy.

Pharmacy Phone Number	Pharmacy Email
Pharmacy Owner or Community Health Center Affiliation	

SECTION III: Enhanced-Services Pharmacy Attestation

☐ The pharmacy is enrolled in the MassHealth Pharmacy Program.

The pharmacy offers the following services to MassHealth members (please check all that apply; all must be selected for the pharmacy to be considered for the enhanced services pharmacy dispensing fee).

☐ Pharmacy-provided home delivery (please provide details below, including frequency of delivery, as well as delivery locations—including group homes, long-term care, personal residence, etc.):

☐ Adherence and blister packaging: unit dose packaging, such as bubble packing, blister cards, or other compliance packaging (please provide details below):

☐ Comprehensive medication therapy management (MTM): at direction of MassHealth, for identified populations, provide at least an annual assessment of patient's medications to identify and prioritize medication-related problems and create a patient-specific plan to resolve medication therapy problems (please provide details below on current MTM activities, including frequency and type of medication reviews):

☐ Medication synchronization: align all of the patient's chronic or maintenance medications to be filled at the same time each month (please provide details below):

☐ Immunizations: screen patients for Advisory Committee on Immunization Practices (ACIP)-recommended immunizations, counseling, and administering (please provide details below on the current frequency and screening protocols):

☐ Medication reconciliation: prepare a comprehensive list of all of the patient's active medications, including instructions on how the patient should take the medications (please provide details below):

☐ As further specified by MassHealth, I agree to work on care gap closures for MassHealth members identified with certain targeted disease states, and provide follow-up to MassHealth at a specified frequency and format.

I certify under the pains and penalties of perjury that the information on this form and any attached statement that I have provided has been reviewed and signed by me, and is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

The person signing this Enhanced Services Pharmacy Attestation warrants that they have actual authority to bind the pharmacy.

Pharmacy Name

Printed Legal Name of Individual Signing

Title

Signature

Date

The form can either be signed traditionally and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.

INDEPENDENT PHARMACY AND ENTITY-OWNED COMMUNITY HEALTH CENTER PHARMACY ATTESTATION

Commonwealth of Massachusetts | Executive Office of Health and Human Services | www.mass.gov/masshealth

SECTION I: Instructions

MassHealth will collect and maintain a copy of the Independent Pharmacy and Entity-Owned Community Health Center Pharmacy Attestation for each of its participating pharmacies, signed by someone with actual authority to bind the participating pharmacy. The pharmacy must complete this form and email it to Jessica.Robinson@mass.gov for review. Independent pharmacy and entity-owned community health center pharmacy attestation and enrollment will occur on an annual basis. MassHealth may use this information in connection with dispensing fee reimbursement designations.

SECTION II: Pharmacy Information

Pharmacy Name		Pharmacy Tax ID
Pharmacy Street Address		
Pharmacy City	Pharmacy State	Pharmacy Zip Code

Pharmacy MassHealth Provider ID Site/Location (PID/SL) – Please include all PID/SLs associated with the pharmacy.

Pharmacy NPI(s) – Please include all NPIs associated with the pharmacy.

Pharmacy Phone Number	Pharmacy Email

Pharmacy Owner or Community Health Center Affiliation

SECTION III: Independent Pharmacy and Entity-Owned Community Health Center Pharmacy Attestation

The pharmacy must meet all of the following criteria:

- ☐ The pharmacy is enrolled in the MassHealth Pharmacy Program.
- ☐ The pharmacy is one of three or fewer pharmacies under common ownership.

OR

The pharmacy must meet all of the following criteria:

- ☐ The pharmacy is enrolled in the MassHealth Pharmacy Program.
- ☐ The pharmacy is owned by a community health center.

I certify under the pains and penalties of perjury that the information on this form and any attached statement that I have provided has been reviewed and signed by me, and is true, accurate, and complete, to the best of my knowledge. I understand that I may be subject to civil penalties or criminal prosecution for any falsification, omission, or concealment of any material fact contained herein.

The person signing this Independent Pharmacy and Entity-Owned Community Health Center Pharmacy Attestation warrants that they have actual authority to bind the pharmacy.

Pharmacy Name

Printed Legal Name of Individual Signing

Title

Signature

Date

The form can either be signed traditionally and then scanned, or it can be signed electronically using DocuSign or Adobe Sign. For electronic signatures, the signer can upload a picture of their wet signature. The typed text of a signature is not an acceptable form of an electronic signature.

Long-Acting Injectable Antipsychotic Medications Administered in Inpatient Psychiatry Units

Effective May 15, 2024, the Long-Acting Injectable Antipsychotic Medication Administered in Inpatient Psychiatry Units section of the MassHealth Drug List (MHDL) applies to participating in-state MassHealth acute hospital (acute) and freestanding inpatient psychiatric hospital (psychiatric) providers of inpatient psychiatric services. This list identifies the current list of long-acting injectable antipsychotic medications that, when administered in an inpatient psychiatry unit, are reimbursable outside of the applicable per diem rates for acute and psychiatric hospitals. Drug specific prior authorization criteria, if applicable, must be met as listed on the MHDL. Other requirements, such as preferred drug designation or quantity limits, may apply. This list, prior authorization status, and other requirements may be updated from time to time.

The Antipsychotic Prior Authorization Form includes a section to denote that the request is for a member currently admitted to an inpatient psychiatry unit.

Hospitals should also review any special billing instructions for Long-Acting Injectable Antipsychotic Medications Administered in Inpatient Psychiatry Units posted on the "Billing Tips" section of the MassHealth website.

The Long-Acting Injectable Antipsychotics are listed sequentially by J-Code as follows:

- J0401 – Aripiprazole (Abilify Maintena), extended release 1 mg
- J0402 – Aripiprazole (Abilify Asimtufii), 1 mg
- J1631 – Haloperidol decanoate, per 50 mg
- J1943 – Aripiprazole lauroxil (Aristada Initio), 1 mg
- J1944 – Aripiprazole lauroxil (Aristada), 1 mg
- J2358 – Olanzapine (Zyprexa Relprevv), long acting, 1 mg
- J2426 – Paliperidone palmitate extended release (Invega Sustenna), 1 mg
- J2427 – Paliperidone palmitate extended release (Invega Hafyera, or Invega Trinza), 1 mg
- J2680 – Fluphenazine decanoate, up to 25 mg
- J2794 – Risperidone (Risperdal Consta), 0.5 mg
- J2798 – Risperidone (Perseris), 0.5 mg
- J2799 – Risperidone (Uzedy), 1 mg
- J2801 – Risperidone (Rykindo), 0.5 mg

Long-Acting Injectable Antipsychotics covered outside the per diem for Acute and Psychiatric Hospitals shall be billed using the appropriate J-Code (according to the Physician Subchapter 6). Definitions, payment rules, and rates for these Long-Acting Injectable Antipsychotics are contained in 101 CMR 317.00: *Rates for medicine services*.

MassHealth Acute Hospital Carve-Out Drugs List

This MassHealth Acute Hospital Carve-Out Drugs List section of the MassHealth Drug List (MHDL) applies to participating in-state MassHealth Acute Hospital providers, and as applicable to out-of-state MassHealth acute hospital providers pursuant to 130 CMR 450.233(D). This List identifies the current list of "**Adjudicated Payment Amount per Discharge (APAD) Carve-Out Drugs**" and "**Adjudicated Payment per Episode of Care (APEC) Carve-Out Drugs**" for purposes of Sections 5.B.8.b and 5.C.9 of the current MassHealth Acute Hospital Request for Applications for in-state acute hospitals (Acute Hospital RFA), and regulations at 130 CMR 450.233(D) for out-of-state acute hospitals.

The hospital must obtain prior authorization (PA) from MassHealth for the APAD Carve-Out Drugs and APEC Carve-Out Drugs on this list, and the associated treatment will be subject to monitoring, as indicated below. Other requirements also apply. This list, and the PA and other requirements, may be updated from time to time.

Hospitals should also review any special billing instructions for APAD Carve-Out Drugs and APEC Carve-Out Drugs posted on the "Billing Tips" section of the MassHealth website.

I. APAD Carve-Out Drugs (administered in an *acute inpatient hospital* setting)

The drugs and biologics listed in this Part I are "**APAD Carve-Out Drugs**" for purposes of Section 5.B.8.b of the Acute Hospital RFA and MassHealth regulations at 130 CMR 450.233(D). The APAD Carve-Out Drugs will be listed alphabetically by therapeutic class, then by the name of the drug or drug ingredients.

Prescriber must submit a request for PA using a Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved. Should PA be granted, the admitting provider must then submit a preadmission screening request for the acute inpatient hospital admission to the MassHealth acute hospital utilization review contractor, Permedion, in accordance with applicable MassHealth regulations and guidelines. Once both have been approved, the treatment plan can be initiated.

Please note that, in addition to PA and other requirements, these therapies require both short- and long-term monitoring for efficacy and durability of response. MassHealth will be conducting outreach to prescriber's offices to gather the applicable information.

Anti-Hemophilia Gene Therapy

See Therapeutic Class Table 80 on the MassHealth Drug List for additional information on Anti-Hemophilia Gene Therapy, including approval criteria and monitoring parameters.

- Roctavian (valoctocogene roxaparvovec-rvox) – **PA**
- Hemgenix (etranacogene dezaparvovec-drlb) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Hemophilia Gene Therapies Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Autologous T-Cell Immunotherapy

See Therapeutic Class Table 75 on the MassHealth Drug List for additional information on Autologous T- Cell Immunotherapy, including approval criteria and monitoring parameters.

- Amtagvi (lifileucel) – **PA**

Process: Prescriber must submit a request for PA for the CAR-T therapy to MassHealth using the T-cell Immunotherapies Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Beta Thalassemia Gene Therapy

See Therapeutic Class Table 45 on the MassHealth Drug List for additional information on Zynteglo, including approval criteria and monitoring parameters.

- Zynteglo (betibeglogene autotemcel) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

CAR-T Therapies

See Therapeutic Class Table 75 on the MassHealth Drug List for additional information on CAR-T Therapies, including approval criteria and monitoring parameters.

- Abecma (idecabtagene vicleucel) – **PA**
- Breyanzi (lisocabtagene maraleucel) – **PA**
- Carvykti (ciltacabtagene autoleucel) – **PA**
- Kymriah (tisagenlecleucel) – **PA****
  ** *Please note that PA approval will require a letter from the hospital's financial department addressing participation status in the manufacturer's outcomes-based contract.*
- Tecartus (brexucabtagene autoleucel) – **PA**
- Yescarta (axicabtagene ciloleucel) – **PA**

Process: Prescriber must submit a request for PA for the CAR-T therapy to MassHealth using the Chimeric Antigen Receptor (CAR)-T Immunotherapies Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Cerebral Adrenoleukodystrophy Gene Therapy

See Therapeutic Class Table 72 on the MassHealth Drug List for additional information on Skysona, including approval criteria and monitoring parameters.

- Skysona (elivaldogene autotemcel) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Skysona Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Duchenne Muscular Dystrophy Gene Therapy

See Therapeutic Class Table 76 on the MassHealth Drug List for additional information on Elevidys, including approval criteria and monitoring parameters.

- Elevidys (delandistrogene moxeparvovec-rokl) – **PA**

Process: Prescriber must submit a request for PA using the Neuromuscular Agents Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Inherited Retinal Disease Gene Therapy

See Therapeutic Class Table 72 on the MassHealth Drug List for additional information on Luxturna, including approval criteria and monitoring parameters.

- Luxturna (voretigene neparvovec-rzyl) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Luxturna Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Metachromatic Leukodystrophy Therapy

See Therapeutic Class Table 72 on the MassHealth Drug List for additional information on Lenmeldy, including approval criteria and monitoring parameters.

- Lenmeldy (atidarsagene autotemcel) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Lenmeldy Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Sickle Cell Disease Gene Therapy

See Therapeutic Class Table 45 on the MassHealth Drug List for additional information on Sickle Cell Disease Gene Therapy, including approval criteria and monitoring parameters.

- Casgevy (exagamglogene autotemcel for sickle cell disease) – **PA**
- Lyfgenia (lovotibeglogene autotemcel) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Spinal Muscular Atrophy Gene Therapy

See Therapeutic Class Table 76 on the MassHealth Drug List for additional information on Zolgensma, including approval criteria and monitoring parameters.

- Zolgensma (onasemnogene abeparvovec-xioi) – **PA**

Process: Prescriber must submit a request for PA using the Neuromuscular Agents Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Stem Cell Therapy

See Therapeutic Class Table 72 on the MassHealth Drug List for additional information on Omisirge, including approval criteria and monitoring parameters.

- Omisirge (omidubicel-onlv) – **PA**

Process: Prescriber must submit a request for PA using the General Drug Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved.

MassHealth evaluates the PA status of drugs on an ongoing basis. Drugs and biologics may be added to this Part as appropriate and updated on the MHDL accordingly.

FDA-Approved New-to-Market Drugs

FDA-approved new-to-market drugs and biologics that are not listed in the MHDL will be handled on a case-by-case basis until MassHealth has concluded its evaluation of the drug or biologic. Hospitals should contact MassHealth regarding whether an FDA-approved new-to-market drug or biologic not listed in the MHDL is an "APAD Carve-Out Drug" for purposes of the Acute Hospital RFA (or MassHealth regulations, as applicable) and this Part I.

II. APEC Carve-Out Drugs (administered in an *acute outpatient hospital* setting)

The drugs and biologics listed in this Part II are "**APEC Carve-Out Drugs**" for purposes of Section 5.C.9 of the Acute Hospital RFA, and MassHealth regulations at 130 CMR 450.233(D). The APEC Carve-Out Drugs will be listed alphabetically by therapeutic class, then by the name of the drug or drug ingredients.

Please note that, in addition to PA and other requirements, these therapies require both short- and long-term monitoring for efficacy and durability of response. MassHealth will be conducting outreach to prescriber's offices to gather the applicable information.

Anti-Hemophilia Gene Therapy

See Therapeutic Class Table 80 on the MassHealth Drug List for additional information on Anti-Hemophilia Gene Therapy, including approval criteria and monitoring parameters.

- Roctavian (valoctocogene roxaparvovec-rvox) – **PA**
- Hemgenix (etranacogene dezaparvovec-drlb) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Hemophilia Gene Therapies Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved.

Autologous T-Cell Immunotherapy

See Therapeutic Class Table 75 on the MassHealth Drug List for additional information on Autologous T- Cell Immunotherapy, including approval criteria and monitoring parameters.

- Amtagvi (lifileucel) – **PA**

Process: Prescriber must submit a request for PA for the CAR-T therapy to MassHealth using the T-cell Immunotherapies Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Beta Thalassemia Gene Therapy

See Therapeutic Class Table 45 on the MassHealth Drug List for additional information on Zynteglo, including approval criteria and monitoring parameters.

- Zynteglo (betibeglogene autotemcel) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved.

CAR-T Therapies

See Therapeutic Class Table 75 on the MassHealth Drug List for additional information on CAR-T Therapies, including approval criteria and monitoring parameters.

- Abecma (idecabtagene vicleucel) – **PA**
- Breyanzi (lisocabtagene maraleucel) – **PA**
- Carvykti (ciltacabtagene autoleucel) – **PA**
- Kymriah (tisagenlecleucel) – **PA****

  ** *Please note that PA approval will require a letter from the hospital's financial department addressing participation status in the manufacturer's outcomes-based contract.*

- Tecartus (brexucabtagene autoleucel) – **PA**
- Yescarta (axicabtagene ciloleucel) – **PA**

Process: Prescriber must submit a request for PA for the CAR-T therapy to MassHealth using the Chimeric Antigen Receptor (CAR)-T Immunotherapies Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved.

Cerebral Adrenoleukodystrophy Gene Therapy

See Therapeutic Class Table 72 on the MassHealth Drug List for additional information on Skysona, including approval criteria and monitoring parameters.

- Skysona (elivaldogene autotemcel) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Skysona Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved.

Duchenne Muscular Dystrophy Gene Therapy

See Therapeutic Class Table 76 on the MassHealth Drug List for additional information on Elevidys, including approval criteria and monitoring parameters.

- Elevidys (delandistrogene moxeparvovec-rokl) – **PA**

Process: Prescriber must submit a request for PA using the Neuromuscular Agents Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Inherited Retinal Disease Gene Therapy

See Therapeutic Class Table 72 on the MassHealth Drug List for additional information on Luxturna, including approval criteria and monitoring parameters.

- Luxturna (voretigene neparvovec-rzyl) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Luxturna Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved.

Metachromatic Leukodystrophy Therapy

See Therapeutic Class Table 72 on the MassHealth Drug List for additional information on Lenmeldy, including approval criteria and monitoring parameters.

- Lenmeldy (atidarsagene autotemcel) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Lenmeldy Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Sickle Cell Disease Gene Therapy

See Therapeutic Class Table 45 on the MassHealth Drug List for additional information on Sickle Cell Disease Gene Therapy, including approval criteria and monitoring parameters.

- Casgevy (exagamglogene autotemcel for sickle cell disease) – **PA**
- Lyfgenia (lovotibeglogene autotemcel) – **PA**

Process: Prescriber must submit a request for PA to MassHealth using the Beta Thalassemia, Myelodysplastic Syndrome, and Sickle Cell Disease Agents Prior Authorization Request form. Once the PA request **and** preadmission screening request for the acute inpatient hospital admission have been approved, the treatment plan can be initiated.

Spinal Muscular Atrophy Gene Therapy

See Therapeutic Class Table 76 on the MassHealth Drug List for additional information on Zolgensma, including approval criteria and monitoring parameters.

- Zolgensma (onasemnogene abeparvovec-xioi) – **PA**

Process: Prescriber must submit a request for PA using the Neuromuscular Agents Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved.

Stem Cell Therapy

See Therapeutic Class Table 72 on the MassHealth Drug List for additional information on Omisirge, including approval criteria and monitoring parameters.

- Omisirge (omidubicel-onlv) – **PA**

Process: Prescriber must submit a request for PA using the General Drug Prior Authorization Request form. The prescriber will be notified via fax if the PA request has been approved.

MassHealth evaluates the PA status of drugs on an ongoing basis. Drugs and biologics will be added to this Part as appropriate and updated on the MHDL accordingly.

FDA-Approved New-to-Market Drugs

FDA-approved new-to-market drugs and biologics that are not listed in the MHDL will be handled on a case-by-case basis until MassHealth has concluded its evaluation of the drug or biologic. Hospitals should contact MassHealth regarding whether an FDA-approved new-to-market drug or biologic not listed in the MHDL is an “APEC Carve-Out Drug” for purposes of the Acute Hospital RFA (or MassHealth regulations, as applicable) and this Part II.

MassHealth Brand Name Preferred Over Generic Drug List

This is the list of brand name drugs that MassHealth prefers over their generic equivalents because the net cost of the brand name drugs adjusted for rebates is lower than the net cost of the generic equivalents.

Please note that MassHealth may still require prior authorization (PA) for clinical reasons. Drugs that require additional PA requirements are noted with "PA" on this list.

In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

This list may be updated often and is subject to change at any time.

- Absorica (isotretinoin) – **PA**
- Adderall XR (amphetamine salts extended-release) – **PA < 3 years or ≥ 21 years and PA > 2 units/day**
- Advair (fluticasone/salmeterol inhalation)
- Afinitor (everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg) – **PA**
- Afinitor Disperz (everolimus tablets for oral suspension) – **PA**
- Airduo Respiclick (fluticasone/salmeterol inhalation powder) – **PA**
- Alphagan P (brimonidine 0.1%, 0.15% eye drops)
- Ancobon (flucytosine)
- Apriso (mesalamine 0.375 gram extended-release capsule)
- Atelvia (risedronate delayed-release) – **PA**
- Atralin (tretinoin 0.05% gel) – **PA**
- Azasite (azithromycin ophthalmic solution) – **PA**
- Azopt (brinzolamide)
- Banzel (rufinamide) – **PA**
- Bepreve (bepotastine)
- Bethkis (tobramycin inhalation solution) – **PA**
- Biltricide (praziquantel)
- Breo (fluticasone/vilanterol)
- Buphenyl (sodium phenylbutyrate)
- Butrans (buprenorphine transdermal) – **PA > 20 mcg/hr and PA > 4 patches/28 days**
- Byetta (exenatide 5 mcg injection) – **PA > 1.2 mL/30 days**
- Byetta (exenatide 10 mcg injection) – **PA > 2.4 mL/30 days**
- Carac (fluorouracil 0.5% cream) – **PA**
- Carbaglu (carglumic acid) – **PA**
- Cleocin T (clindamycin lotion)
- Clindagel (clindamycin gel)
- Complera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate)
- Concerta (methylphenidate extended-release) – **PA < 3 years or ≥ 21 years and PA > 2 units/day**
- Condylox (podofilox gel)
- Copaxone (glatiramer)
- Cosopt PF (dorzolamide/timolol, preservative free) – **PA**
- Cuprimine (penicillamine capsule)
- Cystadane (betaine)
- Daraprim (pyrimethamine) – **PA**
- Daytrana (methylphenidate transdermal) – **PA < 3 years or ≥ 21 years and PA > 1 unit/day**
- Demser (metyrosine)
- Denavir (penciclovir)
- Depakote (divalproex sprinkle capsule) – **PA < 6 years**
- Dermotic (fluocinolone oil, otic drops)
- Dexilant (dexlansoprazole)

- Diclegis (doxylamine/pyridoxine delayed-release) – **PA**
- Divigel (estradiol)
- Duetact (glimepiride/pioglitazone) – **PA**
- Dulera (mometasone/formoterol)
- Dymista (azelastine/fluticasone propionate)
- Edurant (rilpivirine)
- Efudex (fluorouracil 5% cream)
- Elidel (pimecrolimus)
- Emend (aprepitant trifold pack) – **PA > 2 packs/28 days**
- Emflaza (deflazacort) – **PA**
- Emtriva (emtricitabine)
- Eurax (crotamiton lotion) – **PA**
- Exelon (rivastigmine patch) – **PA > 1 unit/day**
- Exjade (deferasirox 125 mg, 250 mg, 500 mg)
- Fabior (tazarotene foam) – **PA**
- Farxiga (dapagliflozin)
- Finacea (azelaic acid foam) – **PA**
- Firvanq (vancomycin oral solution)
- Flovent (fluticasone propionate inhalation)
- Focalin XR (dexmethylphenidate extended-release) – **PA < 3 years or ≥ 21 years and PA > 2 units/day**
- Forteo (teriparatide 600 mcg/2.4 mL) – **PA**
- Frova (frovatriptan) – **PA**
- Gattex (teduglutide injection) – **PA**
- Gelnique (oxybutynin gel)
- Hetlioz (tasimelteon) – **PA**
- Horizant (gabapentin enacarbil) – **PA < 6 years and PA > 1200 mg/day**
- Humira (adalimumab) – **PA**
- Inspra (eplerenone)
- Intelence (etravirine)
- Isentress (raltegravir)
- Isordil (isosorbide dinitrate 40 mg tablet) – **PA**
- Istalol (timolol)
- Kitabis Pak (tobramycin inhalation solution)
- Kombiglyze XR (saxagliptin/metformin extended-release)
- Lantus (insulin glargine)
- Lialda (mesalamine 1.2 gram delayed-release tablet)
- Lotemax (loteprednol 0.5%)
- Lyrica CR (pregabalin extended-release) – **PA**
- Marinol (dronabinol 2.5 mg) – **PA > 2 units/day**
- Mestinon (pyridostigmine bromide solution)
- Minivelle (estradiol)
- Mitigare (colchicine capsule) – **PA**
- Moviprep (polyethylene glycol-electrolyte solution)
- Mycobutin (rifabutin)
- Myrbetriq (mirabegron extended-release)
- Neupro (rotigotine transdermal system) – **PA > 1 unit/day**
- Nexavar (sorafenib) – **PA**
- Nexium (esomeprazole magnesium 10 mg, 20 mg, 40 mg suspension)
- Nitrolingual (nitroglycerin lingual spray) – **PA**
- Norvir (ritonavir tablet)
- Noxafil (posaconazole injection) – **PA**
- Nucynta (tapentadol) – **PA**
- Nucynta (tapentadol extended-release) – **PA**
- Olux-E (clobetasol propionate foam/emollient)
- Onexton (clindamycin/benzoyl peroxide gel pump) – **PA**
- Onglyza (saxagliptin)
- Oxtellar XR (oxcarbazepine extended-release) – **PA**
- Oxycontin (oxycodone extended-release tablet) – **PA**
- Pentasa (mesalamine 250 mg, 500 mg controlled-release capsule)
- Pradaxa (dabigatran capsule)
- Pred Forte (prednisolone acetate 1% ophthalmic suspension)
- Prevacid Solutab (lansoprazole orally disintegrating tablet) – **PA ≥ 2 years**
- Proglycem (diazoxide)
- Prolensa (bromfenac 0.07%)
- Promacta (eltrombopag olamine) – **PA**
- Protonix (pantoprazole 40 mg suspension) – **PA**
- Pylera (bismuth subcitrate/metronidazole/ tetracycline)
- Qudexy XR (topiramate extended-release capsule) – **PA < 6 years**
- Remodulin (treprostinil injection) – **PA**

- Restasis (cyclosporine 0.05% ophthalmic emulsion)
- Retin-A (tretinoin) – **PA ≥ 21 years**
- Retin-A Micro (tretinoin microspheres) – **PA**
- Revatio (sildenafil oral suspension) – **PA**
- Revlimid (lenalidomide) – **PA**
- Risperdal Consta (risperidone 12.5 mg, 25 mg, 37.5 mg, 50 mg extended-release intramuscular injection) – **PA < 10 years and PA > 2 injections/28 days**
- Rozerem (ramelteon) – **PA > 1 unit/day**
- Sabril (vigabatrin) – **PA**
- Samsca (tolvaptan) – **PA**
- Solodyn (minocycline extended-release 55 mg, 65 mg, 80 mg, 105 mg, 115 mg tablet)
- Spiriva Handihaler (tiotropium inhalation powder)
- Sporanox (itraconazole solution)
- Sprycel (dasatinib)
- Suboxone (buprenorphine/naloxone film ≤ 24 mg/day)
- Suboxone (buprenorphine/naloxone film) – **PA > 90 days (> 24 mg/day and ≤ 32 mg/day)**
- Suboxone (buprenorphine/naloxone film) – **PA > 32 mg/day**
- Suprep (sodium sulfate/potassium sulfate/ magnesium sulfate)
- Sutent (sunitinib) – **PA**
- Symbicort (budesonide/formoterol)
- Syprine (trientine 250 mg capsule)
- Taclonex (betamethasone/calcipotriene topical suspension) – **PA**
- Tasigna (nilotinib)
- Targretin (bexarotene)
- Teflaro (ceftaroline)
- Tegretol XR (carbamazepine extended-release) – **PA < 6 years**
- Tekturna (aliskiren) – **PA**
- Testim (testosterone 1% gel tube) – **PA**
- Thalomid (thalidomide)
- Thiola (tiopronin)
- Thiola EC (tiopronin delayed-release)
- Timoptic Ocudose (timolol ophthalmic unit dose solution) – **PA**
- Tirosint (levothyroxine)
- Toujeo (insulin glargine)
- Tracleer (bosentan) – **PA**
- Transderm-Scop (scopolamine transdermal patch)
- Travatan Z (travoprost 0.004% eye drop)
- Tresiba (insulin degludec)
- Trileptal (oxcarbazepine suspension) – **PA < 6 years**
- Trokendi XR (topiramate extended-release capsule) – **PA**
- Tykerb (lapatinib)
- Uceris (budesonide extended-release tablet)
- Vascepa (icosapent ethyl) – **PA**
- Valcyte (valganciclovir powder for oral solution) – **PA**
- Ventolin (albuterol inhaler)
- Victoza (liraglutide) – **PA > 9 mL/30 days**
- Vivelle-Dot (estradiol)
- Votrient (pazopanib) – **PA**
- Vusion (miconazole/zinc oxide ointment)
- Vyvanse (lisdexamfetamine capsule) – **PA < 3 years or ≥ 21 years and PA > 2 units/day**
- Vyvanse (lisdexamfetamine chewable tablet) – **PA**
- Xenical (orlistat) – **PA**
- Xigduo XR (dapagliflozin/metformin extended-release)
- Xyrem (sodium oxybate) – **PA**
- Zavesca (miglustat 100 mg) – **PA**
- Zioptan (tafluprost) – **PA**
- Zovirax (acyclovir cream)
- Zyclara (imiquimod 2.5%, 3.75% cream) – **PA**
- Zyvox (linezolid suspension) – **PA**

MassHealth 90-Day Supply

The MassHealth agency has established a 90-Day Supply Medication Initiative that includes mandatory and allowable dispensing of certain medications.

Certain generic drugs and other low-net-cost drugs, designated with M90, will be mandated to a 90-day supply after an initial fill of medication. Medications designated with M90 are typically maintenance medications. Mandatory dispensing in a 90-day supply may not apply to all formulations of a drug, and certain other restrictions including but not limited to Prior Authorization (PA) requirements and quantity limits may apply. In general, generic formulation will be required unless a particular form of the drug (for example, specific strength or formulation) does not have a generic equivalent, or the drug is listed on the MassHealth Brand Name Preferred Over Generic Drug List, in which case the brand name drug may be dispensed. Where applicable due to package size, allowances may be made for dispensing greater or less than exactly a 90-day supply of medication. The 90-Day Supply mandate may apply to medications not listed on the MassHealth Drug List. This requirement does not apply to drugs dispensed to members in certain long term care facilities, hospices, and group homes, or as specified by law or regulation.

Certain generic drugs and other low-net-cost drugs, designated with A90, may be allowed to be dispensed in up to a 90-day supply. Allowed dispensing in a 90-day supply may not apply to all formulations of a drug, and certain other restrictions including but not limited to PA requirements and quantity limits may apply. In general, the generic formulation will be required unless the drug is listed on the MassHealth Brand Name Preferred Over Generic Drug List, in which case the brand name drug may be allowed.

In addition, medications not designated with A90 or M90 will be excluded from dispensing in a 90-day supply. Examples of medications and medication formulations that are excluded from dispensing in a 90-day supply include but are not limited to health care professional administered drugs, hospital outpatient administered drugs, injectable formulations, and Prescription Monitoring Program (PMP) designated agents.

Medication status denoted as mandatory 90-day dispensing, allowed 90-day dispensing, or excluded from 90-day dispensing may be updated often and is subject to change at any time.

MassHealth Medication Therapy Management Program

BACKGROUND

The MassHealth Medication Therapy Management (MTM) program is a clinical outreach initiative developed to provide additional support to MassHealth members enrolled in fee-for-service (FFS), primary care clinician (PCC), or primary care accountable care organization (PCACO) plans who may benefit from medication reviews by a pharmacist. Members will be enrolled quarterly based on targeted disease states and MassHealth eligibility.

The goals of the program are to serve as a resource for members to learn more about their medications by conducting personalized medication reviews and to work with their healthcare providers to optimize their medication regimens. Additional program goals include improving medication adherence, increasing the use of appropriate preventive measures such as vaccines, identifying potential drug-related problems, and improving overall health outcomes.

Members will receive a letter informing them of their enrollment in the outreach program, with the opportunity to opt out. They will then be contacted by phone to schedule an appointment with a MassHealth pharmacist to complete an annual medication review. Pharmacists will review the member's medications with them, discuss any of the member's medication-related concerns, and create a comprehensive medication list that will be shared with the member. The member will also receive a to-do list that will highlight any counseling points and recommendations to be discussed with their provider. Members will be instructed not to make any changes without discussing with their healthcare provider(s). After the appointment, the pharmacist will contact the member's provider(s) with any medication-related questions or recommendations.

Interpretation and translation services will be available for all aspects of this program.

CURRENT ELIGIBLE MEMBERS

- Members diagnosed with sickle cell disease (SCD)

Q&A ABOUT THE MASSHEALTH MEDICATION THERAPY MANAGEMENT PROGRAM

What are the goals of this initiative?

The primary goals of the program include educating members about their medications, resolving potential drug-related problems, collaborating with providers to optimize medication regimens, and improving health outcomes of members.

What is a medication review?

Medication reviews are scheduled annually with a pharmacist. During the appointment, the pharmacist will ask about a member's medical history, recent hospitalizations or emergency department visits, and their medications. Any problems, questions, or concerns about medications can be discussed during this appointment. The pharmacist may share their recommendations with the member's providers. A comprehensive medication list will be mailed to the member and include any recommendations to discuss with their provider. The appointment typically takes about 30 minutes.

How often will medication reviews occur?

Medication reviews will occur annually with a pharmacist. Follow-up calls may occur if necessary.

Will there be a copay for the appointment?

No, there is no cost for the annual medication review or any follow-up calls.

Can the pharmacist prescribe medications or make changes to medications?

No, the pharmacist cannot prescribe medications. If the pharmacist has any recommendations, they will follow up with the member's provider. The provider will then make any changes to medications if necessary.

Is it possible to be removed from the program?

Yes, if a member would like to be removed, they can call us at 877-297-3776 from 8:00 a.m. to 4:00 p.m. Monday through Friday and opt out of the program. Members can sign back up at any time.

Is there anything healthcare providers need to do?

Healthcare providers do not need to do anything for members to be enrolled in this program. Healthcare providers caring for enrolled members may receive phone calls and faxes from a MassHealth pharmacist with questions or recommendations related to a member's medications.

How can the program be contacted?

For Pharmacists and Prescribers

If you have questions about a specific member affected by the program, please call the direct phone number, 877-297-3776, Monday through Friday, from 8:00 am to 4:00 pm or email questions to MassHealthClinicalOutreachProgram@umassmed.edu.

For MassHealth Members

If you have questions about the program, please call the direct phone number, 877-297-3776, Monday through Friday, from 8:00 am to 4:00 pm or email questions to MassHealthClinicalOutreachProgram@umassmed.edu

MassHealth Non-Drug Product List

This page lists the non-drug products that MassHealth pays for through the Pharmacy Online Processing System (POPS). Products that require prior authorization are noted with the designation "PA." Payment is calculated in accordance with the Executive Office of Health and Human Service's regulations at 114.3 CMR 22.00: Durable Medical Equipment and 101 CMR 317.00: Medicine.

Medical Supplies

- Alcohol swabs
- Automatic blood pressure monitors
- Disposable syringe and needle units
- Freestyle (test strips, blood glucose, preferred) – **PA > 100 units/month**
- Freestyle Insulinx (test strips, blood glucose, preferred) – **PA > 100 units/month**
- Freestyle Lite (test strips, blood glucose, preferred) – **PA > 100 units/month**
- Freestyle Neo (test strips, blood glucose, preferred) – **PA**
- Lancets
- Medically necessary enteral nutritional liquid
- Medically necessary formula
- Peak flow meters
- Pediatric enteral special formula
- Precision Xtra (test strips, blood glucose, preferred) – **PA > 100 units/month**
- Test strips, blood glucose, all other non-preferred – **PA**
- Thickening agents
- Urine glucose testing reagent strips used for the management of diabetes
- Urine protein testing reagent strips
- Vaporizers

Devices

- Cequr Simplicity (insulin bolus delivery patch) – **PA**
- Dexcom G6 (continuous glucose monitoring system) – **PA**
- Dexcom G7 (continuous glucose monitoring system) – **PA**
- Drug delivery systems for use with metered dose inhalers (for example, aerochambers)
- Freestyle Libre 14 day (continuous glucose monitoring system) – **PA**
- Freestyle Libre 2 (continuous glucose monitoring system) – **PA**
- Freestyle Libre 3 (continuous glucose monitoring system) – **PA**
- Hyper-Sal (sodium chloride 3.5%, 7% for inhalation)
- Insulin cartridge delivery devices and needles or other devices for injection of medication (for example, epinephrine auto-injectors)
- Nasal adaptor/mucosal atomization device (needle-free injection device) as part of nasal naloxone rescue kit, two per kit
- Nebusal (sodium chloride 6% for inhalation)
- Omnipod 5 (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod Classic (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod Dash (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod Go (insulin continuous subcutaneous infusion pump) – **PA**
- Pulmosal (sodium chloride 7% for inhalation)
- sodium chloride for inhalation
- V-Go (insulin continuous subcutaneous infusion patch) – **PA**

COVID-19 at-home antigen self-test kits

- Binaxnow – **PA > 2 tests/28 days**
- Carestart – **PA > 2 tests/28 days**
- CVS COVID-19 At-Home Test – **PA > 2 tests/28 days**
- Flowflex – **PA > 2 tests/28 days**
- Genabio – **PA > 2 tests/28 days**
- Ihealth – **PA > 2 tests/28 days**
- Inteliswab – **PA > 2 tests/28 days**
- On-Go – **PA > 2 tests/28 days**
- Quickvue – **PA > 2 tests/28 days**

MassHealth Over-the-Counter Drug List

This page lists the only over-the-counter (OTC) drugs that are covered by MassHealth without prior authorization (PA). All other OTC drugs require PA, except select OTC insulins. All OTC insulins are covered for members at home, in nursing facilities, or in rest homes; however, PA restrictions apply as listed in the MassHealth Drug List. Please refer to 130 CMR 406.411(A) and 406.412 (A)(2) for further information on OTC drugs. The items are listed alphabetically by therapeutic class, then by the generic name of the drug or drug ingredients. In general, MassHealth pays only for generic versions of these OTC drugs, singly or in combination, regardless of strength or dosage formulation unless otherwise specified. Combination products that contain active ingredients that are not included in this list require PA. Notwithstanding the above, MassHealth may pay for a brand-name OTC product if that product is medically necessary under 130 CMR 450.204. All brand-name OTC products currently covered by MassHealth without PA are listed by brand name, below.

Allergy Agents, Ophthalmic
ketotifen
Lastacaft (alcaftadine)
naphazoline
Naphcon-A (naphazoline/ pheniramine)
Opcon-A (naphazoline/ pheniramine)

Analgesics
acetaminophen ≤ 4 grams/day
aspirin 81 mg
aspirin 325 mg, 500 mg, 650 mg
aspirin suppository
aspirin with buffers
capsaicin
ibuprofen
lidocaine 4% patches ≤ 4 patches/day
naproxen capsule, tablet

Anthelmintic Agents
Reese's Pinworm (pyrantel pamoate)

Antihistamines/ Decongestants
cetirizine syrup, tablet
cetirizine/pseudoephedrine
chlorpheniramine
diphenhydramine
doxylamine
fexofenadine tablet
fexofenadine/pseudoephedrine
loratadine tablet, solution
loratadine/pseudoephedrine
pseudoephedrine ≤ 240 mg/day

Antimicrobials, Topical
bacitracin
chlorhexidine gluconate
clotrimazole
double antibiotic ointment
hydrogen peroxide
iodine
isopropyl alcohol
miconazole
neomycin
povidone
tolnaftate cream, powder
triple antibiotic ointment

Compounding Agents
cherry syrup
gelatin capsule, empty
Ora-Plus suspending vehicle
Ora-Sweet oral syrup
Ora-Sweet-SF oral syrup
simple syrup

Contraceptives, Oral
levonorgestrel 1.5 mg tablet
Opill (norgestrel tablet)

Contraceptives, Topical
nonoxynol-9 *

Dermatologic Agents, Topical
benzoyl peroxide
calamine lotion
colloidal oatmeal
hydrocortisone cream, lotion, ointment
hydrophilic ointment
lanolin
petrolatum
selenium sulfide
vitamin A and D ointment
witch hazel
zinc oxide

Gastrointestinal Agents
Align (bifidobacterium infantis) < 21 years
aluminum carbonate
aluminum hydroxide
bisacodyl enema, suppository
bisacodyl tablet
bismuth subsalicylate
calcium polycarbophil
cimetidine
Culturelle (lactobacillus rhamnosus GG) < 21 years
dextrin
docusate sodium capsule, tablet
docusate sodium enema
docusate sodium solution, syrup

* Branded OTC nonoxynol-9 products are covered by MassHealth without PA.

Gastrointestinal Agents (continued)
famotidine tablet
Florastor (saccharomyces boulardii) < 21 years
glycerin
lactase
loperamide
magaldrate
magnesium salts
meclizine
methylcellulose
mineral oil
polyethylene glycol 3350
psyllium capsule
psyllium powder
sennosides tablet
sennosides syrup
simethicone
sodium bicarbonate
sodium phosphate

Intranasal Sprays
budesonide nasal spray ≤ 1 inhaler/30 days
triamcinolone nasal spray ≤ 1 inhaler/30 days

Medical Foods
levomethylfolate tablet ≤ 1 unit/day

Opioid Reversal Agents
Narcan (naloxone 4 mg nasal spray) †
Rivive (naloxone 3 mg nasal spray)

Otic Agents
carbamide peroxide

Pediculicides/Scabicides
permethrin
piperonyl butoxide/pyrethrins

Respiratory Agents
sodium chloride for inhalation

Smoking Cessation
nicotine gum, lozenge, patch

Tear/Saliva Replacement Agents
artificial tears
saliva substitute

Vitamins/Nutrients/ Supplements
calcium replacement
cod liver oil
coenzyme Q10 < 21 years
electrolyte solution, pediatric
ferrous fumarate
ferrous gluconate
ferrous sulfate
folic acid
glucose products < 19 years
iron polysaccharide complex
magnesium salts
melatonin gummy, solution, tablet
melatonin/pyridoxine tablet
multivitamins
niacinamide
nicotinic acid
pediatric multivitamins
Phos-Flur (sodium fluoride oral rinse)
prenatal vitamins
potassium phosphate
sodium chloride tablet
sodium fluoride
vitamin A (retinol)
vitamin B-1 (thiamine)
vitamin B-2 (riboflavin)
vitamin B-3 (niacin)
vitamin B-6 (pyridoxine)
vitamin B-12 (cyanocobalamin)
vitamin B complex
vitamin C (ascorbic acid)
vitamin D
vitamin E, oral
vitamins, multiple
vitamins, multiple/minerals
vitamins, pediatric
vitamins, prenatal

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† Brand and generic products are covered by MassHealth without PA.

MassHealth Pharmacy Covered Professional Services List

This page lists professional services that MassHealth pays for through the Pharmacy Online Processing System (POPS). The service must be provided by a properly trained and certified pharmacist or other appropriately certified health care professional in accordance with Massachusetts Department of Public Health regulations and employed or contracted by a MassHealth pharmacy provider. MassHealth pays for the services at the applicable mid-level practitioner rate found in 101 CMR 317.00: Medicine.

- Administration of the following vaccines
  - COVID-19 Moderna vaccine*
  - COVID-19 Novavax vaccine*
  - COVID-19 Pfizer vaccine*
  - diphtheria, tetanus, and acellular pertussis vaccine
  - diphtheria, tetanus vaccine
  - DTaP, hepatitis B, and inactivated poliovirus vaccine
  - DTaP, inactivated poliovirus, and *Haemophilus influenzae* type B vaccine
  - DTaP, inactivated poliovirus, *Haemophilus influenzae* type B, and hepatitis B vaccine
  - DTaP and inactivated poliovirus vaccine
  - haemophilus influenzae type b
  - hepatitis A vaccine
  - hepatitis A and hepatitis B vaccine
  - hepatitis B vaccine
  - human papillomavirus vaccine
  - influenza vaccine
  - measles, mumps, and rubella vaccine
  - measles, mumps, rubella, and varicella vaccines
  - meningococcal serogroup B vaccine
  - meningococcal serogroups A, C, W, Y vaccine
  - pentavalent meningococcal vaccine
  - pneumococcal 13-valent conjugate vaccine
  - pneumococcal 15-valent conjugate vaccine
  - pneumococcal 20-valent conjugate vaccine
  - pneumococcal 21-valent conjugate vaccine
  - pneumococcal 23-valent polysaccharide vaccine
  - poliovirus vaccine (inactivated)
  - respiratory syncytial virus vaccine
  - respiratory syncytial virus vaccine, adjuvanted
  - rotavirus vaccine
  - smallpox and monkeypox vaccine
  - tetanus and diphtheria toxoids
  - tetanus and diphtheria toxoids and acellular pertussis vaccine
  - varicella vaccine
  - zoster vaccine, recombinant

*For billing details of COVID-19 vaccines and allowable administration fees, see Pharmacy Facts #170 available at https://www.mass.gov/doc/pharmacy-facts-170-august-19-2021-0/download.

MassHealth Pharmacy Naloxone Availability and Coverage

The standing order for dispensing naloxone rescue kits authorizes licensed pharmacists to dispense naloxone rescue kits to a person at risk of experiencing an opioid-related overdose. Licensed pharmacists may also dispense the naloxone rescue kits to a family member, friend, or other person in a position to assist a person at risk of experiencing an opioid-related overdose. Please refer to M.G.L. c. 94C, § 19B for further information on the standing order for naloxone (https://www.mass.gov/doc/naloxone-standing-order-1/download).

This page lists prescription and over-the-counter (OTC) naloxone products that are covered by MassHealth without prior authorization (PA). These products are available at no out-of-pocket cost and without quantity limits. Naloxone products recently approved for OTC use have been added to the MassHealth OTC Drug List and the OTC Drug List will be updated as needed with new formulations.

- Kloxxado (naloxone 8 mg/0.1 mL nasal spray)
- naloxone 4 mg nasal spray
- naloxone vial, 0.4 mg/mL syringe, 2 mg/2 mL syringe
- Narcan (naloxone 4 mg nasal spray)
- Rivive (naloxone 3 mg nasal spray)*
- Zimhi (naloxone 5 mg /0.5 mL syringe)

* FDA-approved over-the-counter formulation

When dispensing naloxone products, pharmacies should submit claims as a 1-day supply. If additional naloxone is needed for a member within the same day, pharmacists should contact the MassHealth Drug Utilization Review Program for an emergency override at 1-800-745-7318 during normal business hours. Outside of business hours, pharmacies may submit an emergency override claim with a value of “03” for level of service (Field 418-DI).

MassHealth Pharmacy Operational Page

This page lists operational information related to the MassHealth Pharmacy Program.

Any drug that does not appear on the MassHealth Drug List (MHDL) requires prior authorization (PA).

Brand name (no substitution) drugs with FDA "A"-rated generic equivalents and non-preferred drug generic equivalents for drugs appearing on the MassHealth Brand Name Preferred Over Generic Drug List

Typically, the generic is preferred when available unless the brand-name drug appears on the MassHealth Brand Name Preferred Over Generic Drug List. In general, when requesting the non-preferred version, whether the brand or generic, the prescriber must provide medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself.

- Documentation of all of the following is required:
    - individual drug PA criteria must be met first where applicable; **and**
    - medical records documenting one of the following:
        - an allergic response or adverse reaction to the preferred drug product or history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug product; **or**
        - an inadequate response to the preferred drug product.

New-to-market drugs and biologics

FDA-approved new-to-market drugs and biologics that are not listed in the MHDL are under review and will be handled on a case-by-case basis until MassHealth has concluded its evaluation of the drug or biologic.

- Documentation of all of the following is required:
    - appropriate diagnosis; **and**
    - medical necessity based on diagnosis and existing treatment options.

New indications evaluation for oncology drugs and biologics

New FDA-approved indications for oncology drugs and biologics that are not listed in the MHDL are under review and will be handled on a case-by-case basis until MassHealth has concluded its evaluation of the new indication. Evaluation of a new indication includes a thorough review by physicians and pharmacists using medical literature and consulting with specialists, other physicians, or both. References used may include National Comprehensive Cancer Network (NCCN).

Non-FDA-approved drugs and biologics

Non-FDA-approved drugs and biologics require PA and will be evaluated for medical necessity.

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - trials of all clinically appropriate FDA-approved alternatives.

Non-Rebate drugs and biologics

MassHealth does not pay for drugs that are manufactured by companies that have not signed rebate agreements with the U.S. Secretary of Health and Human Services. Non-rebate drugs and biologics require PA and will be evaluated for medical necessity. Rebate status is subject to change and the MassHealth Drug List may be updated at a future rollout.

- Documentation of all of the following is required:
  - appropriate diagnosis; **and**
  - trials of all clinically appropriate alternatives whose manufacturers participate in the federal rebate program; **and**
  - clinical rationale for use of a drug whose manufacturer does not participate in the federal rebate program.

Cosmetic or Hair Growth Agents for Medical Necessity:

The MassHealth agency does not pay for any drug when used for cosmetic purposes or for hair growth, unless medically necessary. Requests must have documentation of a severe and persistent or widespread condition, rationale or documentation of no other available treatment options, and a provider attestation of a negative impact on the member's life.

Gender-affirming Care Requests:

For a member who has undergone gender transition or is in the process of a gender transition, requests for the following may be approved with documentation of a severe and persistent or widespread condition, and rationale or documentation of no other available treatment options (pharmacological or non-pharmacological) for either of the following:

- an agent for the reduction of hair growth in a person with male sex assigned at birth/biologic male (transgender male to female)
- Both of the following:
  - The provider attests the drug is necessary to the member's identity
  - Documentation that the condition to be treated is negatively affecting the member's life as a transgender individual

MassHealth Preferred Non-Drug Product List

This page list those non-drug products for which MassHealth has entered into a rebate agreement with product manufacturers, allowing MassHealth the ability to provide coverage of non-drug products at the lowest possible costs.

The products are listed alphabetically by therapeutic class, then by the name of the non-drug product. Please note that MassHealth may still require prior authorization for clinical reasons. Products that require additional prior authorization requirements are noted with PA on this list.

Devices:

See Therapeutic Class Table 78 on the MassHealth Drug List for Diabetes Medical Supplies and Emergency Treatments.

- Cequr Simplicity (insulin bolus delivery patch) – **PA**
- Dexcom G6 (continuous glucose monitoring system) – **PA**
- Dexcom G7 (continuous glucose monitoring system) – **PA**
- Freestyle Libre 14 day (continuous glucose monitoring system) – **PA**
- Freestyle Libre 2 (continuous glucose monitoring system) – **PA**
- Freestyle Libre 3 (continuous glucose monitoring system) – **PA**
- Omnipod Classic (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod Dash (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod 5 (insulin continuous subcutaneous infusion pump) – **PA**
- Omnipod Go (insulin continuous subcutaneous infusion pump) – **PA**
- V-Go (insulin continuous subcutaneous infusion patch) – **PA**

Medical Supplies:

See Therapeutic Class Table 78 on the MassHealth Drug List for Diabetes Medical Supplies and Emergency Treatments.

- Freestyle (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Freestyle Insulinx (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Freestyle Lite (test strips, blood glucose, preferred) – **PA > 100 units/30 days**
- Freestyle Neo (test strips, blood glucose, preferred) – **PA**
- Precision Xtra (test strips, blood glucose, preferred) – **PA > 100 units/30 days**

MassHealth Supplemental Rebate/ Preferred Drug List

This page list those drugs for which MassHealth has entered into a supplemental rebate agreement with drug manufacturers, allowing MassHealth the ability to provide medications at the lowest possible costs.

The items are listed alphabetically by therapeutic class, then by the name of the drug or drug ingredients. Please note that MassHealth may still require prior authorization for clinical reasons. Drugs that require additional prior authorization requirements are noted with PA on this list.

In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

Antidepressant Agents:

See Therapeutic Class Table 17 on the MassHealth Drug List for Antidepressant Agents

- Zurzuvae (zuranolone) – **PA**

Antidiabetic Agents:

See Therapeutic Class Table 26 on the MassHealth Drug List for Antidiabetic Agents

- Lantus (insulin glargine)

Anti-Hemophilia Agents:

See Therapeutic Class Table 80 on the MassHealth Drug List for Anti-Hemophilia Agents.

- Benefix (factor IX human recombinant)
- Hemlibra (emicizumab-kxwh)
- Jivi (antihemophilic factor, recombinant pegylated-aucl)
- Kogenate (antihemophilic factor, recombinant)
- Kovaltry (antihemophilic factor, recombinant)
- Xyntha (antihemophilic factor, recombinant)

Anti-Hypoglycemic Agent:

See Therapeutic Class Table 78 on the MassHealth Drug List for Diabetes Emergency Treatment Agents.

- Baqsimi (glucagon nasal powder)

Anti-Obesity Agent:

See Therapeutic Class Table 81 on the MassHealth Drug List for Anti-Obesity Agents.

- Saxenda (liraglutide) – **PA**

- Wegovy (semaglutide injection) – **PA**
- Zepbound (tirzepatide) – **PA**

Antiretroviral/HIV Agents:

See Therapeutic Class Table 38 on the MassHealth Drug List for Antiretroviral/HIV Agents.

- Apretude (cabotegravir injection)
- Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide)
- Cabenuva (cabotegravir/rilpivirine)
- Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate)
- Descovy (emtricitabine/tenofovir alafenamide)
- Dovato (dolutegravir/lamivudine)
- Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide)
- Juluca (dolutegravir/rilpivirine)
- Norvir (ritonavir tablet)
- Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide)
- Pifeltro (doravirine)
- Prezcobix (darunavir/cobicistat)
- Rukobia (fostemsavir) – **PA**
- Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide)
- Triumeq (abacavir/dolutegravir/lamivudine)

Anti-TNF Agents:

See Therapeutic Class Table 5 on the MassHealth Drug List for Anti-TNF Agents.

- Enbrel (etanercept) – **PA**
- Humira (adalimumab) – **PA**

Antipsychotic Agent oral Second Generation (Atypical):

See Therapeutic Class Table 24 on the MassHealth Drug List for oral Second Generation (Atypical) Antipsychotic Agents.

- Vraylar (cariprazine) – **PA**

Asthma and Allergy Agent:

See Therapeutic Class Table 64 on the MassHealth Drug List for Asthma/Allergy Monoclonal Antibodies.

- Dupixent (dupilumab) – **PA**

Beta Thalassemia Gene Therapy:

See Therapeutic Class Table 45 on the MassHealth Drug List for Beta Thalassemia Gene Therapies.

- Zynteglo (betibeglogene autotemcel) – **PA**

Calcitonin Gene-Related Peptide Inhibitors:

See Therapeutic Class Table 14 on the MassHealth Drug List for Calcitonin Gene-Related Peptide Inhibitors.

- Ajovy (fremanezumab-vfrm) – **PA**
- Emgality (galcanezumab-gnlm) – **PA**
- Nurtec (rimegepant) – **PA**
- Qulipta (atogepant) **– PA**
- Ubrelvy (ubrogepant) – **PA**

Cystic Fibrosis Agents:

See Therapeutic Class Table 21 on the MassHealth Drug List for Cystic Fibrosis Agents.

- Kalydeco (ivacaftor) – **PA**
- Orkambi (lumacaftor/ivacaftor) – **PA**
- Symdeko (tezacaftor/ivacaftor) – **PA**
- Trikafta (elexacaftor/tezacaftor/ivacaftor) – **PA**

Drug and Alcohol Cessation Agents:

See Therapeutic Class Table 36 on the MassHealth Drug List for Drug and Alcohol Cessation Agents.

- Sublocade (buprenorphine extended-release injection)
- Suboxone (buprenorphine/naloxone film ≤ 24 mg/day)
- Suboxone (buprenorphine/naloxone film) – **PA > 90 days (> 24 mg/day and ≤ 32 mg/day)**
- Suboxone (buprenorphine/naloxone film) – **PA > 32 mg/day**
- Vivitrol (naltrexone injection)

Enzyme and Metabolic Disorder Therapy:

See Therapeutic Class Table 65 on the MassHealth Drug List for Enzyme and Metabolic Disorder Therapies.

- Carbaglu (carglumic acid) – **PA**

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist:

See Therapeutic Class Table 26 on the MassHealth Drug List for GLP-1 Receptor Agonists.

- Trulicity (dulaglutide) – **PA > 2 mL/28 days**

Growth Hormone:

See Therapeutic Class Table 9 on the MassHealth Drug List for Growth Hormones.

- Genotropin (somatropin) – **PA**
- Skytrofa (lonapegsomatropin-tcgd) – **PA**

Hepatitis Antivirals:

See Therapeutic Class Table 44 on the MassHealth Drug List for Hepatitis Antiviral Agents.

- ledipasvir/sofosbuvir* – **PA**

- Mavyret (glecaprevir/pibrentasvir) – **PA**
- sofosbuvir/velpatasvir* – **PA**
- Vemlidy (tenofovir alafenamide)

* Please note, pediatric dosing formulations of Brand name Epclusa and Harvoni are preferred. For all other strengths, generics are preferred.

Interleukin Antagonists:

See Therapeutic Class Table 5 on the MassHealth Drug List for Interleukin Antagonist.

- Stelara (ustekinumab 45 mg/0.5 mL prefilled syringe, 90 mg/mL prefilled syringe, 45 mg/0.5 mL vial) – **PA**
- Taltz (ixekizumab) – **PA**

Long-Acting Aripiprazole Agents:

See Therapeutic Class Table 24 on the MassHealth Drug List for Long-Acting Aripiprazole and Second Generation (Atypical) Antipsychotic Agents.

- Aristada (aripiprazole lauroxil 441 mg, 662 mg, 882 mg) – **PA < 10 years and PA > 1 injection/28 days**
- Aristada (aripiprazole lauroxil 1,064 mg) – **PA < 10 years and PA > 1 injection/56 days**
- Aristada Initio (aripiprazole lauroxil 675 mg) – **PA < 10 years and PA > 1 injection/28 days**

Long-Acting Risperidone Agents:

See Therapeutic Class Table 24 on the MassHealth Drug List for Long-Acting Risperidone and Second Generation (Atypical) Antipsychotic Agents.

- Perseris (risperidone 90 mg, 120 mg extended-release subcutaneous injection) – **PA < 10 years and PA > 1 injection/28 days**
- Uzedy (risperidone 50 mg, 75 mg, 100 mg, 125 mg extended-release subcutaneous injection) – **PA < 10 years and PA > 1 injection/28 days**
- Uzedy (risperidone 150 mg, 200 mg, 250 mg extended-release subcutaneous injection) – **PA < 10 years and PA > 1 injection/56 days**

Long-Acting Paliperidone Agents:

See Therapeutic Class Table 24 on the MassHealth Drug List for Long-Acting Paliperidone and Second Generation (Atypical) Antipsychotic Agents.

- Invega Hafyera (paliperidone extended-release 6-month injection) – **PA < 10 years and PA > 1 injection/168 days**
- Invega Sustenna (paliperidone extended-release 1-month injection) – **PA < 10 years, PA > 2 injections/28 days within the first 28 days of therapy and PA > 1 injection/28 days after 28 days of therapy**
- Invega Trinza (paliperidone extended-release 3-month injection) – **PA < 10 years and PA > 1 injection/84 days**

Oncology Agents:

See Therapeutic Class Table 57 on the MassHealth Drug List for Oncology Agents.

- Ibrance (palbociclib) – **PA**

Opioid Reversal Agent:

See Therapeutic Class Table 36 on the MassHealth Drug List for Drug and Alcohol Cessation Agents.

- Kloxxado (naloxone 8 mg nasal spray)

Sickle Cell Disease Gene Therapy:

See Therapeutic Class Table 45 on the MassHealth Drug List for Sickle Cell Disease Agents Gene Therapies.

- Casgevy (exagamglogene autotemcel for sickle cell disease) – **PA**

Small Interfering RNA Agents:

See Therapeutic Class Table 72 on the MassHealth Drug List for Agents not Otherwise Classified.

- Amvuttra (vutrisiran) – **PA**
- Givlaari (givosiran) – **PA**
- Onpattro (patisiran) – **PA**
- Oxlumo (lumasiran) – **PA**

Spinal Muscular Atrophy Agent:

See Therapeutic Class Table 76 on the MassHealth Drug List for Spinal Muscular Atrophy Agents.

- Zolgensma (onasemnogene abeparvovec-xioi) – **PA**

Topical Immune Suppressant:

See Therapeutic Class Table 42 on the MassHealth Drug List for Immune Suppressants – Topical.

- Eucrisa (crisaborole) – **PA**

Medicare Part D Exclusion Drug List

The following drugs or drug classes are excluded by Medicare Part D. For dually eligible members (members who are eligible for both Medicare Part D and MassHealth), MassHealth may pay for some of these drugs or drug classes, subject to the prior authorization (PA) requirements listed on the MassHealth Drug List.

- **Over-the-counter (OTC) Drugs**
  Except for insulin and supplies associated with the injection of insulin, OTC drugs are excluded by Medicare Part D. OTC drugs that are covered by MassHealth can be found on the MassHealth OTC Drug List at www.mass.gov/druglist.

- **Prescription Vitamins and Minerals**
  Except for prenatal vitamins, fluoride-containing products, prescription vitamins, and minerals are excluded by Medicare Part D. Prescription vitamins that are covered by MassHealth are listed on the MassHealth Drug List.

- **Weight-management Drugs**
  Some drugs used for weight gain (dronabinol, megestrol, oxandrolone, somatropin) may be excluded by Medicare Part D plans. MassHealth will cover these products only if they are denied by the Medicare Part D plan. PA requirements for these drugs can be found on the MassHealth Drug List.
  Drugs FDA-approved for treatment of obesity are excluded by Medicare Part D plans. PA requirements for these drugs can be found on the MassHealth Drug List.
  Some drugs may be excluded by Medicare Part D plans when used off-label for treatment of obesity. MassHealth will cover these products only if they are denied by the Medicare Part D plan. PA requirements for these drugs can be found on the MassHealth Drug List.

- **Medicare Part B**
  There has been no change to Medicare Part B. Products that were covered under Medicare Part B before January 1, 2006, continue to be covered under Medicare Part B. MassHealth continues to act as secondary payer for these services. PA requirements for drugs covered under Medicare Part B can be found on the MassHealth Drug List.

MassHealth Quick Reference Guide

Antibiotics
amoxicillin/clavulanate ER-PA
azithromycin-F
cefpodoxime susp-PA
cephalexin 100 mg tab, 750 mg cap-PA
linezolid suspension-PA
nitrofurantoin-F
ofloxacin-PA
tigecycline-PA
tinidazole
Baxdela-PA
Dificid-PA
Nuzyra-PA
Solosec-PA
Xifaxan 550 mg-PA

Anticonvulsants[1,3]
carbamazepine IR, XR
clobazam
clonazepam-F
clorazepate-PA
diazepam
divalproex
ethosuximide
felbamate
fosphenytoin
gabapentin-Q
lacosamide injection, tablet, solution
lamotrigine
lamotrigine ER, ODT-PA
levetiracetam injection, soln, tab
methsuximide
oxcarbazepine
phenobarbital tablet, solution, injection
phenytoin
pregabalin-Q
primidone
rufinamide-PA
tiagabine-PA
topiramate tab, cap
topiramate ER cap-F
valproate
valproic acid
vigabatrin-PA
zonisamide capsule
Aptiom-PA
Briviact-PA
Diacomit-PA
Elepsia XR-PA
Epidiolex-PA
Eprontia-PA
Equetro
Fintepla-PA
Fycompa-PA
Libervant-A,Q
Motpoly XR-PA
Nayzilam-Q
Oxtellar XR-PA
Spritam-PA
Sympazan-PA
Valtoco-Q
Xcopri-PA
Zonisade-PA
Ztalmy-PA

Antidepressants[1]
amoxapine-PA
bupropion IR
bupropion SR
bupropion XL 150mg, 300mg-Q
bupropion XL 450mg-PA
citalopram-F
clomipramine-PA
desipramine-PA
desvenlafaxine ER-PA
desvenlafaxine succinate ER-Q
duloxetine 20, 30, 60 mg
duloxetine 40 mg cap-PA
escitalopram
fluoxetine 10, 20, 40 mg cap, soln 10, 20 mg tab
fluoxetine 60 mg tab, 90 mg DR capsule-PA
fluvoxamine ER-PA
imipramine hydrochloride
imipramine pamoate-PA
mirtazapine
mirtazapine ODT-PA
nefazodone
paroxetine
paroxetine CR-PA
protriptyline-PA
sertraline-F
trazodone
trimipramine-PA
venlafaxine IR
venlafaxine ER capsule
venlafaxine HC ER tab-PA
vilazodone-PA
Aplenzin-PA
Drizalma-PA
Emsam-PA
Fetzima-PA
Marplan-PA
Spravato-PA
Trintellix-PA
Zurzuvae-PA

Cerebral Stimulants and ADHD Agents[1]
amphetamine ER 1.25 mg/mL oral susp-A,PA
amphetamine salts ER and IR-A,F,Q
amphetamine sulfate-A,PA
atomoxetine
clonidine ER 0.1 mg tab-Q
dexmethylphenidate ER and IR-A,Q
methylphenidate transdermal-A,Q
methylphenidate ER tab, IR, SR, chew tab-A,Q
methylphenidate ER cap-A,PA
Adzenys XR-ODT-A,PA
Aptensio XR-A,PA
Azstarys-A,PA
Cotempla XR-ODT-A,PA
Dyanavel XR-A,PA,Q
Evekeo ODT-A,PA
Jornay PM-A,PA
Qelbree-PA
Quillichew ER-A,PA
Quillivant XR-A,PA,Q
Relexxi-A,PA
Vyvanse-A,F,Q
Xelstrym-A,PA

Antidiabetic: Insulin and Injectable Combinations
insulin aspart
insulin glargine
insulin lispro
Admelog-PA
Afrezza-PA
Apidra
Basaglar-PA
Basaglar Tempo-PA
Fiasp-PA
Humalog 50/50, 75/25
Humalog Tempo-PA
Humulin R
Humulin N-PA
Lantus
Levemir
Lyumjev-PA
Lyumjev Tempo-PA
Novolin R and N
Rezvoglar-PA
Semglee-PA
Soliqua-PA
Tresiba
Xultophy-PA

Antidiabetic: Non-Insulin Single Agents
alogliptin-PA
dapagliflozin
liraglutide (Victoza)-Q
metformin IR-F
metformin ER-F
metformin IR solution-A
nateglinide
pioglitazone
repaglinide
Bydureon Bcise-PA
Byetta-Q
Invokana
Januvia
Jardiance
Mounjaro-PA
Onglyza
Ozempic-PA
Riomet ER-PA
Rybelsus-PA
Steglatro-PA
Symlinpen
Tradjenta
Trulicity-Q

Antidiabetic: Non-Insulin Combinations
alogliptin/metformin-PA
alogliptin/pioglitazone-PA
dapagliflozin/metformin extended release
repaglinide/metformin-PA
saxagliptan/metformin extended release
Glyxambi-PA
Invokamet IR, XR
Janumet IR, XR
Jentadueto IR, XR
Qtern-PA
Segluromet-PA
Steglujan-PA
Synjardy IR, XR
Trijardy XR-PA
Zituvio- PA

Antihistamines
carbinoxamine 4mg
carbinoxamine 6mg-PA
cetirizine
desloratadine tab-PA
dexchlorpheniramine-PA
diphenhydramine
hydroxyzine
levocetirizine soln-PA
levocetirizine tablet
loratadine

Antipsychotics[1]
aripiprazole-Q
aripiprazole ODT-PA
asenapine sublingual tablet-PA
clozapine
clozapine ODT-PA
lurasidone-Q
olanzapine-Q
olanzapine IM
olanzapine ODT-Q
paliperidone tablet-Q
quetiapine-Q
quetiapine ER-Q
risperidone-Q
risperidone ER IM injection-Q
risperidone ODT 3 mg, 4 mg-PA
risperidone ODT 0.25 mg, 0.5 mg, 1 mg, 2 mg-Q
ziprasidone-Q
ziprasidone IM
Abilify Asimtufii-PA
Abilify Maintena-PA
Abilify Mycite-PA
Aristada-Q
Aristada Initio-Q
Caplyta-PA
Fanapt-PA
Invega Hafyera-Q
Invega Sustenna-Q
Invega Trinza-Q
Lybalvi-PA
Perseris-Q
Rexulti-PA
Rykindo-PA
Secuado-PA
Uzedy-Q
Versacloz-PA
Vraylar-PA
Zyprexa IM
Zyprexa Relprevv-Q

Asthma
albuterol inhalation soln, syrup, tablet
albuterol inhaler-PA
budesonide-F
budesonide/formoterol
fluticasone propionate inh aerosol-A
fluticasone propionate inh powder-PA
fluticasone/salmeterol inhalation
fluticasone/vilanterol
ipratropium
levalbuterol inh soln-PA
levalbuterol inhaler
Airsupra-PA
Alvesco-PA
Armonair Digihaler-PA
Arnuity-PA
Asmanex HFA
Asmanex Twisthaler-A
Dulera
Proair Digihaler-PA
Proair Respiclick
Qvar Redihaler-PA
Serevent-PA
Spiriva
Ventolin

Hypnotics[1]
doxepin tab-PA
estazolam-Q
eszopiclone-Q
flurazepam-PA
temazepam 22.5mg-PA
temazepam 7.5 mg, 15 mg, 30 mg-Q
triazolam-Q
zaleplon-Q
zolpidem-Q
zolpidem ER-Q
zolpidem 1.75 mg, 3.5 mg sublingual tab-PA
Belsomra-PA
Dayvigo-PA
Edluar-PA
Quviviq-PA

Narcotic Agonist Analgesics[2, 3]
buprenorphine transdermal-Q
fentanyl buccal tab-PA
fentanyl patch-F, Q
fentanyl transmucosal system-PA
hydrocodone ER cap-PA
hydrocodone ER tab-PA
hydromorphone ER-PA
levorphanol-PA
meperidine-PA
methadone-PA
morphine CR tablet-Q
morphine ER cap-PA
oxycodone ER-PA
oxymorphone ER, IR-PA
tramadol-A,F,Q
Belbuca-PA
Nucynta ER, IR-PA
Seglentis-PA
Xtampza-PA

This document does not represent the complete MassHealth Drug List. If applicable, drugs may also be subject to additional PA restrictions for polypharmacy, dose, quantity limit, and age. For more information, please visit the MassHealth web site at **www.mass.gov/druglist**. MassHealth evaluates the prior-authorization status of drugs on an ongoing basis and updates the MassHealth Drug List accordingly.

[1] = Listing may be subject to additional PA requirements per Pediatric Behavioral Health Medication Initiative (PBHMI) for members < 18 years of age.

[2] = Listing may be subject to additional PA requirements (Duplicate Opioid, Concurrent Opioid Dependence or Benzodiazepine Agent, High Dose Short-Acting Monotherapy).

[3] = Listing may be subject to additional PA requirements per Concomitant Opioid Benzodiazepine Initiative (COBI).

PA = Prior-authorization required. Prior-authorization forms can be found at www.mass.gov/druglist.

Q = PA is required to exceed certain quantity limits.

A = PA is required to exceed certain age limits.

F = PA depends on formulation.

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