Prescription Drug Program Prior Authorization Criteria

Revised 8/1/2025

This document is an informational listing of the medications requiring a Prior Authorization through the Arkansas Medicaid Pharmacy Program, and a description of the associated criteria. Inclusion in this document does not guarantee market availability and products must meet the Centers for Medicare and Medicaid Services (CMS) definition of a covered outpatient drug and pay CMS rebate to be covered by Arkansas Medicaid. Select covered over the counter medications are covered pursuant to a valid prescription but are not covered for Long Term Care eligible beneficiaries.

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Prescribers may request an override for nonpreferred drugs by calling the Prime Therapeutics State Government Solutions Help Desk at 1-800-424-7895 (toll-free) or fax letter of medical necessity along with any documentation to substantiate the medical necessity of the request to 1-800-424-7976.

For assistance on all other drugs, prescribers may call Prime Therapeutics State Government Solutions at 1-800-424-7895 (toll-free). The appropriate number is indicated with the associated drug.

Please refer to the Arkansas Medicaid Pharmacy Webpage for a complete list of drugs at this link:

ar.primetherapeutics.com/provider-documents

The Arkansas Medicaid Preferred Drug List may be found at this link:

ar.primetherapeutics.com/documents/d/arkansas/crm-attachment_pdl-document

Acitretin capsule (Soriatane®)

(Implemented 3/26/2008)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with severe psoriasis
- Must be prescribed by, or in consultation with, a dermatologist
- Beneficiary must be unresponsive to other therapies or have a clinical contraindication to the use of other treatments
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Severely impaired liver or kidney function
  - Abnormally elevated blood lipids
  - Requires concomitant tetracycline use
  - Develops capillary leak syndrome
  - Pregnant
  - Females of reproductive potential that will not use reliable contraception during treatment and for at least 3 years following discontinuation
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Description of body surface area (BSA) and severity of psoriasis
  - Two (2) negative pregnancy tests for patients of reproductive potential with the 2nd being during the first 5 days of the menstrual period
  - Documentation of the 2 forms of contraception that will be used
  - Attestation that the female of reproductive potential will have monthly pregnancy tests
  - Letter of medical necessity over all other medications used for psoriasis
- Initial PA for 3 months

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate an improvement in psoriasis with decrease in body surface area (BSA) and/or severity
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to treatment
  - Current negative pregnancy test for females of reproductive potential
  - Attestation that the beneficiary remains on 2 forms of contraception

Quantity Edits

- 60 capsules per 30 days

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Acoramidis HCl tablet (Attruby®)

(Implemented 4/16/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have the diagnosis of cardiomyopathy of wild-type or variant transthyretinmediated amyloidosis (ATTR-CM) confirmed with **TWO** of the following:
  - Echocardiogram; **OR**
  - Tissue biopsy confirming the presence of transthyretin amyloid deposits; **OR**
  - Cardiovascular magnetic resonance imaging
    - If consistent with cardiac amyloidosis, the following should be done to document the presence or absence of monoclonal protein confirmed by **ALL** of the following:
      - Serum kappa/lambda free light chain ratio analysis
      - Serum protein immunofixation
      - Urine protein immunofixation
    - If monoclonal protein is not found, bone tracer cardiac scintigraphy (pyrophosphate scan) should be performed. Presence of grade 2 or 3 is highly specific for ATTR cardiac disease and tissue biopsy is not needed, but genetic testing is needed to confirm TTR variant.
- Must be prescribed by, or in consultation with, a cardiologist
- Beneficiary must have New York Heart Association Class (NYHA) I, II, or III heart failure with symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema)
- Beneficiary must have left ventricular wall (interventricular septum or left ventricular posterior wall) thickness ≥ 12 mm
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Impaired renal function (eGFR < 15 mL/min/1.73m^2)
  - Baseline NT-proBNP < 300 pg/ml or ≥ 8500 pg/ml
  - Goal of treatment is strictly polyneuropathy
- Prescriber must submit the following:
  - Current chart notes
  - Symptoms specific to this patient to support diagnosis
  - Baseline 6-minute walk distance (6MWD)
  - Current labs including baseline eGFR and NT-proBNP level (≥ 300 pg/ml)
  - Baseline echocardiogram with NYHA classification and documentation of tests results to confirm diagnosis
  - Baseline Kansas City Cardiomyopathy Questionnaire-Overall Summary (CKKQ-OS) score

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to treatment
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of patient specific symptoms compared to baseline
  - Updated 6-minute walk distance (6MWD)
  - Current Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score

Quantity Edits

- #120/30 days

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Acyclovir cream, ointment

(Implemented 03/19/2013)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that do not require prior authorization

- Docosanol 10% cream (Abreva)

Drugs that require manual review for prior authorization

- Acyclovir 5% cream (Zovirax)
- Acyclovir 5% ointment (Zovirax)
- Acyclovir-Hydrocortisone 5%-1% cream (Xerese)
- Penciclovir 1% cream 5 gram (Denavir) *(Implemented 09/23/2014)*

Additional Criteria

- Quantity edits apply

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Albuterol IR and ER oral tablets and syrup (Vospire®)

(Implemented 03/18/2014)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for these products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Drugs that require manual review for prior authorization

- Albuterol 2 mg IR, 4 mg IR
- Albuterol 4 mg ER, 8 mg ER (generic for Vospire ER®)
- Albuterol 2 mg/5 ml syrup

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with reversible obstructive airway disease experiencing bronchospasms
- Prescriber must submit the following:
  - Current chart notes
  - Diagnosis
  - Previous therapies tried
  - Letter of medical necessity for albuterol oral tablets over inhaled bronchodilators such as single agent (e.g., Ventolin HFA®) and combination agent (e.g., Symbicort®) products which are available without prior authorization

Quantity Edits

- 2 mg and 4 mg IR: #120 tablets for 30 days
- 4 mg ER: #60 tablets for 30 days
- 8 mg ER: #120 tablets for 30 days
- Syrup: 120 ml per claim

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Allergen Induced Rhinitis (Ragwitek®, Grastek®, Oralair®, Odactra™)

(Implemented 09/23/2014)
(Updated 07/17/2015)
(Updated 7/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis consistent with the FDA approved package insert. Any off-label requests will be reviewed on a case-by-case basis.
    - **Grastek®—**immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens
    - **Odactra™—**immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or by positive skin testing to licensed house dust mite allergen extracts
    - **Oralair®—**immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the five grass species contained in this product
    - **Ragwitek®—**immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen
- Beneficiary must have appropriate testing for the specific allergen (e.g., grass, pollens, ragweed, dust mites) for the drug requested. The testing can be either serum testing for the specific IgE antibodies or skin test and must be positive for the specific allergen.
- For Grastek®, Oralair®, and Ragwitek®, the previous allergy season for either ragweed or grass pollen will be reviewed for Medicaid drug claims that are used to treat allergy symptoms. For Odactra™, the Medicaid drug claims for the past 6 months will be reviewed. The beneficiary must have filled drugs to treat allergy symptoms in at least 2 of the following categories during the previous allergy season for Grastek®, Oralair®, and Ragwitek® or in the last 6 months for Odactra™ and have at least 2 claims in consecutive months in each category:
    - Nasal inhaled steroid
    - Oral (systemic) antihistamine
    - Leukotriene modifier

  - Ophthalmic allergy drops (topical ocular mas cell stabilizers or antihistamines) for treating allergic conjunctivitis
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Duplication of therapy with allergy shots or other SL allergen extract tablet
  - Has severe, unstable or uncontrolled asthma
  - For continued approval, beneficiary must remain compliant

Quantity Edits

- #31/ 31 days

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Alpelisib (Vijoice®)

(Implemented 7/20/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 2 years of age; **AND**
- Beneficiary must have a diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) requiring systemic therapy **OR** a diagnosis consistent with any updated FDA approved indications; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Genetic testing results identifying a PIK3CA mutation and/or the clinical presentation confirming the diagnosis; **AND**
  - Identify which PROS disease has been confirmed; **AND**
  - Current labs including fasting plasma glucose and HbA1c; **AND**
  - Previous treatment including surgery (provide explanation if surgery is not an option); **AND**
  - Baseline size/volume of target lesion(s); AND
  - Attestation that both males and females of reproductive potential have been counseled on the importance of contraception; **AND**
  - Current dose requested (Patients unable to swallow tablets can use any dose to make a suspension based on preparation guidance from the packet insert.)
    - Beneficiary < 6 years - max of 50 mg daily
    - Beneficiary 6-17 years of age - 50 mg daily for at least 24 weeks before increasing to 125 mg daily
    - Beneficiary ≥ 18 years of age - max of 250 mg daily

Denial Criteria

- Beneficiary does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Beneficiary is pregnant; **OR**
- Beneficiary has been diagnosed with severe cutaneous adverse reactions (SCARs) including Stevens-Johnson Syndrome, Erythema Multiforme or Toxic Epidermal Necrolysis or pneumonitis; **OR**
- Beneficiary cannot tolerate the minimum dose of 50 mg daily; **OR**
- Beneficiary requires a concomitant strong CYP3A4 inducer or BCRP inhibitor; **OR**
- Beneficiary has Type 1 or uncontrolled Type 2 diabetes

Quantity Edits

- 50 mg - #31/month

- 125 mg - #31/month
- 250 mg pack - #62/month

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Alpha-1 Proteinase Inhibitors

(Implemented 10/1/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Prolastin-C
- Aralast
- Glassia
- Zemaira

Approval Criteria

- Age ≥18 years old
- Manual review on a case-by-case basis
- Request from pulmonologist
- Required diagnoses consistent with indication
  - Diagnosis of emphysema in the previous 2 years; **AND**
  - Diagnosis of alpha-1 antitrypsin deficiency in the previous 2 years
- Documentation of smoking status—must be a current non-smoker and need confirmation with carbon monoxide test
- Documentation of low serum concentration of AAT ≤ 11µM/L or ≤ 80 mg/dL; **OR** documentation of high-risk homozygous protein phenotypes (i.e. PiZZ, PiSZ, or Pi (null, null))
- Baseline PFTs with FEV1 30-65%
- Current chart notes with weight for calculating dosage
- Continued optimal conventional treatment for emphysema (e.g. bronchodilators, supplemental oxygen if needed, etc.)

Denial Criteria

- Does not meet above approval criteria
- Pregnant
- Request for diagnoses considered investigational (i.e. Cystic Fibrosis, no AATD)
- Billed diagnosis of Immunoglobulin A (IgA) deficiency (IgA < 15mg/dL)
  - D80.2 Selective deficiency of immunoglobulin A (IgA)

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Alzheimer's Agents

(Implemented 10/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Donepezil 5mg and 10 mg tablet (generic for Aricept®)
- Exelon® patch (rivastigmine) – **BRAND ONLY**
- Memantine tablet (generic for Namenda®)

Non-Preferred Agents

- Adlarity® (donepezil patch)
- Aricept® tablet (donepezil)
- Donepezil ODT (generic for Aricept® ODT)
- Donepezil 23 mg tablet (generic for Aricept®)
- Galantamine tablet (generic for Razadyne®)
- Galantamine ER capsule (generic for Razadyne® ER)
- Galantamine solution (generic for Razadyne®)
- Memantine ER capsule (generic for Namenda® XR)
- Memantine solution (generic for Namenda®)
- Memantine/donepezil capsule (generic for Namzaric®)
- Namenda® XR capsule (memantine ER)
- Namzaric® capsule (memantine/donepezil)
- Razadyne® ER capsule (galantamine)
- Rivastigmine patch (generic for Exelon®)
- Rivastigmine capsule (generic for Exelon®)
- Zunveyl® DR tablet (benzgalantamine)

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Amifampridine (Firdapse®)

(Implemented 7/17/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Fordapse®

Approval Criteria

- Manual review on a case-by-case basis
- ≥ 6 years of age
- Confirmed diagnosis of LEMS based on either neurophysiology studies or a positive anti-P/Q type voltage-gated calcium channel antibody test
- Current chart notes
- If receiving peripherally acting cholinesterase inhibitors, a stable dose is required for at least 7 days
- If receiving oral immunosuppressants, a stable dose is required for the last 30 days
- Negative pregnancy test
- Provide labs including renal and liver function
  - Creatinine clearance from 15-90ml/min must start on lower dose of 15mg per day; no dosage recommendations for ESRD
  - Any decrease in liver function requires a lower starting dose of 15mg per day
- Provide the Quantitative Myasthenia Gravis (QMG) score for baseline
- Provide the medical necessity over guanidine hydrochloride, IVIG, and immunosuppressants (such as azathioprine) if not currently taking
- If diagnosed with cancer, provide treatment plan

Denial Criteria

- < 6 years old
- No confirmation of the LEMS diagnosis
- History of seizures or taking other medications that can lower the seizure threshold
- Pregnant
- End stage renal disease
- Caution with lactation
- Use of guanidine hydrochloride in the last 7 days
- Currently uncontrolled asthma due to increased respiratory infections with this medication

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Amikacin liposome inhalation suspension (Arikayce®)

(Implemented 4/17/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Will require manual review PA on a case-by-case basis
- Age ≥ 18 years old
- Patient must be diagnosed with refractory Mycobacterium avium complex (MAC) lung disease o Receiving ATS/IDSA guideline-based treatment with a multi-drug regimen for at least 6 months with persistently positive cultures
- Provide documentation of previous multi-drug MAC regimen
- Patient must be diagnosed with non-tuberculosis mycobacterial lung disease in accordance with the 2007 ATS/IDSA criteria:
  - Patient must have pulmonary symptoms with evidence of nodular bronchiectasis via radiograph and/or cavitary disease by CT
  - Appropriate exclusion of other diagnoses
  - Positive culture results from at least 2 separate sputum samples or positive culture via bronchial lavage or wash or via transbronchial lung biopsy
- Provide current labs including CBC and basic metabolic panel
- If child-bearing age, recommend a pregnancy test due to risk of congenital deafness

Denial Criteria

- Patients with non-refractory MAC lung disease
- Currently takes medications associated with neurotoxicity, nephrotoxicity, and ototoxicity.
- Currently takes ethacrynic acid, furosemide, urea, or intravenous mannitol due to increased aminoglycoside toxicity.
- Pregnancy due to potential birth defects.
- FEV1 < 30% predicted
- Active pulmonary malignancy or active pulmonary TB
- Lung transplant patient
- Conditions requiring continuous oxygen supplementation
- Smoking within the last 6 months

Quantity Edits

- #28 vials/ 28 days

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Ammonul 10%-10%Vial

(Updated 05/20/2015)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Ammonul 10%-10%

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Amyotrophic Lateral Sclerosis (ALS) Medications

(Implemented 5/10/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

Riluzole tablet

- No PA required
- Quantity limit applies

Exservan® and Tiglutik®

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a maximum dose based on support in manufacturer's package insert or official Compendia
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous and current therapies
  - Baseline ALS Functional Rating Scale-Revised score
  - Baseline PFTs
  - Medical necessity over riluzole tablets

Radicava® ORS (edaravone)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of amyotrophic lateral sclerosis (ALS) **OR** a diagnosis consistent with any updated FDA approved indications
- Beneficiary should meet the following at baseline:
  - Beneficiary has a disease duration < 2 years
  - Beneficiary has FVC ≥ 80% at baseline
  - Baseline ALSFRS-R score documents the retention of functionality for most activities of daily living (defined as scores of 2 points or better on each individual item)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous and current therapies
  - Baseline ALS Functional Rating Scale-Revised score
  - Current PFTs
  - Duration of symptoms
  - Documentation of concomitant meds for ALS (are they planning on riluzole and/or Relyvrio® as well)

Relyvrio™ (sodium phenylbutyrate/taurursodiol powder) for suspension

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a maximum dose based on support in manufacturer's package insert or official Compendia
- Beneficiary must have a diagnosis of sporadic or familial amyotrophic lateral sclerosis (ALS) **OR** a diagnosis consistent with any updated FDA approved indications
- Beneficiary must not have any of the following:
  - Require bile acid sequestrants, probenecid, or cyclosporine
  - Have moderate to severe renal or hepatic impairment
- Beneficiary should meet the following at baseline:
  - Beneficiary has initial symptoms no longer than 18 months prior to starting medications
  - Beneficiary has a slow vital capacity (SVC) > 60% at baseline
- Prescriber must submit
  - Current chart notes
  - Documentation of previous and current therapies
  - Baseline ALS Functional Rating Scale-Revised score
  - Current PFTs (including SVC)
  - Duration of symptoms
  - Documentation of concomitant meds for ALS (are they planning on riluzole and/or Radicava® ORS as well)

Renewal Requirements

(pertains to Exservan®, Tiglutik®, Radicava® ORS, or Relyvrio™):

- Beneficiary remains compliant on therapy (defined as 75% utilization)
- Beneficiary does not become dependent on invasive ventilation or tracheostomy
- Prescriber must submit the following:
  - Current chart notes
  - Current PFTs
  - Current ALSFRS-R score

Quantity Edits

Riluzole

- #62 per 31 days

Exservan®

- #62 per 31 days

Tiglutik®

- #620 mL per 31 day

Radicava® ORS

- 50 mL bottle--#1 per 28 days
- 70 mL bottle--#1 per 28 days

Relyvrio™

- #62 per 31 days

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Anaphylaxis Agents (Epinephrine, Self-Administered)

(Updated 7/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- EpiPen®
- EpiPen Jr®
- Epinephrine 0.15mg, 0.3mg (authorized generic for EpiPen® and EpiPen Jr®) injection

Non-Preferred Agents

- Auvi-Q® 0.1 mg, 0.15 mg, 0.3 mg
- Epinephrine 0.15 mg, 0.3 mg (generic for Adrenaclick®)
- Epinephrine 0.15 mg, 0.3 mg (non-authorized generic for EpiPen Jr® and EpiPen®)
- Neffy® 1 mg/0.1 ml, 2 mg/0.1 ml nasal spray
- Symjepi® 0.15 mg, 0.3 mg

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Angiotensin Receptor Modulators

(Implemented 10/01/2008)
(Updated 01/27/2017)
(Updated 1/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Angiotensin Converting Enzyme (ACE) Inhibitors/Combination Products

Preferred Agents

- Benazepril (generic for Lotensin)
- Benazepril/Amlodipine (generic for Lotrel)
- Benazepril/HCTZ (generic for Lotensin HCT)
- Enalapril (generic for Vasotec)
- Enalapril/HCTZ (generic for Vaseretic)
- Fosinopril (generic for Monopril)
- Fosinopril/HCTZ (generic for Monopril HCT)
- Lisinopril (generic for Zestril)
- Lisinopril/HCTZ (generic for Zestoretic)
- Quinapril (generic for Accupril)
- Quinapril/HCTZ (generic for Accuretic)
- Ramipril (generic for Altace)

Non-Preferred Agents

- Accupril (quinapril)
- Accuretic (quinapril/HCTZ)
- Altace (ramipril)
- Captopril/HCTZ (generic for Capozide)
- Enalapril solution (generic for Epaned)
- Epaned solution (enalapril)
- Lotensin (benazepril)
- Lotensin HCT (benazepril/HCTZ)
- Lotrel (benazepril/amlodipine)
- Moexipril (generic for Univasc)
- Moexipril/HCTZ (generic for Uniretic)
- Perindopril (generic for Aceon)
- Qbrelis (lisinopril solution)
- Tarka (trandolapril/verapamil)
- Trandolapril (generic for Mavik)
- Trandolapril/Verapamil (generic for Tarka)

- Vasotec (enalapril)
- Zestoretic (lisinopril/HCTZ)
- Zestril (lisinopril)

Non-Preferred Agents With Criteria

- Captopril (point-of-sale Approval for children ≤ 12 years of age)

Direct Renin Inhibitors

Preferred Agents

- **NONE**

Non-Preferred Agents

- Aliskiren (generic for Tekturna)
- Tekturna (aliskiren)
- Tekturna HCT (aliskiren/HCTZ)

Angiotensin II Receptor Blockers (ARB)/ARB Combination Products

Preferred Agents

- Irbesartan (generic for Avapro)
- Irbesartan/HCTZ (generic for Avalide)
- Losartan (generic for Cozaar)
- Losartan/HCTZ (generic for Hyzaar)
- Olmesartan (generic for Benicar)
- Olmesartan/amlodipine (generic for Azor)
- Valsartan tablet (generic for Diovan)
- Valsartan/HCTZ (generic for Diovan HCT)
- Valsartan/Amlodipine (generic for Exforge)
- Valsartan/Amlodipine/HCTZ (generic for Exforge HCT)

Preferred Agents With Criteria

- Entresto sprinkle (valsartan/sacubitril)
- Entresto tablet (valsartan/sacubitril) **– BRAND ONLY**
  - Point-of-sale approval for diagnosis in Medicaid medical history in previous 2 years of congestive heart failure (CHF)
  - Point-of-sale denial if female beneficiary is currently pregnant
  - Age edits may apply

Non-Preferred Agents

- Atacand (candesartan)
- Atacand HCT (candesartan/HCTZ)
- Avalide (irbesartan/HCTZ)
- Avapro (irbesartan)
- Azor (olmesartan/amlodipine)
- Benicar (olmesartan)
- Benicar HCT (olmesartan/HCTZ)

- Candesartan (generic for Atacand)
- Candesartan/HCTZ (generic for Atacand HCT)
- Cozaar (losartan)
- Diovan (valsartan)
- Diovan HCT (valsartan/HCTZ)
- Edarbi (azilsartan)
- Edarbyclor (azilsartan/chlorthalidone)
- Eprosartan (generic for Tevetan)
- Exforge (valsartan/amlodipine)
- Exforge HCT (valsartan/amlodipine/HCTZ)
- Hyzaar (losartan/HCTZ)
- Micardis (telmisartan)
- Micardis HCT (telmisartan/HCTZ)
- Olmesartan/HCTZ (generic for Benicar HCT)
- Olmesartan/Amlodipine/HCTZ (generic for Tribenzor)
- Telmisartan (generic for Micardis)
- Telmisartan/Amlodipine (generic for Twynsta)
- Telmisartan/HCTZ (generic for Micardis HCT)
- Valsartan solution (generic for Diovan)
- Valsartan/sacubitril tablet (generic for Entresto)

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Anticoagulants (Oral and LMWH)

(Effective 4/01/2018)
(Updated 4/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Preferred Agents

- Dabigatran capsule (generic for Pradaxa®)
- Eliquis® tablet (apixaban)
- Enoxaparin injection (generic for Lovenox®)
- Pradaxa® capsule (dabigatran) **BRAND ONLY** (Will be moved to NPD effective 9/1/2025)
- Warfarin tablet (generic for Coumadin®)
- Xarelto® tablet (rivaroxaban) **BRAND ONLY**

Approval Criteria

- No Therapeutic duplication allowed between different strengths of the same anticoagulant;
- One (1) therapeutic duplication with overlapping days' supply will be allowed once per 186 days for an inferred change in therapy between a preferred anticoagulant **AND**
- The claims cannot have the same date of service.

Non-Preferred Agents

- Arixtra® injection (fondaparinux)
- Coumadin® tablet
- Fondaparinux injection (generic for Arixtra®)
- Fragmin® injection (dalteparin)
- Lovenox® injection
- Pradaxa pellet pack (dabigatran)
- Rivaroxaban 2.5 mg tablet (generic for Xarelto®)
- Rivaroxaban suspension (generic for Xarelto®)
- Savaysa® tablet (edoxaban)
- Xarelto® suspension (rivaroxaban) **BRAND ONLY IF APPROVED**

Additional Criteria

- Quantity limits apply

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Anticonvulsants

(Effective 4/01/2022)
(Updated 7/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Preferred Agents

NOTE: Patients compliant on a non-preferred agent will be able to continue that medication without a PA if there is a claim in their Medicaid profile in the previous 60 days. Many anticonvulsants have criteria established. See the notations below for clarification. Anticonvulsants have quantity limits as well based on the manufacturer's package inserts and support in MicroMedex®.

*Point-of-sale criteria
**Follows NPO rules (either <7 years of age OR NPO within the past 365 days)
***Manual review criteria

- Carbamazepine 100 mg chew tablet (generic for Tegretol®)
- Carbamazepine tablet (generic for Tegretol®)
- Clobazam suspension (generic for Onfi®)
- Clobazam tablet (generic for Onfi®)
- Divalproex DR tablet (generic for Depakote DR®)
- Divalproex ER tablet (generic for Depakote ER®)
- Ethosuximide capsule (generic for Zarontin®)
- Gabapentin capsule/tablet (generic for Neurontin®)
- Lacosamide solution (generic for Vimpat®)
- Lacosamide tablets (generic for Vimpat®)
- Lamotrigine tablet (generic for Lamictal®)
- Levetiracetam solution (generic for Keppra®)
- Levetiracetam tablet (generic for Keppra®)
- Oxcarbazepine tablet (generic for Trileptal®)
- Phenytoin capsule (generic for Dilantin®)
- Pregabalin capsule (generic for Lyrica®)
- Primidone tablet (generic for Mysoline®)
- Qudexy XR® capsule (topiramate) **BRAND ONLY**
- Sabril® tablet (vigabatrin) **BRAND ONLY**
- Tegretol® suspension (carbamazepine) **BRAND ONLY**
- Topiramate tablet (generic for Topamax®)
- Trileptal® suspension (oxcarbazepine) **BRAND ONLY**
- Valproic acid capsule (generic for Depakene®)
- Valproic acid solution (generic for Depakene®)
- Vigabatrin powder pack (generic for Sabril®)
- Zonisamide capsule (generic for Zonegran®)

Non-Preferred Agents

- Aptiom® (eslicarbazepine acetate)
- Banzel® suspension (rufinamide) Banzel® tablet (rufinamide)
- Briviact® solution (brivaracetam)
- Briviact® tablet (brivaracetam)
- Carbamazepine 200 mg chew tab (generic for Tegretol®)
- Carbamazepine ER capsule (generic for Carbatrol®)
- Carbamazepine ER tablet (generic for Tegretol XR®)
- Carbamazepine suspension (generic for Tegretol®)
- Carbatrol ER® capsule (carbamazepine)
- Celontin® capsule (methsuximide)
- Depakote DR® tablet (divalproex)
- Depakote ER® tablet (divalproex)
- Depakote® sprinkle capsule (divalproex)
- Diacomit® capsule (stiripentol)
- Diacomit® powder packet (stiripentol)
- Dilantin® capsule (phenytoin)
- Dilantin® Infatab tablet (phenytoin)
- Dilantin® suspension (phenytoin)
- Divalproex sprinkle capsule (generic for Depakote®)
- Elepsia XR® tablet (levetiracetam)
- Epidiolex® solution (cannabidiol)*** (Link to Epidiolex Oral Solution)
- Eprontia® solution (topiramate)
- Equetro® capsule (carbamazepine)
- Eslicarbazepine (generic for Aptiom®)
- Ethosuximide solution (generic for Zarontin®)
- Felbamate suspension (generic for Felbatol®)
- Felbamate tablet (generic for Felbatol®)
- Felbatol® suspension (felbamate)
- Felbatol® tablet (felbamate)
- Fintepla® solution (fenfluramine)*** (Link to Fenfluramine Solution (Fintepla)
- Fycompa® suspension (perampanel)
- Fycompa® tablet (perampanel) **BRAND PREFERRED OVER GENERIC WHEN APPROVED**
- Gabapentin solution (generic for Neurontin®)**
- Gabarone™tablet (gabapentin)
- Gabitril® tablet (tiagabine)
- Keppra® solution (levetiracetam)
- Keppra® tablet (levetiracetam)
- Keppra XR® tablet (levetiracetam)
- Lamictal® dispersible tablet (lamotrigine)
- Lamictal® dose pack (lamotrigine)
- Lamictal® ODT dose pack (lamotrigine)
- Lamictal® ODT tablet (lamotrigine)
- Lamictal® tablet (lamotrigine)
- Lamictal® XR tablet (lamotrigine ER)
- Lamictal® XR dose pack (lamotrigine)
- Lamotrigine dispersible tablet (generic for Lamictal®)
- Lamotrigine dose pack (generic for Lamictal®)

- Lamotrigine ER tablet (generic for Lamictal XR®)
- Lamotrigine ODT dose pack (generic for Lamictal®)
- Lamotrigine ODT tablet (generic for Lamictal®)
- Levetiracetam ER tablet (generic for Keppra XR®)
- Levetiracetam tablet (generic for Spritam®)
- Methsuximide capsule (generic for Celontin®)
- Motpoly XR® capsule (lacosamide)
- Mysoline® tablet (primidone)
- Onfi® suspension (clobazam)
- Onfi® tablet (clobazam)
- Oxcarbazepine ER tablet (generic for Oxtellar XR®)
- Oxcarbazepine suspension (generic for Trileptal®)
- Oxtellar XR® tablet (oxcarbazepine) **BRAND PREFERRED OVER GENERIC WHEN APPROVED**
- Perampanel tablet (generic for Fycompa®)
- Phenobarbital elixir
- Phenobarbital tablet
- Phenytek® capsule (phenytoin ER)
- Phenytoin chew tablet (generic for Dilantin Infatab®)
- Phenytoin ER capsule (generic for Phenytek®)
- Phenytoin suspension (generic for Dilantin®)
- Rufinamide suspension (generic for Banzel®)
- Rufinamide tablet (generic for Banzel®)
- Sabril® Powder Packet
- Spritam® tablet (levetiracetam)
- Sympazan® film (clobazam)***
- Tegretol® tablet (carbamazepine)
- Tegretol XR® tablet (carbamazepine ER)
- Tiagabine tablet (generic for Gabitril®)
- Topamax® sprinkle (topiramate)
- Topamax® tablet (topiramate)
- Topiramate ER capsule (generic for Qudexy® and Trokendi XR®)
- Topiramate solution (generic for Eprontia®)
- Topiramate sprinkle (generic for Topamax® sprinkle)
- Trileptal® tablet (oxcarbazepine)
- Trokendi XR® capsule (topiramate)
- Vigabatrin tablet (generic for Sabril®)
- Vigafyde™ solution (vigabatrin)
- Vimpat® solution (lacosamide)
- Vimpat® tablet (lacosamide)
- Vimpat® tablet dose pack (lacosamide)
- Xcopri® tablet (cenobamate)
- Xcopri® titration pack (cenobamate)
- Zarontin® capsule (ethosuximide)
- Zarontin® solution (ethosuximide)
- Zonisade® suspension (zonisamide)

Rescue Anticonvulsants

Preferred Agents

- ~~Diastat Acudial® (diazepam)~~
- ~~Diastat® Rectal Gel (diazepam)~~
- Diazepam Rectal Gel System (generic for Diastat Acudial®)
- Diazepam Rectal Gel Kit (generic for Diastat®)
- Nayzilam® nasal spray (midazolam)
- Valtoco® nasal spray (diazepam)

Non-Preferred Agents

- Libervant™ Buccal Film (diazepam)

Quantity Edits

- NAYZILAM - 10 doses per month
- VALTOCO - 10 doses per month
- DIASTAT - 3 doses per claim

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Antidepressants - Second-generation (SGAD)

(Implemented 01/01/2010)
(Updated 01/10/2019)
(Updated 10/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Preferred Agents with Criteria

- Bupropion HCl regular-release (generic for Wellbutrin®)
- Bupropion HCl extended-release (generic for Wellbutrin XL®)
- Bupropion HCl sustained-release (generic for Wellbutrin SR®)
- Citalopram hydrobromide tablet and solution (generic for Celexa®)
- Desvenlafaxine succinate ER tablet (generic for Pristiq®)
- Duloxetine (generic for Cymbalta®)
- Escitalopram oxalate tablet and solution (generic for Lexapro®)
- Fluoxetine HCl 10mg, 20mg, 40mg capsule and 20mg/5ml solution (generic for Prozac®)
- Fluoxetine HCl/olanzapine (Symbyax®)
- Fluvoxamine maleate tablet (generic for Luvox®)
- Mirtazapine 7.5mg, 15mg, 30mg, 45mg tablet (generic for Remeron®)
- Paroxetine HCl regular-release tablet (generic for Paxil®)
- Sertraline HCl tablet and oral conc (generic for Zoloft®)
- Trazodone 50mg, 100mg, 150mg tablet (generic for Desyrel®)
- Venlafaxine HCl extended-release capsule (generic for Effexor ER®)
- Venlafaxine HCl regular-release tablet (generic for Effexor®)

Non-Preferred Agents

- Aplenzin® (bupropion hydrobromide extended-release tablet)
- Auvelity® (dextromethorphan/bupropion) tablets
- Bupropion HCl extended-release tablet (generic for Forfivo XL®)
- Celexa® tablet (citalopram)
- Citalopram capsules (generic for Celexa®)
- Desvenlafaxine extended-release tablet
- Duloxetine HCl 40 mg DR capsules (generic for Irenka DR®)
- Effexor XR® capsule (venlafaxine)
- Emsam® patch (selegiline)
- Fetzima® (levomilnacipran) capsules
- Fluoxetine HCl 10mg, 15mg, 20mg, and 60mg tablet (generic for Prozac®)
- Fluoxetine HCl 90mg weekly capsule (generic for Prozac®)
- Fluvoxamine maleate extended-release (generic for Luvox CR®)
- Forfivo XL® tablets (bupropion)
- Lexapro® tablet (escitalopram)
- Marplan® tablet (isocarboxazid)
- Mirtazapine orally disintegrating tablet (generic for Remeron® SolTab)

- Nardil® tablet (phenelzine)
- Nefazodone HCl (generic for Serzone®)
- Paroxetine HCl controlled-release tablet, and 10mg/5ml suspension (generic for Paxil®)
- Paroxetine mesylate capsules (generic for Brisdelle®)
- Paxil® IR tablet, CR tablet, and suspension
- Pexeva® tablet (paroxetine mesylate)
- Phenelzine tablet (generic for Nardil®)
- Pristiq® tablet (desvenlafaxine)
- Prozac® capsule (fluoxetine)
- Raldesy™ solution (trazodone)
- Remeron® SolTab and tablet (mirtazapine)
- Savella® tablet (milnacipran HCl)
- Sertraline capsule (generic for Zoloft®)
- Spravato® nasal spray (esketamine) (manual review criteria)
- Tranylcypromine tablet (generic for Parnate®)
- Trazodone 300mg tablet
- Trintellix® tablet (vortioxetine HBr)
- Venlafaxine ER tablet (generic for Effexor®)
- Viibryd® tablet (vilazodone)
- Vilazodone HCl tables (generic for Viibryd®)
- Wellbutrin® SR tablet and XL tablet (bupropion)
- Zoloft® tablet and oral conc (sertraline)
- Zurzuvae® (zuranolone) (manual review criteria)

Approval Criteria for Preferred Agents with Criteria

- Drug daily dose ≤ maximum daily dose (Table 1)

Approval Criteria for Preferred Agents Involving a Therapeutic Duplication

- If applicable for a change in therapy or concomitant therapy of two agents and only one or neither are SSRIs and/or SSNRIs (including combinations) (Table 1.2):
  - Drug in history reflects a minimal therapeutic dose (Table 1) for at least four weeks

  OR
- If applicable for a change in therapy for two SSRIs and/or SSNRIs (including combinations) (Table 1.2)
  - Drug in history reflects a minimal therapeutic dose (Table 1) for at least four weeks, **AND**
  - No prior therapeutic duplication for two different SSRIs and/or SSNRIs (including combinations) (Table 1.2) within the past 365 days.

Approval Criteria for All Non-Preferred Agents Except Milnacipran (Continuation Criteria)

- Continuation criteria is defined as at least 90 days' supply in the previous 186 days for the same drug, strength, and daily dose with the denial exception of a therapeutic duplication between an SSRI and/or SNRI between incoming claim and history.

Denial Criteria for All Agents

- Preferred agents
  - Therapeutic duplication of three agents
  - Therapeutic duplication of two SSRIs and/or SSNRIs (including combinations) (Table 1.2) more than once per 365 days
- Nonpreferred drugs for patients who do not meet continuation criteria of > 90 days' supply in the previous 186 days for the same drug, strength, and daily dose

Table 1 – Minimum and maximum dose for second-generation antidepressants

Effective 7/1/2024, minimum daily therapeutic doses will be removed from the Approval Criteria. This table is for historical reference only.

Drug	Minimal daily therapeutic dose	Maximum daily dose
Bupropion	150mg	450mg
Citalopram	20mg	40mg
Desvenlafaxine	50mg	400mg
Duloxetine	40mg	120mg
Escitalopram	10mg	20mg
Fluoxetine	20mg	60mg
Fluoxetine/olanzapine*	25mg	75mg
Fluvoxamine	100mg	300mg
Levomilnacipran	40mg	120mg
Milnacipran	100mg	200mg
Mirtazapine	15mg	45mg
Nefazodone	200mg	600mg
Paroxetine	20mg	60mg (CR 62.5mg)
Sertraline	50mg	200mg
Venlafaxine	75mg	375mg
Vilazodone	20mg	40mg
Vortioxetine	10mg	20mg

* Minimum therapeutic dose and maximum dose based on SSRI component of the combination agent.

Table 1.2 – Selective Serotonin (norepinephrine) Reuptake Inhibitors (combinations)**SSRI, SSNRI, or SSRI Combinations**
Citalopram
Desvenlafaxine ER
Duloxetine
Escitalopram
Fluoxetine

Fluoxetine/olanzapine
Fluvoxamine
Paroxetine
Sertraline
Venlafaxine

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Antidiabetic Agents

(Implemented 01/01/2009)
(Updated 8/12/2020) (Effective 10/1/2020)
(Updated 10/19/2022)
(Updated 4/1/2025)

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Alpha Glucosidase Inhibitors

Preferred Agents

- Acarbose (generic for Precose®)

Non-Preferred Agents

- Miglitol (generic for Glyset®)
- Precose® (acarbose)

Amylin Analogues

Preferred Agents

- None

Non-Preferred Agents

- Symlin® (pramlintide)

DPP-4 Inhibitors

Preferred Agents

- Janumet® (sitagliptin/metformin)
- Januvia® (sitagliptin)
- Saxagliptin (generic for Onglyza®)
- Tradjenta® (linagliptin)

Non-Preferred Agents

- Alogliptin (generic for Nesina®)
- Alogliptin/metformin (generic for Kazano®)
- Alogliptin/pioglitazone (generic for Oseni®)
- Brynovin™ solution (sitagliptin)
- Glyxambi® (linagliptin/empagliflozin)
- Janumet® XR (sitagliptin/metformin ER)
- Jentadueto® (linagliptin/metformin)
- Jentadueto XR® (linagliptin/metformin ER)
- Kazano® (alogliptin/metformin)
- Nesina® (alogliptin)
- Oseni® (alogliptin/pioglitazone)
- Saxagliptin/metformin ER (generic for Kombiglyze® XR)

- Sitagliptin (generic for Zituvio®)
- Sitagliptin/metformin (generic for Zituvimet®)
- Sitagliptin/metformin XR (generic for Zituvimet® XR)
- Steglujan® (sitagliptin/ertugliflozin)
- Trijardy® XR (linagliptin/empagliflozin/metformin ER)
- Zituvimet® (sitagliptin/metformin)
- Zituvimet® XR (sitagliptin/metformin ER)
- Zituvio® (sitagliptin)

Approval Criteria for Preferred DPP-4 Inhibitors

- Medicaid pharmacy profile indicates a paid claim in the last 60 days for a preferred DPP-4 Inhibitor
- Diagnosis of type 2 diabetes mellitus; **AND**
  - Metformin claim in the last 186 days; **OR**
  - HbA1c ≥ 9 in the last 186 days

*** NOTE:** Non-preferred products will continue to require a prior authorization.

GLP-1 Agonists

(Updated 6/1/2025)

Preferred Agents

- Byetta® pen (exenatide) – **UNTIL NO MORE PRODUCT IS ON THE MARKET**
- Victoza® pen (liraglutide) – **BRAND ONLY**
- Trulicity® pen (dulaglutide)

Non-Preferred Agents

- Exenatide (generic for Byetta®)
- Liraglutide (generic for Victoza®)
- Mounjaro® injection (tirzepatide)
- Ozempic® injection (semaglutide)
- Rybelsus® tablet (semaglutide)
- Soliqua® injection (lixisenatide/insulin glargine)
- Xultophy® injection (insulin degludec/liraglutide)

Approval Criteria for Preferred GLP-1 Agonists

- Medicaid pharmacy profile indicates a paid claim in the last 60 days for a preferred GLP-1 receptor agonist
- Diagnosis of type 2 diabetes mellitus; **AND**
  - Metformin claim in the last 186 days; **OR**
  - HbA1c ≥ 9 in the last 186 days; **OR**
  - Diagnosis of ASCVD (e.g., CABG, Angina, CHD, CAD, MI, heart failure, CVD, TIA, PAD, aortic atherosclerosis, thoracic or abdominal aortic aneurysm)

***NOTE:** Non-preferred products will continue to require a prior authorization.

Insulins – Please see Insulins

Meglitinides

Preferred Agents

- Nateglinide (generic for Starlix®)
- Repaglinide (generic for Prandin®)

Non-Preferred Agents

- None

Metformins

Preferred Agents

- Metformin 500 mg (generic for Glucophage®)
- Metformin 850 mg (generic for Glucophage®)
- Metformin 1000 mg (generic for Glucophage®)
- Metformin ER 500 mg (generic for Glucophage XR®)
- Metformin ER 750 mg (generic for Glucophage XR®)

Non-Preferred Agents

- Glumetza® (metformin ER)
- Metformin 625 mg, 750 mg
- Metformin ER Gastric 500 mg and 1000 mg (generic for Glumetza®)
- Metformin ER Osmotic 500 mg and 1000 mg (generic for Fortamet®)
- Metformin solution (generic for Riomet®)
- Riomet® solution (metformin)

SGLT-2 Inhibitors

Preferred Agents

- Farxiga® (dapagliflozin) – **BRAND ONLY**
- Jardiance® (empagliflozin)
- Synjardy® (empagliflozin/metformin)
- Xigduo® ER (dapagliflozin/metformin ER) – **BRAND ONLY**

Non-Preferred Agents

- Dapagliflozin (generic for Farxiga®)
- Dapagliflozin/metformin ER (generic for Xigduo® ER)
- Inpefa® (sotagliflozin)
- Invokamet® (canagliflozin/metformin)
- Invokamet® XR (canagliflozin/metformin ER)
- Invokana® (canagliflozin)
- Segluromet™ (ertugliflozin/metformin)
- Steglatro™ (ertugliflozin)
- Synjardy® XR (empagliflozin/metformin ER)

Approval Criteria for Preferred SGLT-2 Inhibitors:

- Medicaid pharmacy profile indicates a paid claim in the last 60 days for a preferred SGLT-2 inhibitor; **OR**

- Diagnosis of type 2 diabetes mellitus; **AND**
  - Metformin claim in the last 186 days; **OR**
  - HbA1c ≥ 9 in the last 186 days; **OR**
  - Diagnosis of ASCVD (e.g., CABG, Angina, CHD, CAD, MI, heart failure, CVD, TIA, PAD, aortic atherosclerosis, thoracic or abdominal aortic aneurysm); **OR**
- Diagnosis of heart failure; **OR**
- Diagnosis of CKD

***NOTE:** Non-preferred products will continue to require a prior authorization.

Sulfonylureas

Preferred Agents

- Glimepiride 1 mg, 2 mg, 4 mg (generic for Amaryl®)
- Glimepiride/ pioglitazone (generic for Duetact®)
- Glipizide (generic for Glucotrol®)
- Glipizide ER (generic for Glucotrol XL®)
- Glipizide/metformin (generic for Metaglip®)
- Glyburide (generic for Diabeta®)
- Glyburide micronized (generic for Micronase®, Glynase®)
- Glyburide/metformin (generic for Glucovance®)

Non-Preferred Agents

- Duetact® (glimepiride/metformin)
- Glimepiride 3 mg tablet
- Glucotrol XL® (glipizide)

Thiazolidinediones

Preferred Agents

- Pioglitazone (generic for Actos®)
- Pioglitazone/metformin (generic for ActoPlus Met®)
- Pioglitazone/glimepiride (generic for Duetact®)

Non-Preferred Agents

- ActoPlus Met® (pioglitazone/metformin)
- Actos® (pioglitazone)
- Duetact® (glimepiride/metformin)

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Antiemetic Agents - (HT3 or NK1 Receptor Antagonists)

(Implemented 09/14/2009)
(Updated 08/18/2015)
(Updated 4/1/2025)

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Preferred Agents with Criteria

- Ondansetron HCl 4 mg, 8 mg tablet (generic for Zofran®)
- Ondansetron 4 mg, 8 mg oral-disintegrating tablet (generic for Zofran ODT®)
- Ondansetron 4 mg/2 ml preservative-free vial (generic for Zofran®)
- Ondansetron 40 mg/20 ml vial (generic for Zofran®)

Non-Preferred Agents

- Alkynzeo® capsule (netupitant-palonosetron HCL)
- Aprepitant (generic for Emend®)
- Emend® (aprepitant)
- Granisetron (generic for Kytril®)
- Ondansetron 16 mg oral-disintegrating tablet
- Ondansetron 4 mg/2 ml ampule and syringe (generic for Zofran®)
- Ondansetron 4 mg/5 ml solution (generic for Zofran®)
- Sancuso® patch (granisetron)

Approval Criteria for Preferred Agents with Criteria

- No therapeutic duplication with other 5-HT3 receptor antagonists

Additional Criteria

- Quantity limits apply

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Antifungals - Topical

(Implemented 09/21/2009)
(Effective 4/1/2020)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Topical Antifungal Agents

- Clotrimazole 1% Rx Cream
- Clotrimazole-Betamethasone Rx Cream
- Ketoconazole 2% Rx Shampoo
- Nystatin ointment, cream, powder
- Nystatin/triamcinolone ointment
- Tolnaftate 1% topical cream OTC
- Tolnaftate 1% topical powder OTC
- Tolnaftate 1% topical solution OTC

Non-Preferred Topical Antifungal Agents

- Ciclodan® 0.77% cream, kit (ciclopirox)
- Ciclopirox 0.77% cream, gel, topical suspension (generic for Loprox®)
- Ciclopirox 1% shampoo (generic for Loprox®)
- Clotrimazole 1% Rx solution
- Clotrimazole/betamethasone Rx lotion
- Econazole 1% cream, ~~foam~~
- Ertaczo® 2% cream (sertaconazole)
- Extina® foam (ketoconazole)
- Ketoconazole 2% cream (generic for Nizoral®)
- Ketoconazole 2% foam (generic for Extina®)
- Klayesta® powder (nystatin)
- Loprox® 0.77% cream, topical suspension (ciclopirox)
- Luliconazole 1% cream (generic for Luzu™)
- Luzu™ 1% cream (luliconazole)
- Miconazole 0.25%/zinc oxide 15%/white petrolatum 81.35% ointment (generic for Vusion®)
- Naftifine 1%, 2% cream and 2% gel (generic for Naftin®)
- Nystatin/triamcinolone cream
- Oxiconazole 1% cream, ~~lotion~~ (generic for Oxistat®)
- Oxistat® 1% lotion (oxiconazole)
- Vusion® ointment (miconazole/zinc oxide/white petrolatum)

Non-Preferred Topical Antifungal Agents for Onychomycosis

- Ciclodan® 8% topical nail solution (ciclopirox)

- Ciclopirox 8% topical nail solution (generic for Penlac® Nail Lacquer)
- Jubila® 10% nail solution (efinaconazole)
- Tavaborole 5% topical nail solution (generic for Kerydin®)

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Antihistamines - Oral (Second-Generation)

(Implemented 11//2007)
(Updated 4/1/2018)
(Updated 4/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Preferred Agents

- Cetirizine HCl 1 mg/ml solution, 10 mg swallow tablet (generic for Zyrtec®)
- Loratadine (generic for Claritin®)

Non-Preferred Agents

- Cetirizine 5 mg swallow tablet, 5 mg and 10 mg chewable tablet (generic for Zyrtec®)
- Clarinex® (desloratadine)
- Desloratadine (generic for Clarinex®)
- Fexofenadine 180 mg tablet (generic for Allegra®)
- Levocetirizine (generic for Xyzal®)

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Anti-Hyperuricemics

(Implemented 4/1/18)
(Updated 4/1/2021)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Allopurinol 100 mg, 300 mg tablet (generic for Zyloprim®)
- Colchicine tablet (generic for Colcrys®)
- Probenecid tablet
- Probenecid/colchicine tablet

Non-Preferred Agents

- Allopurinol 200 mg tablet (generic for Zyloprim®)
- Colchicine capsule (generic for Mitigare®)
- Colcrys® tablet (colchicine)
- Febuxostat tablet (generic for Uloric®)
- Gloperba® solution (colchicine)
- Mitigare® capsule (colchicine)
- Uloric® tablet (febuxostat)
- Zyloprim® tablet (allopurinol)

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Anti-inflammatory Agents (NSAIDs)

(Implemented 06/18/2007)
(Updated 08/14/2015)
(*Updated 1/1/2020)*
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Preferred Agents

- Celecoxib capsule (generic for Celebrex®)
- Diclofenac sodium 25 mg, 50 mg, and 75 mg tablet (generic for Voltaren®)
- Diclofenac sodium topical 1% gel (generic for Voltaren®)
- Ibuprofen 100 mg/5 ml suspension (generic for Motrin®)
- Ibuprofen 400 mg, 600 mg, 800 mg tablet (generic for Motrin®)
- Indomethacin 25 mg, 50 mg capsule (generic for Indocin®)
- Meloxicam 7.5 mg, 15 mg tablet (generic for Mobic®)
- Nabumetone tablet (generic for Relafen®)
- Naproxen 250 mg, 375 mg, 500 mg tablet (generic for Naprosyn®)
- Naproxen 375 mg, 500 mg enteric coated tablet (generic for EC-Naprosyn®)
- Naproxen 275 mg, 550 mg tablet (generic for Anaprox®)

Preferred Agent with Criteria

- Ketorolac (generic for Toradol®)

Non-Preferred Agents

- Arthrotec® tablet (diclofenac sodium/misoprostol)
- Celebrex® (celecoxib)
- Daypro® (oxaprozin)
- Diclofenac epolamine 1.3% patch (generic for Flector®)
- Diclofenac potassium tablet (generic for Cataflam®)
- Diclofenac potassium capsule (generic for Zipsor®)
- Diclofenac sodium ER tablet (generic for Voltaren XR®)
- Diclofenac sodium 1.5%, 2% topical solution (generic for Pennsaid®)
- Diclofenac sodium/misoprostol tablet (generic for Arthrotec®)
- Diflunisal tablet (generic for Dolobid®)
- Dolobid® tablet (diflunisal)
- Etodolac (generic for Lodine®)
- Etodolac ER (generic for Lodine XL®)
- Feldene® (piroxicam)
- Fenoprofen capsule, tablet (generic for Nalfon®)
- Fenopron® capsule (fenoprofen calcium)
- Flurbiprofen tablet (generic for Ansaid®)
- Ibuprofen 300 mg tablet (generic for Motrin®)
- Ibuprofen/famotidine tablet (generic for Duexis®)

- Indomethacin 25 mg/5 ml suspension (generic for Indocin®)
- Indomethacin 75 mg SA capsule (generic for Indocin®)
- Indomethacin 50 mg suppository (generic for Indocin®)
- Ketoprofen 200 mg extended-release capsule (generic for Oruvail®)
- Ketoprofen capsule (generic for Orudis®)
- Meclofenamate sodium capsule (generic for Meclomen®)
- Mefenamic acid capsule (generic for Ponstel®)
- Meloxicam capsule (generic for Vivlodex®)
- Nalfon® capsule, tablet (fenoprofen)
- Naprelan CR tablet (naproxen)
- Naproxen sodium 375 mg, 500 mg, 750 mg ER/CR tablet (generic for Naprelan®)
- Naproxen/esomeprazole magnesium tablet (generic for Vimovo®)
- Oxaprozin tablet (generic for Daypro®)
- Pennsaid 2% topical solution (diclofenac sodium)
- Piroxicam capsule (generic for Feldene®)
- Relafen DS® tablet (nabumetone)
- Salsalate tablet (generic for Disalcid®)
- Sulindac tablet (generic for Clinoril®)
- Tolectin® tablet (tolmetin)
- Tolmetin sodium capsule (generic for Tolectin® DS)
- Tolmetin sodium tablet (generic for Tolectin® 600)

Non-Preferred Agents with Criteria

- Diclofenac sodium 3% gel (generic for Solaraze®)
- Naproxen 125mg/ml suspension (generic for Naprosyn® suspension)

Approval Criteria for Non-Preferred Agents with Criteria

- Diclofenac sodium 3% gel (generic for Solaraze®)
  - Diagnosis of Actinic Keratosis in the past two months
- Naproxen 125mg/ml suspension (generic for Naprosyn® suspension)
  - < 7 years of age **OR** NPO (Appendix A) in the past year.

Denial Criteria for Preferred Agent with Criteria

- Ketorolac (generic for Toradol®)
  - History of ketorolac use in the last 60 days, OR
  - NSAID claim in the past 30 days, OR
  - Dose greater than four per day, OR
  - Day supply greater than five, OR
  - Quantity greater than 20, OR
  - Greater than 20 units per 60 days

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Antiparkinson's Agents

(Effective 1/1/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Preferred Agents

- Amantadine capsule (generic for Symmetrel®)
- Amantadine syrup (generic for Symmetrel®)
- Benztropine (generic for Cogentin®)
- Carbidopa/levodopa ER (generic for Sinemet CR®)
- Carbidopa/levodopa (generic for Sinemet®)
- Pramipexole (generic for Mirapex®)
- Ropinirole (generic for Requip®)
- Trihexyphenidyl (generic for Artane®)
- Trihexyphenidyl elixir (generic for Artane®)

Non-Preferred Agents

- Amantadine tablet (generic for Symmetrel®)
- Apokyn® (apomorphine)
- Azilect® (rasagiline)
- Bromocriptine (generic for Parlodel®)
- Carbidopa (generic for Lodosyn®)
- Carbidopa/levodopa ODT (generic for Parcopa®)
- Carbidopa/levodopa/entacapone (generic for Stalevo®)
- Comtan® (entacapone)
- Crexont ER® capsule (carbidopa/levodopa)
- Duopa® suspension (carbidopa/levodopa)
- Entacapone (generic for Comtan®)
- Gocovri® capsule (amantadine)
- Lodosyn® (carbidopa)
- Mirapex ER® (pramipexole ER)
- Neupro® patch (rotigotine)
- Osmolex ER™ tablet (amantadine)
- Parlodel® (bromocriptine)
- Pramipexole ER (generic for Mirapex ER®)
- Rasagiline (generic for Azilect®)
- Ropinirole ER (generic for Requip XL®)
- Rytary® (carbidopa/levodopa ER)
- Selegiline capsule (generic for Eldepryl®)
- Selegiline tablet (generic for Zelapar®)
- Sinemet® (carbidopa/levodopa)
- Stalevo® (carbidopa/levodopa/entacapone)

- Tasmar® (tolcapone)
- Tolcapone (generic for Tasmar®)
- Xadago® (safinamide)
- Zelapar® (selegiline)

Non-Preferred Agents with Criteria

- Inbrija® (levodopa) See Criteria for Inbrija
- Nourianz® (istradefylline) See Criteira for Nourianz
- Ongentys® (opicapone) See Criteria for Ongentys

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Antipsychotics, Injectable Long-acting

(Implemented 01/12/2010)
(Effective 10/1/2020)
(Updated 10/1/2023)
(Updated 1/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for LAI products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents with Criteria

- Abilify Asimtufii® (aripiprazole ER)
- Abilify Maintena® (aripiprazole ER)
- Aristada® (aripiprazole lauroxil ER)
- Aristada® Initio (aripiprazole lauroxil ER)
- Fluphenazine decanoate (generic for Prolixin® decanoate)
- Haloperidol decanoate (generic for Haldol® decanoate)
- Invega Hafyera® (paliperidone palmitate)
- Invega Sustenna® (paliperidone palmitate)
- Invega Trinza® (paliperidone palmitate)
- Perseris ER® kit (risperidone)
- Risperdal Consta® (risperidone microspheres) **BRAND ONLY**
- Uzedy ER® (risperidone)

Non-Preferred Agents with Criteria

- Erzofri® (paliperidone palmitate)
- Risperidone ER microsphere (generic of Risperdal Consta®)
- Rykindo ER® (risperidone)
- Zyprexa Relprevv™ (olanzapine)

General Approval Criteria

Long-Acting injectable antipsychotics will be available through POS edits for the preferred agents based on requirements in the package insert. Non-preferred agents follow the below criteria and require documentation of the medical necessity over preferred options.

- All requests for beneficiaries < 18 years of age will continue to require manual review.
- Each product will require a trial of oral tolerability
- No therapeutic duplication with another long-acting antipsychotic allowed in the past 23 days
- Allowed ≤ 1 oral antipsychotic used concomitantly
- If medication is changed between LAIs, the proper time between doses must have elapsed to prevent overlapping of doses.
- Beneficiary must either meet criterion 1 or criterion 2 for the claim to process without a PA.

Abilify Asimtufii® 720 mg and 960 mg

• Maximum of 1 injection every 2 months

Criterion 1

• Requires at least two weeks of oral aripiprazole in the previous 732 days prior to approval to assess tolerability

• After the first Abilify Asimtufii injection, administer oral aripiprazole for 14 consecutive days **OR** if already stable on another oral antipsychotic, continue treatment with that medication for 14 consecutive days

• If changing from Abilify Maintena® to Abilify Asimtufii®, no oral doses are required. Dose can be given at next scheduled Abilify Maintena® dosing interval.

Criterion 2

• Abilify Asimtufii® claim in the last 93 days or Abilify Maintena® in the last 45 days

Abilify Maintena® 300 mg and 400 mg

• Monthly dosing for 300 mg and 400 mg

Criterion 1

• Requires at least two weeks of oral aripiprazole in the previous 732 days prior to approval to assess tolerability

• After the first Abilify Maintena® injection, administer oral aripiprazole for 14 consecutive days **OR** if already stable on another oral antipsychotic, continue treatment with that medication for 14 consecutive days

Criterion 2

• Abilify Maintena® claim in history in last 45 days or Abilify Asimtufii® in the last 93 days

Aristada® 441 mg, 662 mg, 882 mg and 1064 mg

• Monthly dosing for 441 mg and 662 mg; maximum duration of 6 weeks for 882 mg; maximum of every 8 weeks for 1064 mg.

Criterion 1

• Requires at least two weeks of oral aripiprazole in the previous 732 days prior to approval to assess tolerability

• Initiation of treatment after tolerability has been established requires one of the following:

- Administer Aristada Initio® 675 mg injection and one dose of oral aripiprazole 30 mg with first Aristada® injection **OR**
- Administer 21 consecutive days of oral aripiprazole in conjunction with first Aristada® injection

Criterion 2

• Aristada® 441 mg and 662 mg claim in history in last 45 days; Aristada® 882 mg and 1064 mg claim in history in the last 93 days.

Aristada Initio® 675 mg

• Requires at least two weeks of oral aripiprazole in the previous 732 days prior to approval to assess tolerability

• Administer with one dose of oral aripiprazole 30 mg with first dose of Aristada® injection

• Limit 1 per year

Fluphenazine decanoate 25 mg/mL
• Dosing individualized but many dose every 3 weeks

Criterion 1
• Requires previous history of a short-acting form of fluphenazine in the previous 732 days to assess tolerability

Criterion 2
• Fluphenazine decanoate claim in the last 186 days (5 mL vials)

Haloperidol decanoate 50 mg and 100 mg
• Monthly dosing

Criterion 1
• Requires previous history of a short-acting form of haloperidol in the previous 732 days to assess tolerability

Criterion 2
• Haloperidol decanoate claim in the last 45 days

Invega Hafyera® 1092 mg and 1560 mg
• Maximum dosing every 6 months

Criterion 1
• Requires previous history of Invega Sustenna® for at least 120 days in the last 186 days **OR** Invega Trinza® for at least 90 days in the last 124 days

Criterion 2
• Invega Hafyera® claim in the last 217 days

Invega Sustenna® 39 mg, 78 mg, 117 mg, 156 mg and 234 mg
• Monthly dosing

Criterion 1
• Prior to approval must have taken oral paliperidone, oral risperidone, or injectable risperidone in the previous 732 days to assess tolerability

Criterion 2
• Invega Sustenna® claim in the last 45 days, Invega Hafyera® in the last 217 days, or Invega Trinza® in the last 124 days

Invega Trinza® 273 mg, 410 mg, 546 mg, and 819 mg
• Maximum dosing every 3 months

Criterion 1
• Request requires adequate treatment of Invega Sustenna® for at least 120 out of 186 days

Criterion 2

• Invega Trinza® claim in the last 124 days, Invega Hafyera® in the last 217 days, or Invega Sustenna® in the last 45 days

Perseris® 90 mg and 120 mg

• Monthly dosing

Criterion 1

• Requires previous history of oral risperidone in the previous 732 days to assess tolerability

Criterion 2

• Perseris® claim in the last 45 days, or Risperdal Consta® in the last 45 days, or Uzedy™ 50 mg, 75 mg, and 125 mg claim in the last 45 days; Uzedy™ 100 mg, 150 mg, 200 mg and 250 mg claim in the last 93 days

Risperdal Consta® 12.5 mg, 25 mg, 37.5 mg, and 50 mg

• Maximum of 2 doses per month

Criterion 1

• Requires previous history of oral risperidone in the previous 732 days to assess tolerability

• Treatment requires concomitant oral risperidone or other antipsychotic medication for 3 weeks

Criterion 2

• Risperdal Consta® claim in the last 45 days, or Perseris® in the last 45 days, or Uzedy™ 50 mg, 75 mg, and 125 mg claim in the last 45 days; Uzedy™ 100 mg, 150 mg, 200 mg and 250 mg claim in the last 93 days

Uzedy™ ER 50 mg, 75 mg, 100 mg, 125 mg, 150 mg, 200 mg, and 250 mg

• 50 mg, 75 mg, 100 mg, and 125 mg may be filled monthly; 150 mg, 200 mg and 250 mg may be filled every 2 months

Criterion 1

• Requires previous history of oral risperidone in the previous 732 days to assess tolerability

Criterion 2

• Uzedy™ 50 mg, 75 mg, and 125 mg claim in the last 45 days; Uzedy™ 100 mg, 150 mg, 200 mg and 250 mg claim in the last 93 days, or Perseris® in the last 45 days, or Risperdal Consta® in the last 45 days

Zyprexa Relprevv® 210 mg, 300 mg, and 405 mg

• 150 mg, 210 mg and 300 mg may have 2 doses per month; 405 mg requires once monthly dosing

• Requires the medical necessity over preferred options

Criterion 1

• Requires previous history of oral olanzapine in the previous 732 days to assess tolerability

Criterion 2

• Zyprexa Relprevv® claim in the last 45 days

Denial Criteria

- Therapeutic duplication with another long acting antipsychotic in the past 23 days

Additional Criteria

- Quantity limits apply

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Antipsychotics, Oral (ALL AGES)

(Implemented 10/1/2019)
(Updated 7/1/2022)
(Updated 1/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the state pharmacy unit at 1-800-424-5851.

First Generation Oral Antipsychotic Agents - Preferred

- Chlorpromazine tablet
- Fluphenazine tablet
- Haloperidol lactate concentrate solution**
- Haloperidol tablet
- Loxapine succinate capsule
- Perphenazine tablet
- Thioridazine tablet

Second Generation Oral Antipsychotic Agents - Preferred

- Aripiprazole tablet (generic for Abilify®)
- Clozapine tablet (generic for Clozaril®)
- Lurasidone tablet (generic for Latuda®)
- Olanzapine ODT** (generic for Zyprexa Zydis®)
- Olanzapine tablet (generic for Zyprexa®)
- Olanzapine/fluoxetine capsule (generic for Symbyax®)***
- Paliperidone tablet (generic for Invega®)
- Quetiapine tablet (generic for Seroquel®)
- Risperidone ODT**(generic for Risperdal®)
- Risperidone solution** (generic for Risperdal®)
- Risperidone tablet (generic for Risperdal®)
- Ziprasidone capsule (generic for Geodon®)

** ODT and Solutions are Preferred ONLY for Ages < 7 y/o or patients with a diagnosis of NPO in history.
***Please see Second Generation Antidepressant criteria.

Preferred Agents with Criteria

- Vraylar® capsule (cariprazine)

Vraylar® has the following point-of-sale (POS) edits:

- Beneficiary must have a billed diagnosis of one of the FDA approved indications:
  - Treatment of schizophrenia in adults
  - Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults

(continued on next page)

  - Treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults
  - Adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults
- Beneficiary with schizophrenia or bipolar disorder must have at least one antipsychotic in their Medicaid profile in the last 2 years
- Beneficiary with major depressive disorder must have at least two different antidepressants in their Medicaid profile in the last 2 years

First Generation Oral Antipsychotic Agents – Non-Preferred

- Chlorpromazine oral concentrate
- Fluphenazine elixir/solution
- Molindone tablet
- Perphenazine/amitriptyline tablet
- Pimozide tablet
- Thiothixene capsule
- Trifluoperazine tablet

Second Generation Oral Antipsychotic Agents – Non-Preferred

- Abilify Mycite® tablet (aripiprazole)
- Abilify® tablet/discmelt/solution (aripiprazole)
- Aripiprazole ODT and Solution (generic for Abilify®)
- Asenapine SL tablet (generic for Saphris®)
- Caplyta® capsule (lumateperone)
- Clozapine ODT tablet (generic for Fazaclo®)
- Clozaril® tablet (clozapine)
- Cobenfy™ capsule (xanomeline/trospium) **APPROVAL CRITERIA ON NEXT PAGE**
- Fanapt® tablet (iloperidone)
- Geodon® capsule (ziprasidone)
- Invega® tablet (paliperidone)
- Latuda® tablet (lurasidone)
- Lybalvi® tablet (olanzapine/samidorphan)
- Nuplazid® tablet/capsule (pimavanserin)
- Opipza® film (aripiprazole)
- Quetiapine EXTENDED-RELEASE tablet (generic for Seroquel® XR)
- Rexulti® tablet (brexpiprazole)
- Risperdal tablet/solution/ODT (risperidone)
- Saphris® SL tablet (asenapine)
- Secuado® transdermal patch (asenapine)
- Seroquel IR/XR tablet (quetiapine)
- Symbyax® capsule (olanzapine/fluoxetine)
- Versacloz® suspension (clozapine)
- Zyprexa® tablet/Zydis (olanzapine)

From the General Medication Coverage Policy July 2023

general-medication-coverage-policy-july-2023-pdf

Before moving to a non-preferred oral antipsychotic medication, the beneficiary must have a documentation of trial and failure of at least **TWO** (2) different chemical entities **unless otherwise noted.**

Cobenfy® Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with schizophrenia **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have a trial and failure of 2 other antipsychotics with differing mechanisms of action
- Beneficiary should not be approved or continue the medication if one or more of the following is met:
  - Has urinary retention
  - Has moderate or severe hepatic impairment
  - Has gastric retention
  - Has untreated narrow-angle glaucoma
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried and results
  - Medical necessity over preferred antipsychotics

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Antipsychotics, Oral – Criteria for Adults

(Implemented 10/1/2019)
(Updated 1/23/2020)
(Updated 2/23/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria for Adults ≥ 18 y/o

- New Starts for **preferred** medications that are **below** the maximum therapeutic dose (*SEE DOSING CHARTS*) will process at point-of sale (POS).
- A beneficiary may continue a drug or dose that is outside of the established criteria (e.g., continue a non-preferred status drug, continue dose higher than the maximum therapeutic dose), or continue therapy with > 2 antipsychotic agents if the beneficiary is "Stable and Compliant" on all antipsychotic drug therapy(-ies).
  - For the purposes of these criteria "Stable and Compliant" is defined as the patient has received at least 2 claims in the previous 120 days.
- Preferred Oral liquids and orally disintegrating tablets (ODTs): Patients ≥ 18 y/o must have an NPO diagnosis code (Appendix A) in the past year.

Denial Criteria for Adults ≥ 18 y/o

- New starts to non-preferred medications will deny.
- New starts above the maximum therapeutic dose of a medication will deny. (*SEE DOSING CHARTS ON NEXT PAGE*)
  - Therapeutic Duplication
  - TD with three or more oral antipsychotic agents will deny for new startsTD for two or more oral antipsychotics and one long-acting injectable antipsychotic agents
- Failure to meet approval criteria

Antipsychotics, Oral – Adult Dosing Charts

ATYPICAL ANTIPSYCHOTIC MAXIMUM THERAPEUTIC DOSING AND QUANTITIES FOR ADULTS (≥ 18 YEARS OLD)			
Aripiprazole (e.g. Abilify®) Tablet Medicaid Max Daily Dose = 30mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Aripiprazole (e.g. Abilify®) 2 mg Tablet	8 mg	4	124
Aripiprazole (e.g. Abilify®) 5 mg Tablet	5 mg	1	31
Aripiprazole (e.g. Abilify®) 10 mg Tablet & Discmelt	10 mg	1	31
Aripiprazole (e.g. Abilify®) 15 mg Tablet & Discmelt	15 mg	1	31
Aripiprazole (e.g. Abilify®) 20 mg Tablet	20 mg	1	31
Aripiprazole (e.g. Abilify®) 30 mg Tablet	30 mg	1	31
Aripiprazole (e.g.Ablify®) 1mg/ml	25mg	25ml	750ml

Asenapine (e.g. Saphris®) SL Tablet Medicaid Max Daily Dose = 20mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Asenapine (e.g. Saphris®) 2.5mg SL Tablet	5 mg	2	62
Asenapine (e.g. Saphris®) 5mg SL Tablet	10 mg	2	62
Asenapine (e.g. Saphris®) 10mg SL Tablet	20 mg	2	62

Brexpiprazole (e.g. Rexulti ®) Tablet Medicaid Max Daily dose = 4mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Brexpiprazole (e.g. Rexulti ®) 0.25mg Tablet	0.25 mg	1	31
Brexpiprazole (e.g. Rexulti ®) 0.5mg Tablet	0.5 mg	1	31
Brexpiprazole (e.g. Rexulti ®) 1mg Tablet	1 mg	1	31
Brexpiprazole (e.g. Rexulti ®) 2mg Tablet	2 mg	1	31
Brexpiprazole (e.g. Rexulti ®) 3mg Tablet	3 mg	1	31
Brexpiprazole (e.g. Rexulti ®) 4mg Tablet	4 mg	1	31

Cariprazine (e.g. Vraylar ®) Capsule Medicaid Max Daily Dose = 6mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Cariprazine (e.g. Vraylar ®) 1.5mg Capsule	1.5 mg	1	31
Cariprazine (e.g. Vraylar ®) 3mg Capsule	3 mg	1	31
Cariprazine (e.g. Vraylar ®) 4.5mg Capsule	4.5 mg	1	31
Cariprazine (e.g. Vraylar ®) 6mg Capsule	6 mg	1	31

Clozapine (e.g. Clozaril ®) Tablet Medicaid Max Daily Dose = 900mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Clozapine (e.g. Clozaril ®) 25mg Tablet	75 mg	3	93
Clozapine (e.g. Clozaril ®) 50mg Tablet	50 mg	1	31
Clozapine (e.g. Clozaril ®) 100mg Tablet	900 mg	9	279
Clozapine (e.g. Clozaril ®) 200mg Tablet	800 mg	4	124

Iloperidone (e.g. Fanapt ®) Tablet Medicaid Max Daily Dose = 24mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Iloperidone (e.g. Fanapt ®) 1mg Tablet	2 mg	2	62
Iloperidone (e.g. Fanapt ®) 2mg Tablet	4 mg	2	62
Iloperidone (e.g. Fanapt ®) 4mg Tablet	8 mg	2	62
Iloperidone (e.g. Fanapt ®) 6mg Tablet	12 mg	2	62
Iloperidone (e.g. Fanapt ®) 8mg Tablet	16 mg	2	62
Iloperidone (e.g. Fanapt ®) 10mg Tablet	20 mg	2	62
Iloperidone (e.g. Fanapt ®) 12mg Tablet	24 mg	2	62

Lurasidone (e.g. Latuda ®) Tablet Medicaid Max Daily Dose = 80mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Lurasidone (e.g. Latuda ®) 20mg Tablet	20 mg	1	31
Lurasidone (e.g. Latuda ®) 40mg Tablet	40 mg	1	31
Lurasidone (e.g. Latuda ®) 60mg Tablet	60 mg	1	31
Lurasidone (e.g. Latuda ®) 80mg Tablet	80 mg	2	62
Lurasidone (e.g. Latuda ®) 120mg Tablet	120mg	1	31

Olanzapine (e.g. Zyprexa ®) Tablet Medicaid Max Daily Dose = 20mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Olanzapine (e.g. Zyprexa ®) 2.5mg Tablet	2.5 mg	1	31
Olanzapine (e.g. Zyprexa ®) 5mg Tablet & ODT	5 mg	1	31
Olanzapine (e.g. Zyprexa ®) 7.5mg Tablet	7.5 mg	1	31
Olanzapine (e.g. Zyprexa ®) 10mg Tablet & ODT	10 mg	1	31
Olanzapine (e.g. Zyprexa ®) 15mg Tablet & ODT	15 mg	1	31
Olanzapine (e.g. Zyprexa ®) 20mgTablet & ODT	20 mg	1	31

Paliperidone ER (e.g. Invega ®) Tablet Medicaid Max Daily dose = 12mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Paliperidone ER (e.g. Invega ®) 1.5mg Tablet	1.5 mg	1	31
Paliperidone ER (e.g. Invega ®) 3mg Tablet	3 mg	1	31
Paliperidone ER (e.g. Invega ®) 6mg Tablet	12 mg	2	62
Paliperidone ER (e.g. Invega ®) 9mg Tablet	9 mg	1	31

Quetiapine (e.g. Seroquel®) Tablet Medicaid Max Daily Dose = 800mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Quetiapine (e.g. Seroquel®) 25mg Tablet	75 mg	3	93
Quetiapine (e.g. Seroquel®) 50mg Tablet	150 mg	3	93
Quetiapine (e.g. Seroquel®) 100mg Tablet	200 mg	2	62
Quetiapine (e.g. Seroquel®) 150mg Tablet	750 mg	5	155
Quetiapine (e.g. Seroquel®) 200mg Tablet	400 mg	2	62
Quetiapine (e.g. Seroquel®) 300mg Tablet	600 mg	2	62
Quetiapine (e.g. Seroquel®) 400mg Tablet	800 mg	2	62

Quetiapine ER (e.g. Seroquel XR®) Tablet Medicaid Max Daily Dose = 800mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Quetiapine ER (e.g. Seroquel XR®) 50mg Tablet	100 mg	2	62
Quetiapine ER (e.g. Seroquel XR®) 150mg Tablet	150 mg	1	31
Quetiapine ER (e.g. Seroquel XR®) 200mg Tablet	200 mg	1	31
Quetiapine ER (e.g. Seroquel XR®) 300mg Tablet	600 mg	2	62
Quetiapine ER (e.g. Seroquel XR®) 400mg Tablet	800 mg	2	62

Risperidone (e.g. Risperdal®) Tablet Medicaid Max Daily Dose = 16mg

DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Risperidone (e.g. Risperdal®) 0.25mg Tablet	0.5 mg	2	62
Risperidone (e.g. Risperdal®) 0.5mg Tablet & ODT	1 mg	2	62
Risperidone (e.g. Risperdal®) 1mg Tablet & ODT	2 mg	2	62
Risperidone (e.g. Risperdal®) 2mg Tablet & ODT	4 mg	2	62
Risperidone (e.g. Risperdal®) 3mg Tablet & ODT	9 mg	3	93
Risperidone (e.g. Risperdal®) 4mg Tablet & ODT	16 mg	4	124
Risperidone (e.g. Risperdal®) 1mg/ml Oral Solution (30ml)	4 mg	4 ml	120

Ziprasidone (e.g. Geodon®) Capsule Medicaid Max Daily Dose = 160mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Ziprasidone (e.g. Geodon®) 20mg Capsule	40 mg	2	62
Ziprasidone (e.g. Geodon®) 40mg Capsule	80 mg	2	62
Ziprasidone (e.g. Geodon®) 60mg Capsule	120 mg	2	62
Ziprasidone (e.g. Geodon®) 80mg Capsule	160 mg	2	62

TYPICAL ANTIPSYCHOTIC MAXIMUM THERAPEUTIC DOSING AND QUANTITIES FOR ADULTS

Chlorpromazine (e.g. Thorazine®) Tablet Medicaid Max Daily Dose = 800mg

DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Chlorpromazine (e.g. Thorazine®) 10mg Tablet	40 mg	4	124
Chlorpromazine (e.g. Thorazine®) 25mg Tablet	75 mg	3	93
Chlorpromazine (e.g. Thorazine®) 50mg Tablet	200 mg	4	124
Chlorpromazine (e.g. Thorazine®) 100mg Tablet	700 mg	7	217
Chlorpromazine (e.g. Thorazine®) 200mg Tablet	800 mg	4	124

Fluphenazine (e.g. Prolixin®) Tablet Medicaid Max Daily Dose = 40mg

DRUG NAME	MEDICAID MAX DAILY DOSE BY STRENGTH	MEDICAID MAX DAILY QUANTITY EDIT	MEDICAID MONTHLY MAX CUMULATIVE QTY
Fluphenazine (e.g. Prolixin®) 1mg Tablet	4 mg	4	124
Fluphenazine (e.g. Prolixin®) 2.5mg Tablet	10 mg	4	124
Fluphenazine (e.g. Prolixin®) 5mg Tablet	20 mg	4	124
Fluphenazine (e.g. Prolixin®) 10mg Tablet	40 mg	4	124
Fluphenazine (e.g. Prolixin®) Elixir	40mg	80ml	2365mL
Fluphenazine (e.g. Prolixin®) Concentrate	40mg	8ml	240ml

Haloperidol (e.g. Haldol®) Tablet Medicaid Max Daily Dose = 40mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Haloperidol (e.g. Haldol®) 0.5mg Tablet	1.5mg	3	93
Haloperidol (e.g. Haldol®) 1mg Tablet	3 mg	3	93
Haloperidol (e.g. Haldol®) 2mg Tablet	6 mg	3	93
Haloperidol (e.g. Haldol®) 5mg Tablet	15 mg	3	93
Haloperidol (e.g. Haldol®) 10mg Tablet	30 mg	3	93
Haloperidol (e.g. Haldol®) 20mg Tablet	40 mg	2	62

Loxapine (e.g. Loxitane®) Capsule Medicaid Max Daily Dose = 250mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAXIMUM CUMULATIVE QTY**
Loxapine (e.g. Loxitane®) 5mg Capsule	20 mg	4	124
Loxapine (e.g. Loxitane®) 10mg Capsule	60 mg	6	186
Loxapine (e.g. Loxitane®) 25mg Capsule	100 mg	4	124
Loxapine (e.g. Loxitane®) 50mg Capsule	250 mg	5	155

Perphenazine (e.g. Trilafon®) Tablet Medicaid Max Daily Dose = 64mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Perphenazine (e.g. Trilafon®) 2mg Tablet	8 mg	4	124
Perphenazine (e.g. Trilafon®) 4mg Tablet	16 mg	4	124
Perphenazine (e.g. Trilafon®) 8mg Tablet	32 mg	4	124
Perphenazine (e.g. Trilafon®) 16mg Tablet	64 mg	4	124
Perphenazine-Amitriptyline (e.g. Etrafon®) Tablet Medicaid Max Daily Dose = 16MG/100MG			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Perphenazine-Amitriptyline (e.g. Etrafon®) 2mg/10mg Tablet	8mg/40mg	4	124
Perphenazine-Amitriptyline (e.g. Etrafon®) 2mg/25mg Tablet	8mg/100mg	4	124
Perphenazine-Amitriptyline (e.g. Etrafon®) 4mg/10mg Tablet	16mg/40mg	4	124
Perphenazine-Amitriptyline (e.g. Etrafon®) 4mg/25mg Tablet	16mg/100mg	4	124
Perphenazine-Amitriptyline (e.g. Etrafon®) 4mg/50mg Tablet	8mg/100mg	2	62

Pimozide (e.g. Orap) Tablet Medicaid Max Daily Dose = 10mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Pimozide (e.g. Orap) 1mg Tablet	3 mg	3	93
Pimozide (e.g. Orap) 2mg Tablet	10 mg	5	155

Thioridazine (e.g. Mellaril®) Tablet Medicaid Max Daily Dose = 800mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Thioridazine (e.g. Mellaril®) 10mg Tablet	40 mg	4	124
Thioridazine (e.g. Mellaril®) 25mg Tablet	100 mg	4	124
Thioridazine (e.g. Mellaril®) 50mg Tablet	200 mg	4	124
Thioridazine (e.g. Mellaril®) 100mg Tablet	800 mg	8	248

Thiothixene (e.g. Navane®) Capsule Medicaid Max Daily Dose = 60mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Thiothixene (e.g. Navane®) 1mg Capsule	3mg	3	93
Thiothixene (e.g. Navane®) 2mg Capsule	8mg	4	124
Thiothixene (e.g. Navane®) 5mg Capsule	15mg	3	93
Thiothixene (e.g. Navane®) 10mg Capsule	60mg	6	186

Trifluoperazine (e.g. Stelazine®) Tablet Medicaid Max Daily Dose = 40mg			
DRUG NAME	**MEDICAID MAX DAILY DOSE BY STRENGTH**	**MEDICAID MAX DAILY QUANTITY EDIT**	**MEDICAID MONTHLY MAX CUMULATIVE QTY**
Trifluoperazine (e.g. Stelazine®) 1mg Tablet	3 mg	3	93
Trifluoperazine (e.g. Stelazine®) 2mg Tablet	8 mg	4	124
Trifluoperazine (e.g. Stelazine®) 5mg Tablet	15 mg	3	93
Trifluoperazine (e.g. Stelazine®) 10mg Tablet	40 mg	4	124

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Antipsychotics, Oral – Criteria for Children

****PREFERRED AND NONPREFERRED AGENTS APPLY TO PATIENTS < 18 Y/O – PLEASE REFER TO PDL DRUGS Antipsychotics, Oral – Preferred Agents for ALL Ages**

(Implemented 07/11/2009)
(Updated 08/14/2015)
(Updated 10/1/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1- 800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria for Children (< 18 y/o)

- At least one paid claim for an oral antipsychotic in the past 45 days, and monitoring for both glucose and lipid screening in the past 9 months (Table 2.3)
- Typical and Atypical antipsychotics:
  - All new start patients or patients changed to a different chemical entity will require a signed informed consent and a copy of a baseline metabolic lab test data. (eff.11/8/11)
    - Medication Informed Consent Document
  - One therapeutic duplication for a change in therapy between two antipsychotics (oral or injectable) with > 25% remaining on the last fill on different dates of service allowed per 93 days.
  - PA required through manual review for beneficiaries < 10 years of age.
- Oral liquids and orally disintegrating tablets (ODTs):
  - Patient must have an NPO code (Appendix A) in the past year **OR**
  - < 7 years of age AND meet criteria for atypical antipsychotics
- Seroquel XR continuation criteria requires ≥ 2 claims on the beneficiary's profile of the same GSN in the past 120 days. Immediate-release quetiapine (Seroquel) is covered via existing criteria.
- Requested dose must meet the dosing requirements by age on the dosing table. (Table 2)
- Requested maximum daily dose must be approved for age range (Table 2.2)

Denial Criteria for Children (< 18 y/o)

- Claims with a therapeutic duplication on the same date of service
- Requests for combination antipsychotic products for patients < 18 years of age
- Failure to meet approval criteria

Table 2 – Approved doses per age range

Drug	Strength	FDA dosing	<6* y/o	6-9 y/o	10-12y/o	13-17y/o
Abilify®	2 mg	QD	2 tabs	2 tabs	2 tabs	2 tabs
Abilify®	5 mg	QD	1 tab	1 tab	1 tab	1 tab
Abilify®	10 mg	QD		1 tab	1 tab	1 tab
Abilify®	15 mg	QD		1 tab	1 tab	1 tab
Abilify®	20 mg	QD			1 tab	1 tab
Abilify®	30 mg	QD				1 tab
Abilify Discmelt®	10 mg	QD		1 tab	2 tabs	2 tabs
Abilify Discmelt®	15 mg	QD		1 tab	1 tab	2 tabs
Abilify Solution®	1 mg/ml	QD	5 mls	15 mls	20 mls	30 mls
Chlorpromazine	10 mg	BID-QID	4 tabs	4 tabs	4 tabs	4 tabs
Chlorpromazine	25 mg	BID-QID	4 tabs	4 tabs	4 tabs	4 tabs
Chlorpromazine	50 mg	BID-QID	2 tabs	4 tabs	4 tabs	4 tabs
Chlorpromazine	100 mg	BID-QID	1 tab	2 tabs	4 tabs	4 tabs
Chlorpromazine	200 mg	BID-QID		1 tab	2 tabs	3 tabs
Fanapt®	1 mg	BID	2 tabs	2 tabs	2 tabs	2 tabs
Fanapt®	2 mg	BID	1 tab	2 tabs	2 tabs	2 tabs
Fanapt®	4 mg	BID		1 tab	2 tabs	2 tabs
Fanapt®	6 mg	BID			1 tab	2 tabs
Fanapt®	8 mg	BID			1 tab	2 tabs
Fanapt®	10 mg	BID				1 tab
Fanapt®	12 mg	BID				1 tab
Fluphenazine	1 mg	BID-QID	2 tabs	4 tabs	4 tabs	4 tabs
Fluphenazine	2.5 mg	BID-QID		2 tabs	4 tabs	4 tabs
Fluphenazine	5 mg	BID-QID		1 tab	2 tabs	4 tabs
Fluphenazine	10 mg	BID-QID			1 tab	2 tabs
Fluphenazine Elixir	2.5mg/5ml	BID-QID	4 mls	10 mls	20 mls	40 mls
Fluphenazine Soln	5 mg/ml	BID-QID	0.4 ml	1 ml	2 mls	4 mls
Geodon®	20 mg	BID	2 caps	2 caps	2 caps	2 caps
Geodon®	40 mg	BID		1 cap	2 caps	2 caps
Geodon®	60 mg	BID		1 cap		2 caps
Geodon®	80 mg	BID				2 caps

Drug	Strength	FDA dosing	<6* y/o	6-9 y/o	10-12y/o	13-17y/o
Haloperidol	0.5 mg	BID-TID	3 tabs	3 tabs	3 tabs	3 tabs
Haloperidol	1 mg	BID-TID	2 tabs	3 tabs	3 tabs	3 tabs
Haloperidol	2 mg	BID-TID	1 tab	2 tabs	3 tabs	3 tabs
Haloperidol	5 mg	BID-TID		1 tab	2 tabs	3 tabs
Haloperidol	10 mg	BID-TID			1 tab	2 tabs
Haloperidol	20 mg	BID-TID				1 tab
Haloperidol Soln	2 mg/ml	BID-TID	1 ml	2.5 ml	5 ml	10 ml
Invega®	1.5 mg	QD	1 tab	1 tab	1 tab	1 tab
Invega®	3 mg	QD	1 tab	1 tab	1 tab	1 tab
Invega®	6 mg	QD			1 tab	1 tab
Invega®	9 mg	QD				1 tab
Latuda®	20 mg	QD	1 tab	1 tab	1 tab	1 tab
Latuda®	40 mg	QD		1 tab	1 tab	1 tab
Latuda®	60 mg	QD				1 tab
Latuda®	80 mg	QD				1 tab
Latuda®	120 mg	QD				
Loxapine	5 mg	BID	2 caps	2 caps	2 caps	2 caps
Loxapine	10 mg	BID	1 cap	2 caps	2 caps	2 caps
Loxapine	25 mg	BID				2 caps
Loxapine	50 mg	BID				1 cap
Orap®	1 mg	QD-BID	1 tab	1 tab	1 tab	1 tab
Orap®	2 mg	QD-BID		1 tab	2 tabs	5 tabs
Perphenazine	2 mg	BID-QID	2 tabs	3 tabs	4 tabs	4 tabs
Perphenazine	4 mg	BID-QID	1 tab	1 tab	2 tabs	4 tabs
Perphenazine	8 mg	BID-QID			1 tab	2 tabs
Perphenazine	16 mg	BID-QID				1 tab
Risperdal®	0.25 mg	BID	2 tabs	2 tabs	2 tabs	2 tabs
Risperdal®	0.5 mg	BID	2 tabs	2 tabs	2 tabs	2 tabs
Risperdal®	1 mg	BID	2 tabs	2 tabs	2 tabs	2 tabs
Risperdal®	2 mg	BID	1 tab	2 tabs	2 tabs	2 tabs
Risperdal®	3 mg	BID			2 tabs	2 tabs
Risperdal®	4 mg	BID		1 tab	1 tab	2 tabs
Risperdal® M Tab	0.25 mg	BID	2 tabs	2 tabs	2 tabs	2 tabs
Risperdal® M Tab	0.5 mg	BID	2 tabs	2 tabs	2 tabs	2 tabs
Risperdal® M Tab	1 mg	BID	2 tabs	2 tabs	2 tabs	2 tabs
Risperdal® M Tab	2 mg	BID	1 tab	2 tabs	2 tabs	2 tabs
Risperdal® M Tab	3 mg	BID			2 tabs	2 tabs
Risperdal® M Tab	4 mg	BID		1 tab	1 tab	2 tabs
Risperdal® Soln	1 mg/ml	BID	2 mls	4 mls	6 mls	8 mls
Saphris® SL	5 mg	BID	1 tab	1 tab	2 tabs	2 tabs
Saphris® SL	10 mg	BID			1 tab	2 tabs
Saphris® SL	2.5 mg	BID	2 tabs	2 tabs	2 tabs	2 tabs
Seroquel®	25 mg	TID	3 tabs	3 tabs	3 tabs	3 tabs
Seroquel®	50 mg	TID	3 tabs	3 tabs	3 tabs	3 tabs

Drug	Strength	FDA dosing	<6* y/o	6-9 y/o	10-12y/o	13-17y/o
Seroquel®	100 mg	TID	1 tab	3 tabs	3 tabs	3 tabs
Seroquel®	200 mg	TID		1 tab	3 tabs	3 tabs
Seroquel®	300 mg	TID		1 tab	2 tabs	2 tabs
Seroquel®	400 mg	TID			1 tab	2 tabs
Seroquel® XR	50 mg	QD	2 tabs	2 tabs	2 tabs	2 tabs
Seroquel® XR	150 mg	QD	1 tab	1 tab	1 tab	1 tab
Seroquel® XR	200 mg	QD		1 tab	1 tab	1 tab
Seroquel® XR	300 mg	QD		1 tab	2 tabs	2 tabs
Seroquel® XR	400 mg	QD			1 tab	2 tabs
Thioridazine	10 mg	BID-TID	3 tabs	3 tabs	3 tabs	3 tabs
Thioridazine	25 mg	BID-TID	2 tabs	3 tabs	3 tabs	3 tabs
Thioridazine	50 mg	BID-TID	1 tab	2 tabs	3 tabs	3 tabs
Thioridazine	100 mg	BID-TID		1 tab	1 tab	2 tabs
Thiothixene	1 mg	TID	3 caps	3 caps	3 caps	3 caps
Thiothixene	2 mg	TID	3 caps	3 caps	3 caps	3 caps
Thiothixene	5 mg	TID	1 cap	1 cap	1 cap	3 caps
Thiothixene	10 mg	TID				1 cap
Trifluoperazine	1 mg	QD-BID	1 tab	2 tabs	2 tabs	2 tabs
Trifluoperazine	2 mg	QD-BID		1 tab	2 tabs	2 tabs
Trifluoperazine	5 mg	QD-BID			1 tab	2 tabs
Trifluoperazine	10 mg	QD-BID				1 tab
Zyprexa®	2.5mg	QD	1 tab	1 tab	1 tab	1 tab
Zyprexa®	5mg	QD	1 tab	1 tab	1 tab	1 tab
Zyprexa®	7.5mg	QD		1 tab	1 tab	1 tab
Zyprexa®	10mg	QD		1 tab	1 tab	1 tab
Zyprexa®	15mg	QD			1 tab	1 tab
Zyprexa®	20mg	QD				1 tab
Zyprexa® Zydis®	5mg	QD	1 tab	1 tab	1 tab	1 tab
Zyprexa® Zydis®	10mg	QD		1 tab	1 tab	1 tab
Zyprexa® Zydis®	15mg	QD			1 tab	1 tab
Zyprexa® Zydis®	20mg	QD				1 tab
*Prior authorization required through manual review for beneficiaries < 10 years of age.						

Table 2.2 – Max daily doses for age categories < 18 years of age

Drug	<6* y/o	6*-9 y/o	10-12 y/o	13-17 y/o
Abilify®	5 mg daily	15 mg daily	20 mg daily	30 mg daily
Geodon®	40 mg daily	60 mg daily	80 mg daily	160 mg daily
Invega®	3 mg daily	3 mg daily	6 mg daily	9 mg daily
Risperdal®	2 mg daily	4 mg daily	6 mg daily	8 mg daily
Seroquel®	150 mg daily	300 mg daily	600 mg daily	800 mg daily
Zyprexa®	5 mg daily	10 mg daily	15 mg daily	20 mg daily
*Prior authorization required through manual review for beneficiaries < 10 years of age.				

Table 2.3 – CPT codes for glucose and lipid monitoring

Glucose codes: Criteria require one of the following CPT codes that contain glucose monitoring in the previous 9 months from claim date of in-process claim:

- 83036 (HbA1c); **OR**
- 80050 (General Health Panel); **OR**
- 80069 (Renal Function Panel); **OR**
- 80047 (Basic Metabolic Panel); **OR**
- 80048 (Basic Metabolic Panel); **OR**
- 80053 (Comprehensive metabolic panel); **OR**
- 82962 (Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use); **OR**
- 82948 (Glucose; blood, reagent strip); **OR**
- 82947 (Glucose; quantitative, blood)

AND, criteria require one of the following lipid panel tests or all of the individual lipid test monitoring codes in previous 9 months from claim date of the in-process claim:

Lipid codes:

- 80061 (Lipid panel); **OR**
- 83701 (High resolution fractionation and quantitation of lipoproteins panel); **OR**
- 82465 (Cholesterol, serum or whole blood, total), **AND** 83718 (HDL cholesterol), **AND** 84478 (Triglycerides), **AND** 83721 (LDL Cholesterol)
- 83700 (Lipoprotein blood electrophoretic); **OR**
- 83704 (Lipoprotein blood quantitation particles); **OR**
- 83715 (Assay of blood lipoproteins); **OR**
- 83716 (Assay of blood lipoproteins); **OR**
- 83719 (Assay of blood lipoproteins); **OR**
- 83722 (Lipoprotein, direct measurement small dense LDI cholesterol)

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Apomorphine 98 mg/20 ml injection (Onapgo™)

(Implemented 4/16/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with advanced Parkinson's disease and experiencing continued motor fluctuations despite compliance on carbidopa/levodopa **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must attest that patient/caregivers have been counseled on potential adverse effects that require monitoring that could require a dose reduction or discontinuation (i.e., hemolytic anemia, reduced resting blood pressure, increase in falls, psychotic-like behavior, etc.)
- Beneficiary must continue to have motor fluctuations with a minimum of 3 hours of "Off" time per day.
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Requires the concomitant use of 5HT3 antagonists (e.g., ondansetron, granisetron, dolasetron, palonosetron)
  - Develops significant daytime sleepiness that interferes with normal daily function (e.g., conversations, eating, driving)
  - Drinks alcohol
  - Has severe renal or severe hepatic impairment
  - Pregnant
- Prescriber must submit the following:
  - Current chart notes
  - Current symptoms of Parkinson's Disease
  - Negative pregnancy test for female patient of reproductive potential
  - Average number of "Off" hours per day
  - Medical necessity over increasing the dose on long and short acting oral carbidopa/levodopa products

Renewal Requirements

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary demonstrates a decrease in "Off" hours compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Attestation that patient continues to be monitored for potential adverse reactions (i.e.,

excessive daytime sleepiness, increase in falls, hemolytic anemia, psychotic-like behavior, etc.)

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Aprocitentan 12.5 mg tablet (Tryvio™)

(Implemented 7/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary is diagnosed with hypertension that is not adequately controlled on at least 3 other antihypertensive drugs **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must continue standard of care antihypertensive medications in combination with TRYVIO
- Prescriber and dispensing pharmacy must be enrolled in the TRYVIO REMS program
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Pregnancy
  - Baseline ALT/AST 3X ULN or moderate to severe hepatic impairment
  - NYHA STAGE III-IV heart failure, unstable cardiac function, or NTproBNP ≥ 500 pg/mL
  - Noncompliant on standard of care pharmacologic treatment at maximally tolerated doses with 3 antihypertensive medications at the same time. Therapies vary by patient, but they typically include ACE inhibitor/ARB, calcium channel blocker, and thiazide diuretic. Optional medications may include beta blockers, alpha blockers, spironolactone, hydralazine, or minoxidil.
- Prescriber must submit the following:
  - Current chart notes
  - Current and previous pharmacologic therapies with pharmacy printouts if new to Medicaid
  - Current blood pressure and blood pressure history if available along with blood pressure cuff size
  - Current labs including CBC (for hemoglobin), LFTs, pregnancy test if female of reproductive potential
  - Current weight to monitor for fluctuations due to potential edema

Renewal Requirements

- Beneficiary must remain compliant on therapy as ordered by the prescriber (defined as 75% utilization)
- Beneficiary should demonstrate improvement in blood pressure compared to baseline
- Prescriber should submit the following:
  - Current chart notes
  - Current blood pressure
  - Current labs including CBC and LFTs
  - Current weight

Quantity Edits

- #31 tablets/31 days

Top of the document

Arimoclomal citrate 47 mg, 62 mg, 93 mg, 124 mg capsule (Miplyffa™)

(Implemented 01/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of Niemann-Pick disease type C (NPC) with variants in the NPC1 or NPC2 genes with neurological manifestations (e.g., gait problems, ataxia, cognitive deterioration, or vertical gaze palsy) and prescribed concomitant miglustat **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPD
- Beneficiary with eGFR ≥ 15 to < 50 mL/minute should decrease MIPLYFFA dose frequency
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Weighs < 8 kg
  - Pregnant
  - Dose requested does not match weight-based dosing found in the package insert
  - Prescribed AQNEURSA (levacetylleucine) to be used concomitantly
  - eGFR< 15 ml/minute
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried with response
  - Molecular genetic testing results confirming biallelic pathogenic variants in the NPC1 or NPC2 genes
  - Current labs including eGFR
  - Current weight and dose requested
  - Neurological symptoms for this specific patient
  - Negative pregnancy test results if applicable
  - Attestation that female beneficiary of reproductive potential has been counseled on the importance of effective contraception
  - Letter of medical necessity for the use over AQNEURSA (levacetylleucine) for this specific patient

Renewal Requirements

- Beneficiary remains compliant with therapy (defined as 75% utilization)
- Beneficiary demonstrates a positive response with a decrease or slowed progression in neurological symptoms compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Response to treatment with updated description of symptoms
  - Attestation that female beneficiary of reproductive potential has been counseled on the importance of continuing effective contraception and is not currently pregnant

Quantity Edits

- #90/30 days

Top of the document

Asfotase Alfa injection (Strensiq®)

(Implemented 07/13/2016)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) confirmed by both of the following:
  - Clinical manifestations consistent with hypophosphatasia (e.g., radiographic evidence, rachitic chest deformity, vitamin B6-dependent seizures, or failure to thrive)
  - Both biochemical and molecular genetic testing confirm diagnosis
- Prescriber must submit the following:
  - Current chart notes with the following parameters as baseline:
    - Current height and weight
    - Current respiratory status (e.g., PFTs, vent settings)
    - Baseline detailed radiology report to compare for efficacy on PA renewal (e.g., x-rays, or other scans)
    - Baseline ophthalmology exam
    - Baseline renal ultrasound
    - Attestation that caregiver has been trained in administration
  - Outlined treatment plan
    - Document how response to treatment will be determined when compared to baseline parameters (specifically growth and radiographical findings) as improvement or lack of improvement could determine if the medication will be continued or if a dose change is needed.
    - Timeline for reassessment of response to treatment compared to baseline
- Since dosing is weight-based, initial prior authorizations may require a more frequent review. Once the patient's weight becomes stable, longer prior authorization durations may be approved.

Renewal Requirements

- Prescriber must submit the following:
  - Current chart notes with updated height/weight to confirm weight-based dose is correct
  - Updated respiratory status, new radiology reports and ophthalmology reports if available (updated information expected at least every 6 months)
  - Requested dose
- Beneficiary must demonstrate a positive response in growth or radiographical findings to continue treatment beyond 12 months

Top of the document

Immunomodulators, Atopic Dermatitis (topicals and biologics)

(Implemented 10/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents

- Tacrolimus ointment (generic for Protopic®)

Preferred Agents with Criteria (*specific manual review criteria)

- Adbry®* syringe and autoinjector (tralokinumab-ldrm)
- Dupixent®* syringe and pen (dupilumab)

Non-Preferred Agents with Criteria (*specific manual review criteria)

Note: Non-preferred agents require documentation of medical necessity over preferred agents in addition to other stated criteria.

- Cibinqo®* tablet (abrocitinib)
- Elidel® cream (pimecrolimus)
- Ebglyss™* (lebrikizumab-lbkz)
- Eucrisa® ointment (crisaborole)
- Nemluvio®* injection (nemolizumab-ilto)
- Opzelura®* cream (ruxolitinib)
- Pimecrolimus cream (generic for Elidel®)
- Protopic® ointment (tacrolimus)
- Rinvoq®* tablet (upadacitinib)
- Vtama®* cream (tapinarof)
- Zoryve®* 0.15% cream (roflumilast)

Approval Criteria for Atopic Dermatitis (Adbry®, Cibinqo®, Dupixent®, Ebglyss™, Nemluvio®, and Rinvoq®)

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis
- Beneficiary has a documented diagnosis of moderate to severe atopic dermatitis with at least **ONE** of the following (baseline at time of biologic request):
  - Baseline impacted body surface area (BSA) ≥ 10%
  - Baseline Eczema Area and Severity Index (EASI) total score of ≥ 16
  - Baseline weekly averaged peak pruritis Numeric Rating Scale (NRS) ≥ 7
  - Baseline Investigator's Global Assessment (IGA) score ≥ 3
  - Baseline Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in the official Compendia
- Beneficiary has no therapeutic duplication with monoclonal antibodies or cytokine & CAM antagonists

- If the request is for a non-preferred medication, the beneficiary must have tried and failed the preferred biologic(s) with this indication before non-preferred options can be approved unless there is a patient specific contraindication to the preferred option(s).
- Beneficiary must have a trial and failure of topical therapy and at a minimum must include:
  - At least **ONE** topical corticosteroid entity over a minimum of 60 days use with topical corticosteroids being "high" potency (Class-2) **OR** superpotent (Class-1) for adults **OR** medium potency for children (unless contraindicated); **AND**
  - At least **ONE** trial of a topical calcineurin inhibitor (TCI) over a minimum of 30 days (i.e., pimecrolimus or tacrolimus)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous therapies with trial length of each medication
  - BSA prior to topical/systemic therapies and current impacted BSA
  - Baseline EASI, NRS, IGA and/or SCORAD and updated score with previous treatment
  - Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
  - Letter of medical necessity over other treatment options for atopic dermatitis

Continuation Criteria for Atopic Dermatitis

- Beneficiary is compliant on this medication
- Beneficiary must show continued positive treatment response with each PA request for continued prior approval with at least one of the following compared to baseline:
  - Decrease in severity scores; **OR**
  - Decrease in BSA impacted; **OR**
  - Decrease in need for systemic or topical rescue treatment
- Prescriber must submit:
  - Current chart notes
  - Current BSA and EASI, NRS, IGA or SCORAD (compared to baseline severity score)

Approval Criteria for Atopic Dermatitis (Opzelura®)

- Beneficiary must be ≥ 12 years of age
- Beneficiary should have mild or moderate atopic dermatitis defined by an Investigator's Global Assessment (IGA) score of 2-3 out of a 0-4 scale **OR** a diagnosis consistent with
- FDA indications
- Beneficiary must have uncontrolled mild to moderate atopic dermatitis with recent claims for topical corticosteroids and topical calcineurin inhibitors (TCI)
  - Trials of at least two different topical corticosteroid entities over a minimum of 60 days use with at least one topical corticosteroid being "high" potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis
  - At least one trial of a TCI over a minimum of 30 days (i.e., tacrolimus, pimecrolimus)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous therapies
  - Current IGA score
  - Current baseline Itch Numerical Rating Scale (Itch NRS)
- If approved, PA will be approved for 2 months

Denial Criteria

- Beneficiary does not meet approval criteria **OR** have a diagnosis supported on the

official Compendia
- Beneficiary has a history of skin cancer
- Beneficiary has severe atopic dermatitis
- Beneficiary's atopic dermatitis affects greater than 20% of BSA
- Prescriber requests continuance beyond 8 weeks without improvement
- Beneficiary has been approved for biologics, JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine

Quantity Edits

- 2 tubes (120 gm)/30 days

Approval Criteria for Atopic Dermatitis (Vtama®)

- Beneficiary must be ≥ 2 years of age
- Beneficiary should have moderate to severe atopic dermatitis defined by an Investigator's Global Assessment (IGA) score of 3-4 out of a 0-4 scale
- Beneficiary must have uncontrolled moderate to severe atopic dermatitis with recent claims for topical corticosteroids and topical calcineurin inhibitors (TCI)
  - Trials of at least **TWO** different topical corticosteroid entities over a minimum of 60 days use with at least **ONE** topical corticosteroid being "high" potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis
  - At least one trial of a TCI over a minimum of 30 days (i.e., tacrolimus, pimecrolimus)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies
  - Current IGA score
  - Current baseline Itch Numerical Rating Scale (Itch NRS)
- If approved, PA will be approved for 2 months

Approval Criteria for Atopic Dermatitis (Zoryve® cream)

- Beneficiary must be ≥ 6 years of age
- Beneficiary should have mild or moderate atopic dermatitis defined by an Investigator's Global Assessment (IGA) score of 2-3 out of a 0-4 scale
- Beneficiary must have uncontrolled mild to moderate atopic dermatitis with recent claims for topical corticosteroids and topical calcineurin inhibitors (TCI)
  - Trials of at least **TWO** different topical corticosteroid entities over a minimum of 60 days use with at least **ONE** topical corticosteroid being "high" potency (Class-2) or super potent (Class-1) depending on location of atopic dermatitis
  - At least one trial of a TCI over a minimum of 30 days (i.e., tacrolimus, pimecrolimus)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies
  - Current IGA score
  - Current baseline Itch Numerical Rating Scale (Itch NRS)
- If approved, PA will be approved for 2 months

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Atovaquone (Mepron®)

(Implemented 09/21/2009)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that do not require prior authorizaiton

- Generic MAC'd sulfamethoxazole-trimethoprim tablets are available without a prior authorization.

Drugs that require manual review for prior authorization

- Mepron suspension

Approval Criteria (Continuation Criteria)

- One or more claims in the previous 60 days for Mepron® Suspension.

Look back in pharmacy claims history 60 days for Mepron® Suspension

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Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder (ADD/ADHD) Agents for Children (< 19 Years of Age)

(Implemented 07/21/2009)
(Updated 11/27/2017, effective 1/1/18) (Updated 2/9/2021)
(Updated 10/19/2021)
(Updated 10/1/2023)
(Updated 7/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL drugs may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Adderall XR® capsule
- Amphetamine/dextroamphetamine salts ER capsule (generic for Adderall XR®)
- Amphetamine/dextroamphetamine salts tablet (generic for Adderall IR®)
- Atomoxetine capsule (generic for Strattera®)
- Clonidine IR tablet (generic for Catapres®)
- Clonidine ER tablet (generic for Kapvay ER®)
- Concerta®
- Daytrana® patch **(BRAND ONLY)**
- Dexmethylphenidate ER capsule (generic for Focalin XR®)
- Dexmethylphenidate IR tablet (generic for Focalin®)
- Dextroamphetamine 5 mg and 10 mg tablet (generic for Zenzedi®)
- Focalin® tablet
- Focalin XR® capsule
- Guanfacine IR tablet (generic for Tenex®)
- Guanfacine ER tablet (generic for Intuniv ER®)
- Methylphenidate tablet (generic for Methylin®, Ritalin IR®)
- Methylphenidate ER tablet (generic for Concerta®)
- Vyvanse® chew tablet **(BRAND ONLY)**
- Vyvanse® capsule **(BRAND ONLY)**

Non-Preferred Agents

- Adhansia XR® capsule
- Adzenys ER® suspension
- Adzenys XR®-ODT
- Amphetamine suspension (generic for Adzenys ER®)
- Amphetamine/dextroamphetamine ER capsule (generic for Mydayis ER®)
- Aptensio XR® capsule
- Azstarys® capsule
- Clonidine ER tablet (generic for Nexiclon XR®)
- Cotempla XR®-ODT
- Desoxyn® tablet
- Dexedrine® spansule

- Dextroamphetamine capsule (generic for Dexedrine® spansule)
- Dextroamphetamine solution (generic for Procentra®)
- Dextroamphetamine 2.5 mg tablet (generic for Zenzedi)
- Dyanavel XR® suspension
- Dyanavel XR® tablet
- Evekeo® tablet
- Evekeo® ODT
- Intuniv ER® tablet
- Jornay PM® capsule
- Kapvay ER® tablet
- Lisdexamfetamine capsule (generic for Vyvanse®)
- Visdexamfetamine chewable tablet (generic for Vyvanse®)
- Methamphetamine tablet (generic for Desoxyn®)
- Methylin® solution
- Methylphenidate chewable tablet (generic for Methylin® chew tablet)
- Methylphenidate CD/ER/LA capsule (generic for Metadate CD®, Ritalin LA®, Aptensio XR®)
- Methylphenidate ER tablet (generic for Relexxii ER®)
- Methylphenidate ER tablet (generic for Metadate ER®, Ritalin SR®)
- Methylphenidate patch
- Methylphenidate solution (generic for Methylin®)
- Mydayis ER® capsule
- Onyda XR® suspension
- Procentra® solution
- Qelbree® capsule
- Quillichew ER® chewable tablet
- Quillivant XR® suspension
- Ritalin IR® tablet
- Ritalin LA® capsule
- Strattera® capsule
- Xelstrym® patch
- Zenzedi® tablet

Approval Criteria for Preferred Agents with Criteria for Children < 19 years

- Beneficiaries < 6 years of age require a prior authorization request for all CII stimulants and non-stimulant medications.

All preferred **extended-release** CII stimulants

- ≤ One therapeutic duplication between long-acting CII stimulants with 75% of the last fill per 93 days **AND**
- If an incoming long-acting CII stimulant claim overlaps with a short-acting CII stimulant that was filled at a dose of >/= to 2 units per day, the long-acting product will require prior authorization

All preferred **immediate-release** CII stimulants:

- ≤ One therapeutic duplication between short-acting CII stimulants with 75% of the last fill per 93 days **AND**
- If an incoming short-acting CII stimulant claim overlaps with a long-acting CII stimulant, the short-acting product will only be approved for a dose of one unit per day

Additional Criteria

- Quantity limits apply

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Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder (ADD/ADHD) Agents for Adults (19 Years of Age or greater)

(Implemented 01/18/2011)
(Updated 11/27/2017)
(Updated 1/1/2021)
(Updated 2/9/2021)
(Updated 10/19/2021)
(Updated 10/19/2022)
(Updated 10/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL drugs may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents: Manually Reviewed agents for adults ≥ 19 years of age

- Adderall XR® capsule
- Amphetamine/dextroamphetamine salts ER capsule (generic for Adderall XR®)
- Amphetamine/dextroamphetamine salts tablet (generic for Adderall IR®)
- Atomoxetine capsule (generic for Strattera®)
- Clonidine IR tablet (generic for Catapres®)
- Clonidine ER tablet (generic for Kapvay ER®)
- Concerta®
- Daytrana® patch **(BRAND ONLY)**
- Dexmethylphenidate ER capsule (generic for Focalin XR®)
- Dexmethylphenidate IR tablet (generic for Focalin®)
- Dextroamphetamine 5 mg and 10 mg tablet (generic for Zenzedi®)
- Focalin® tablet
- Focalin XR® capsule
- Guanfacine IR tablet (generic for Tenex®)
- Guanfacine ER tablet (generic for Intuniv ER®)
- Methylphenidate tablet (generic for Methylin®, Ritalin IR®)
- Methylphenidate ER tablet (generic for Concerta®)
- Vyvanse® chew tablet **(BRAND ONLY)**
- Vyvanse® capsule **(BRAND ONLY)**

Non-Preferred Agents

- Adhansia XR® capsule
- Adzenys ER® suspension
- Adzenys XR®-ODT
- Amphetamine suspension (generic for Adzenys ER®)
- Amphetamine/dextroamphetamine ER capsule (generic for Mydayis ER®)
- Aptensio XR® capsule
- Azstarys® capsule

- Clonidine ER tablet (generic for Nexiclon XR®)
- Cotempla XR®-ODT
- Desoxyn® tablet
- Dexedrine® spansule
- Dextroamphetamine capsule (generic for Dexedrine® spansule)
- Dextroamphetamine solution (generic for Procentra®)
- Dextroamphetamine 2.5 mg tablet (generic for Zenzedi)
- Dyanavel XR® suspension
- Dyanavel XR® tablet
- Evekeo® tablet
- Evekeo® ODT
- Intuniv ER® tablet
- Jornay PM® capsule
- Kapvay ER® tablet
- Lisdexamfetamine capsule (generic for Vyvanse®)
- Visdexamfetamine chewable tablet (generic for Vyvanse®)
- Methamphetamine tablet (generic for Desoxyn®)
- Methylin® solution
- Methylphenidate chewable tablet (generic for Methylin® chew tablet)
- Methylphenidate CD/ER/LA capsule (generic for Metadate CD®, Ritalin LA®, Aptensio XR®)
- Methylphenidate ER tablet (generic for Relexxii ER®)
- Methylphenidate ER tablet (generic for Metadate ER®, Ritalin SR®)
- Methylphenidate patch
- Methylphenidate solution (generic for Methylin®)
- Mydayis ER® capsule
- Onyda XR® suspension
- Procentra® solution
- Qelbree® capsule
- Quillichew ER® chewable tablet
- Quillivant XR® suspension
- Ritalin IR® tablet
- Ritalin LA® capsule
- Strattera® capsule
- Xelstrym® patch
- Zenzedi® tablet

Approval Criteria for CII Stimulants and Non-Stimulants for Adults

- Completed CII stimulant form is required for beneficiaries ≥19 years of age

Forms & Documents - Arkansas (primetherapeutics.com)

- Currently, atomoxetine does not require a prior authorization
- Beneficiary with ADHD
  - Beneficiary must have signs/symptoms in 2 or more settings using a standardized rating scale with at least one of the following:
    - Currently attends school (high school, college, or vocational)
    - Currently employed
    - Currently searching for employment (approval for maximum of 3 months without documentation of employment)
  - Beneficiary must have multiple symptoms of inattention and/or hyperactivity/impulsivity

from the DSM-5 documented on the form for initial approval
    - Beneficiary with co-morbid conditions of bipolar disorder or schizophrenia must be controlled and adherent with appropriate medication therapy, or prescriber must provide adequate documentation as to why the co-morbid condition is no longer being treated
    - Prescriber must submit the following:
        - Completed CII stimulant form
        - Current chart notes
        - Documentation needed to support the diagnosis of ADHD
- Beneficiary without ADHD may be approved for one of the following: (each request is reviewed on a case-by-case basis for medical necessity)
    - Narcolepsy with sleep study results confirming diagnosis
    - Traumatic Brain Injury (TBI)
    - Fatigue due to underlying illness (i.e., cancer or multiple sclerosis)
    - Binge Eating Disorder (BED)—Vyvanse® only

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Auranofin capsule (Ridaura®)

(Implemented 09/18/2013)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with rheumatoid arthritis and had an insufficient response to, or intolerance of, an adequate trial of full doses of one or more nonsteroidal anti-inflammatory drugs (NSAIDs).
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Inadequate response after six month trial
  - Prescriber requests a dose > 9 mg daily
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried with response
  - Letter of medical necessity over NSAIDs

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response after 6 months of usage
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy

Quantity Edits

- #60/ 30 days

Top of the document

Avacopan (Tavneos®)

(Implemented 1/19/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥18 years of age; **AND**
- Beneficiary must have a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis with granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) OR a diagnosis consistent with FDA indications; **AND**
- Beneficiary had previous therapy with an immunosuppressant (i.e., rituximab or cyclophosphamide) and corticosteroids based on treatment guidelines; **AND**
- Beneficiary must be concomitantly prescribed standard therapy; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of previous therapy; **AND**
  - Current labs including positive ANCA test results, anti-PR3 and anti-MPO if available, baseline LFTs, and Hepatitis B serology (HBsAg and anti-HBc); **AND**
  - If available, chest x-ray or CT scan results used for diagnosis confirmation; **AND**
  - If available, biopsy reports used for diagnosis confirmation

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported on the official
- Compendia; **OR**
- Beneficiary has severe hepatic impairment OR AST/ALT >5X ULN OR AST/ALT >3X ULN with bilirubin >2X ULN; **OR**
- Beneficiary should avoid the use of CYP3A4 inhibitors (e.g., ketoconazole, cyclosporine, erythromycin) if possible. If concomitant use is required, TAVNEOS dose should be decreased to 30 mg once daily; **OR**
- Beneficiary develops reactivation of HBV while on TAVNEOS; **OR**
- Beneficiary has an active, serious infection including localized infections; **OR**
- Beneficiary is pregnant or breastfeeding

Quantity Edits

- #180 capsules/ 30 days

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Azithromycin 1 gram powder packet

(Implemented 4/12/2011)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with a sexually transmitted disease caused by *C. trachomatis* **OR** used for prevention of *Mycobacterium avium* complex (MAC) disease **OR** used for treatment of *Mycobacterium avium* complex (MAC) disease
- Dose requested must be consistent with diagnosis
- Prescriber must submit the following:
  - Current chart notes
  - Dosage requested
  - Medical necessity over other azithromycin products available without a PA

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Baloxavir marboxil (Xofluza®)

(Implemented 1/16/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must either have a positive influenza test and have been symptomatic for no more than 48 hours **OR** have been exposed to an individual positive for influenza to be used as post-exposure prophylaxis
- Prescriber must submit the following:
  - Current weight at time of PA request
  - Medical necessity for XOFLUZA over TAMIFLU (oseltamivir) that does not require a PA

Quantity Limits

- Quantity limited to one dose, PA for NDC entered at time of approval
  - XOFLUZA 20 mg tablet, packaged as 2 tablets for single dose of 40 mg
  - XOFLUZA 40 mg tablet, packaged as 2 tablets for single dose of 80 mg

Top of the document

Bedaquiline fumarate tablet (Sirturo®)

(Implemented 12/10/2013)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with pulmonary tuberculosis (TB) due to *Mycobacterium tuberculosis* which is resistant to at least rifampin and isoniazid.
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Latent infection due to *Mycobacterium tuberculosis* (*M. tuberculosis*)
  - Drug-sensitive pulmonary TB
  - Extra-pulmonary TB
  - Infections caused by non-tuberculous mycobacteria
- Prescribing must be coordinated with the Arkansas Department of Health
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried and failed

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Belimumab (Benlysta®)

(Implemented 06/21/2011)
(Updated 4/21/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of either active, autoantibody-positive systemic lupus erythematosus (SLE) who are receiving standard therapy **OR** active lupus nephritis (LN) who are receiving standard therapy **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary with SLE must have:
  - Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of ≥ 8; **AND**
  - Positive autoantibody test (anti-nuclear antibody (ANA) and/or anti-double-stranded DNA (anti-dsDNA))
- Beneficiary with LN must have:
  - Clinical diagnosis of SLE; **AND**
  - Biopsy confirmed active lupus nephritis
- Beneficiary must take concomitant standard therapy which could include corticosteroids (e.g., prednisone), antimalarials (e.g., hydroxychloroquine), NSAIDs, and immunosuppressive (e.g., azathioprine, methotrexate, mycophenolate)
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Progressive multifocal leukoencephalopathy (PML)
  - SELENA-SLEDAI score of < 8 and does not have a positive autoantibody test
  - Prescribed biologic therapies, anti-tumor necrosis factor therapy, interleukin-1 receptor antagonist, IVIG, or plasmapheresis in the previous 3 months; **OR**
  - Beneficiary has severe active CNS lupus
  - Pregnant
  - Not taking concomitant standard therapy
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC with differential, urine protein to creatinine (UPCR) ratio for LN beneficiary, serum potassium levels, and baseline estimated glomerular filtration rate (eGFR) for LN beneficiary. eGFR must be assessed every two weeks for the first month, and every four weeks thereafter
  - Current blood pressure

- Medical necessity over supported immunosuppressive therapy alone for SLE patients (i.e., mycophenolate mofetil or azathioprine).

Renewal Requirements

- Beneficiary must be a responder with a decrease in corticosteroids usage/dosage **AND/OR** improved SELENA-SLEDAI score (for SLE) **AND/OR** improvement in UPCR or eGFR (for LN)
- Beneficiary is compliant on therapy (defined as 75% utilization)
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including eGFR and UPCR
  - Current blood pressure

Quantity Edits

- 4 syringes/ 28 days

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Benign Prostatic Hypertrophy (BPH) Drugs

(Implemented 01/12/2012)
(Updated to PDL on 10/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for these products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Alfuzosin ER tablet (generic for Uroxatral®)
- Doxazosin tablet (generic for Cardura®)
- Dutasteride capsule (generic for Avodart®)
- Finasteride tablet (generic for Proscar®)**
- Tamsulosin capsule (generic for Flomax®)
- Terazosin tablet (generic for Hytrin®)

Non-Preferred Agents

- Avodart® capsule (dutasteride)
- Cardura® tablet (doxazosin)
- Cardura® XL tablet (doxazosin)
- Cialis® tablet (tadalafil)‡
- Dutasteride/tamsulosin capsule (generic for Jalyn®)
- Flomax® capsule (tamsulosin)
- Jalyn® capsule (dutasteride/tamsulosin)
- Proscar® tablet (finasteride)
- Rapaflo® capsule (silodosin)
- Silodosin capsule (generic for Rapaflo®)
- Tadalafil tablet (generic for Cialis®)‡
- Tezruly™ oral solution (terazosin)

**Diagnosis of Benign Prostatic Hypertrophy in the past 3 years

‡Denial for diagnosis of erectile dysfunction

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Benznidazole 12.5 mg, 100 mg tablet

(Updated 9/19/2020)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be a pediatric patient 2 to 12 years of age diagnosed with Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi* **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia. Any off-label requests will be reviewed on a case-by-case basis.
- Must be prescribed by, or in consultation with, an infectious disease specialist
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Dose or duration of therapy that exceeds FDA approved dose and duration
  - Taken disulfiram within the last two weeks
  - Diagnosed with Cockayne Syndrome
  - Pregnant
- Prescriber must submit the following:
  - Current chart notes
  - Prescriber must submit current weight. Weight-based dose will be calculated and monthly quantity entered at the time the PA is approved
  - Attestation that females of reproductive potential are using effective contraception
- Length of PA shall not exceed 60 days

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Benzodiazepine Oral Solid Dosage Forms

(Implementation Date 12/07/2010)
(Update 03/08/2016)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Unless otherwise stated, no therapeutic duplication is allowed between two benzodiazepines with > 10% of the days' supply remaining on the last fill;
- Unless otherwise stated, the quantity edit of the single highest strength of a benzodiazepine tablet or capsule has been reduced to a maximum daily quantity of 2 units per day or a cumulative quantity of 62 units for a 31-day supply;
- Unless otherwise stated, all other strengths of tablet or capsule forms of benzodiazepines have been reduced to a maximum daily quantity edit of 3 units per day or a cumulative quantity of 93 units for a 31-day supply;
- Temazepam 7.5mg capsule approval criteria:
  - Long Term Care Beneficiaries
  - Beneficiaries who are 65 years of age or older

No PA required for requests for Temazepam 7.5mg Capsule for the Beneficiaries listed above

- Alprazolam XR [Xanax XR] additional approval criteria:
  - ≥ 18 years of age, AND
  - >/= 90 days of Alprazolam XR therapy in the past 120 days
- Alprazolam oral-disintegrating tablet [Niravam]
  - ≥ 18 years of age, AND
  - One of the following:
    - Long Term Care
    - NPO (Appendix A) within past 365 days
- An incoming claim for any benzodiazepine medication will trigger a search of the beneficiary's Medicaid medical diagnoses history for diagnosis of poisoning or overdose the previous 12 months.
- If a *diagnosis* for poisoning (overdose) for opioids, narcotics, barbiturates, benzodiazepines, or "unspecified drug or substance" is found in the Medicaid medical history in the previous 12 months, an incoming claim for an opioid pain medication or an incoming claim for a benzodiazepine medication will deny at point of sale.
- Patients who have a diagnosis of malignant cancer in the past 12months:
  - Are exempt from the diagnosis check for a poisoning (overdose) of opioids, narcotics, barbiturates, benzodiazepines, or unspecified drug or substance.

Additional Criteria

- Quantity limits apply

See chart below for summary of maximum daily quantity edits of solid oral dosage forms of benzodiazepines:

Generic Name (Brand name reference only)	Strength	Maximum Daily Quantity Edit (& Maximum Cumulative Quantity edit per 31-days' supply)
Alprazolam (Xanax) tablet & ODT	0.25 mg, 0.5 mg, 1 mg	3 units per day, (93)
Alprazolam (Xanax) tablet & ODT	2 mg	2 units per day, (62)
Chlordiazepoxide (Librium) Capsule	5 mg, 10 mg,	3 units per day, (93)
Chlordiazepoxide (Librium) Capsule	25 mg	2 units per day, (62)
Clonazepam (Klonopin) Tablet	0.125 mg, 0.25 mg, 0.5 mg, 1 mg	3 units per day, (93)
Clonazepam (Klonopin) Tablet	2 mg	2 units per day, (62)
Clonazepam ODT	0.125 mg, 0.25 mg, 0.5 mg, 1 mg	3 units per day, (93)
Clonazepam ODT	2 mg	2 units per day, (62)
Clorazepate (Tranxene) Tablet	3.75 mg, 7.5 mg,	3 units per day, (93)
Clorazepate (Tranxene) Tablet	15 mg	2 units per day, (62)
Diazepam (Valium) Tablet	2 mg, 5 mg	3 units per day, (93)
Diazepam (Valium) Tablet	10 mg	2 units per day, (62)
Lorazepam (Ativan) Tablet	0.5 mg, 1 mg	3 units per day, (93)
Generic Name (Brand name reference only)	**Strength**	**Maximum Daily Quantity Edit (& Maximum Cumulative Quantity edit per 31-days' supply)**
Lorazepam (Ativan) Tablet	2 mg	2 units per day, (62)
Oxazepam (Serax) Capsule	10 mg, 15 mg	3 units per day, (93)
Oxazepam (Serax) Capsule	30 mg	2 units per day, (62)
Clobazam (Onfi) Tablet	10 mg, 20 mg	2 units per day, (62)
Alprazolam (Xanax) ER and XR Tablet	0.5 mg, 1 mg, 2 mg, 3 mg	1 unit per day, (31)
Flurazepam (Dalmane) Capsule	15 mg, 30 mg	1 unit per day (31)
Temazepam (Restoril) Capsule	7.5 mg, 15 mg 30 mg 22.5 mg	1 unit per day (31)
Triazolam (Halcion) Tablet	0.125 mg, 0.25 mg	1 unit per day (31)
Estazolam (Prosom) Tablet	1 mg, 2 mg	1 unit per day (31)

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Benzodiazepine Oral Liquid Dosage Forms

(Implementation Date 12/07/2010)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for these products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- <7 years of age, OR
- NPO (Appendix A) within the past 365 days

Additional Criteria

- Quantity limits apply

Exemption Criteria

- Midazolam 2 mg/ml Syrup
  - Claims for 30 ml or less will pay at point-of-sale for any age.

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Beremagene geperpavec gel (Vyjuvek™)

(Implemented 1/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have one or more chronic or recurrent open wounds with all of the following:
  - Adequate granulation tissue
  - Excellent vascularization
  - No evidence of active wound infection
  - No evidence or history of squamous cell carcinoma
- Prescriber must be a dermatologist or wound care specialist with expertise in DEB
- VYJUVEK gel must be prepared by a pharmacy and delivered directly to the provider for application in the clinic or home setting by a healthcare professional, and it should be used within 8 hours if left unrefrigerated. If immediate use is not possible, Vyjuvek gel can be refrigerated for up to 48 hours.
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation reporting the presence of the COL7A1 gene mutation
  - Plan for acquiring the medication and timeframe for application (application no more than 8 hours after prepared by the pharmacy if left unrefrigerated; administration syringes can be stored for up to 48 hours in the refrigerator)
    - Provide the name of specialty pharmacy/distributor
    - Provide expected delivery date
    - Provide date of Vyjuvek™ application
    - Attestation that medication will be delivered directly to prescriber's clinic or home health professional and not available for patient delivery
  - Baseline description of wound(s)
- Initial PA will be for a maximum of 6 months

Renewal Requirements

- Prescriber must submit the following:
  - Current chart notes
  - Response to therapy with description of wound(s)

  - Medical necessity for continued use
- Treated wounds will be evaluated at 6 months for a positive clinical response with request for PA continuation reviewed on a case-by-case basis. Positive response may include:
  - Decrease in wound size
  - Increase in granulation tissue
  - Complete wound closure

Quantity Edits

- 1 kit per week

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Berotralstat (Orladeyo®)

(Implementation Date 4/21/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥12 years of age; **AND**
- Beneficiary must have a laboratory diagnosis of Type 1 or Type 2 hereditary angioedema **OR**
  a diagnosis consistent with FDA indications; **AND**
- Beneficiary must have ≥ 1 severe or life-threatening laryngeal attack per month or ≥ 4 moderate attacks causing extremity, facial or abdominal swelling despite treatment with medications for acute attacks; **AND**
- Provider (allergist/immunologist/hematologist) must submit the following:
  - Current chart notes with documentation of previous therapies tried with disease history and description of typical angioedema attack; **AND**
  - Proposed treatment plan for both acute attacks and prophylaxis treatment; **AND**
  - Documentation of attack frequency, comorbidities, and access to emergency care for the previous 12 months on the initial request; **AND**
  - Documentation of expected angioedema triggers (Trigger avoidance is crucial); **AND**
  - IF beneficiary has tried and had an insufficient response or contraindication to BOTH of the following classes of medication, provide that documentation; **AND**
  - 17α-alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
  - Antifibrinolytic agents (e.g. ε-aminocaproic acid, tranexamic acid)
  - Provide the following labs:
    - Complement C1 esterase inhibitor level; **AND**
    - Complement C4 level; **AND**
    - Functional C1 inhibitor activity; **AND**
  - Initial PA maximum 3-month trial if approved

Denial Criteria

- Beneficiary does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Prescriber intends for beneficiary to use for the treatment of acute attacks of HAE; **OR**
- Prescriber requests a dose of >150 mg per day; **OR**
- Beneficiary is prescribed an ACEi, estrogen, or other drugs that can possibly be angioedema
  triggers; **OR**
- Prescriber requests a therapeutic duplication with 2 or more preventative agents

Quantity Edits

- #31/ 31 days for each strength

Beta Adrenergic Blocking Agents

(Implemented 10/17/2007)
(Updated1/1/2019)
(Updated 1/1/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Acebutolol (generic for Sectral®)
- Atenolol (generic for Tenormin®)
- Atenolol/chlorthalidone (generic for Tenoretic®)
- Bisoprolol fumarate 5 mg, 10 mg (generic for Zebeta®)
- Bisoprolol/HCTZ (generic for Ziac®)
- Carvedilol tablet (generic for Coreg®)
- Labetalol HCl 100 mg, 200 mg, 300 mg (generic for Normodyne)
- Metoprolol succinate extended-release (generic for Toprol XL®)
- Metoprolol tartrate (generic for Lopressor®)
- Nebivolol HCL (generic for Bystolic®)
- Propranolol HCl immediate-release (generic for Inderal®)
- Sotalol (generic for Betapace®)

Non-Preferred Agents

- Betapace® (sotalol)
- Betaxolone (generic for Kerlone®)
- Bisoprolol 2.5 mg (generic for Zebeta®)
- Bystolic® (nebivolol)
- Carvedilol phosphate CR capsule (Coreg CR®)
- Coreg® (carvedilol)
- Coreg CR® (carvedilol CR)
- Corgard® (nadolol)
- Hemangeol® suspension (propranolol)
- Inderal LA (propranolol ER)
- Labetalol HCL 400 mg (generic for Normodyne®)
- Kapspargo® sprinkle (metoprolol)
- Lopressor® tablet, solution (metoprolol)
- Metoprolol/HCTZ (generic for Lopressor HCT®)
- Nadolol (generic for Corgard®)
- Nadolol/bendroflumethiazide (generic for Corzide®)
- Pindolol (generic for Visken®)
- Propranolol HCl extended-release capsule (generic for Inderal LA®/Innopran XL®)
- Propranolol HCl solution

- Propranolol HCTZ (generic for Inderide®)
- Sotylize®* (See Criteria for Sotalol (Sotylize) Solution)
- Tenoretic® (atenolol/chlorthalidone)
- Tenormin® (atenolol)
- Timolol Maleate (generic for Blocadren)
- Toprol XL® (metoprolol XL)
- Ziac® (bisoprolol/HCTZ)

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Betaine powder for oral solution (Cystadane®)

(Implementation Date 11/15/2017)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Diagnosis of Homocystinuria in the previous 2 years.

Additional Criteria

- Quantity limits apply

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Bezlotoxumab solution, injection for IV infusion (Zinplava™)

(Implemented 05/23/2017)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Zinplava 1000 mg/40 ml (25 mg/ml) solution, injection for IV infusion

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Birch triterpenes 10% gel (Filsuvez®)

(Implemented 04/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB) OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must be a dermatologist or wound care specialist with expertise in DEB and JEB
- Beneficiary must have wound(s) that are 10-50 cm^2 and lasting 21 days - 9 months
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Ordered concomitant beremagene geperpavec-svdt (VYJUVEK)
  - Diagnosed with EB simplex
- Prescriber must submit the following:
  - Current chart notes
  - Genetic testing results confirming DEB or JEB
  - Previous therapies tried
  - Baseline description of wound(s)
  - Number of tubes expected per month

NOTE: For the initial 3 months, the beneficiary may be authorized #30 tubes every 30 days to determine response to treatment. If the beneficiary responds to FILSUVEZ at the 3 month evaluation, more than 1 tube per dressing change will be approved, if needed.

  - Directions on frequency of application
  - Attestation that patient/caregiver has been counseled on proper use
- Initial PA for 3 months; if demonstrates efficacy, subsequent PAs can be approved for 6 mos

Renewal Requirements

- Prescriber must submit the following:
  - Current chart notes
  - Response to therapy with description of wound(s)
  - Medical necessity for continued use
- Treated wounds will be evaluated at 3 months for a positive clinical response with request for PA continuation reviewed on a case-by-case basis. Positive response may include:
  - Decrease in wound size
  - Increase in granulation tissue
  - Complete wound closure
- If beneficiary is receiving a positive clinical response at 3 months, the next PA can be approved for 6 months.

Quantity Edits

- #30 per 30 days initially to determine response to treatment. If the beneficiary responds to FILSUVEZ, more than 1 tube per dressing change will be approved, if needed

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Bowel Prep Agents and Kits

(Implementation Date 10/11/2011)
(Updated 01/01/2019)
(Updated 7/1/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL drugs may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Gavilyte™-C solution
- Gavilyte™-G solution
- Gavilyte™-N solution
- GoLYTELY® solution
- Moviprep® powder pack—**BRAND NAME ONLY**
- PEG-3350 with electrolytes solution (generic for NuLYTELY®)
- PEG-3350 with flavor packs solution

Non-Preferred Agents

- Clenpiq® solution
- OsmoPrep® tablets
- PEG-3350 with electrolytes powder pack (generic for Moviprep®)
- Plenvu® powder pack
- Sodium sulfate-potassium sulfate-magnesium sulfate (generic for Suprep®)
- Suflave® solution
- Suprep® solution
- Sutab® tablets

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Bronchodilators, Inhaled Beta Agonists

(*Implemented 08/11/2009)*
(Effective 1/1/2017)
(Effective 4/1/2020)
(Updated 1/1/2023)
(Updated 10/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL drugs may be faxed to the PrimeTherapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Short-Acting Beta Agonists

- Albuterol sulfate 0.63mg/3ml solution
- Albuterol sulfate 1.25mg/3ml solution
- Albuterol sulfate 2.5mg/0.5ml solution
- Albuterol sulfate 2.5mg/3ml solution
- Albuterol sulfate 5mg/ml solution
- ProAir RespiClick® (albuterol sulfate inhalation powder) - **BRAND ONLY**
- Ventolin® HFA (albuterol) - **BRAND ONLY**
- Xopenex® HFA (levalbuterol) - **BRAND ONLY**

Non-Preferred Short-Acting Beta Agonists

- Albuterol HFA (ALL generics)
- Levalbuterol HFA inhaler (generic for Xopenex HFA®)
- ProAir Digihaler® (albuterol sulfate inhalation powder)
- Xopenex® (levalbuterol) inhalation solution

Preferred Long-Acting Beta Agonists with Criteria

- Serevent Diskus® (salmeterol xiafoate disk with device)

Non-Preferred Long-Acting Beta Agonists

- Arformoterol inhalation solution (generic for Brovana®)
- Brovana® Inhalation Solution (arformoterol)
- Formoterol fumarate inhalation solution (generic for Perforomist®)
- Perforomist® inhalation solution (formoterol fumarate)
- Striverdi Respimat® (olodaterol)

Approval Criteria for Preferred Long-Acting Beta Agonists with Criteria

- COPD diagnosis in history in previous 2 years; **AND**
- Beneficiary is ≥ 40 years of age; **AND**
- No Therapeutic Duplication (TD) with overlapping days' supply between drugs in the same drug classification.

Additional Criteria

- Quantity edits apply

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Bronchodilators, Inhaled Short Acting Muscarinic Antagonist (SAMA)

(Updated 1/1/2020)
(Updated 1/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL drugs may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Atrovent HFA® (ipratropium bromide)
- Combivent Respimat® (ipratropium/albuterol)
- Ipratropium bromide solution (generic for Atrovent® solution)
- Ipratropium/albuterol sulfate (generic for DuoNeb® inhalation solution)

Non-Preferred Agents

- None

Approval Criteria for Preferred Agents with Criteria

- One of the following diagnoses or procedures:
  - Anoxic brain injury (348.1)
  - COPD
  - Heart transplant (V421)
  - Quadriplegic cerebral palsy (343.2)
  - Respiratory insufficiency
    518.82 – Other pulmonary insufficiency, not elsewhere classified
    518.83 – Chronic respiratory failure
    518.84 – Acute and chronic respiratory failure
  - Tracheostomy (Appendix B)
  - Tracheomalacia congenital (748.3)

Additional Criteria

- Quantity limits apply

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Bronchodilators, Inhaled Long-Acting Muscarinic Antagonists (LAMA)

(Implemented 08/11/2009)
(Effective 1/1/17)
(Updated 1/1/2020)
(Updated 1/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL drugs may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Spiriva HandiHaler® (tiotropium bromide) **BRAND ONLY**

Non-Preferred Agents

- Incruse Ellipta® (umeclidinium bromide)
- Lonhala Magnair® (glycopyrrolate)
- Spiriva Respimat® (tiotropium bromide)
- Tiotropium bromide (generic of Spiriva Handihaler®)
- Tudorza Pressair® (aclidinium bromide)
- Yupelri® (revefenacin)

Approval Criteria for Preferred Agents with Criteria

- Diagnosis of COPD in Medicaid history in previous 2 years; **AND**
- No therapeutic duplication with overlapping days' supply between any medications in the same class; **AND**
- Medicaid beneficiary is ≥ 40 years of age

Approval Criteria for Spiriva Respimat® 1.25 mcg

- Beneficiary is ≥ 6 years of age; **AND**
- Beneficiary has diagnosis of severe asthma or refractory asthma with persistent asthma symptoms despite use of appropriate controller drugs (per GINA guidelines) (e.g., moderate/high-dose ICS/LABA) and beneficiary requires a higher level of care and/or add-on treatment; **AND**
- Beneficiary's asthma is poorly controlled despite correct inhaler technique; **AND**
- Beneficiary must be adherent with 2 or more asthma controller medications (e.g., moderate/high dose of ICS/LABA) as maintenance treatment plus use of an as-needed reliever medication; good adherence to controller inhaler(s) for purposes of this criteria is defined as the Medicaid drug profile history shows controller inhaler(s) filled monthly at least 4 months out of previous 6 months. A combination inhaler of ICS/LABA is considered as two asthma controller medications; **AND**

Beneficiary is a non-smoker.

Renewal Criteria for Spiriva Respimat® 1.25 mcg

- Beneficiary continues to meet the above initial criteria; **AND**
- Claims history shows at least 120-day supply in the last 180 days of the requested

medication; **AND**

- Beneficiary has experienced a positive clinical response to treatment but continues to have persistent asthma symptoms that require add-on treatment.

Additional Criteria

- Quantity edits apply

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Bronchodilators, Inhaled Combination Products (LABA/LAMA)

(Updated 1/1/2020)
(Updated 1/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL drugs may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Anoro Ellipta® (umeclidinium/vilanterol) – **BRAND PREFERRED**
- Bevespi Aerosphere® (formoterol/glycopyrrolate)
- Stiolto Respimat® (tiotropium/olodaterol)

Non-Preferred Agents

- Duaklir Pressair® (aclidinium/formoterol)
- Umeclidinium/vilanterol (generic for Anoro Ellipta®)

Approval Criteria for Preferred Agents with Criteria

- **Criterion 1**:
  - COPD diagnosis in the past two years; **AND**
  - ≥ 40 years old; **AND**
  - No therapeutic duplications within same class(es)

  OR

- **Criterion 2**:
  - Paid drug claim in drug history for Anoro®, Bevespi® or Stiolto® in the last six months

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Bronchodilators, Inhaled Combination Products (ICS/LABA)

(Implemented 08/11/2009)
(Effective 1/1/17)
(Updated 1/1/2020)
(Updated 10/202021)
(Updated 1/1/2023)
(Updated 7/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL drugs may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Advair Diskus® (fluticasone propionate/salmeterol)—**BRAND ONLY**
- Advair HFA® (fluticasone propionate/salmeterol)—**BRAND ONLY**
- AirDuo RespiClick® (fluticasone/salmeterol)---**BRAND ONLY**
- Dulera HFA® (mometasone furoate/formoterol fumarate)
- Symbicort HFA® (budesonide/formoterol fumarate)—**BRAND ONLY**

Point of Sale (POS) Approval Criteria for Advair HFA®/Diskus®, AirDuo RespiClick®, Dulera®, and Symbicort®

- **Criterion 1**:
  - COPD diagnosis in the past two years; **AND**
  - ≥ 40 years old

- **Criterion 2**:
  - Paid drug claim in drug history in the last six months for
    - Advair Diskus®
    - Advair HFA®
    - AirDuo RespiClick®
    - Dulera®
    - Symbicort®

- **Criterion 3:**
  - Age: ≥ 4 Years of Age; **AND**
  - Asthma diagnosis in the past two years

- **Criterion 4:**
  - Age ≥ 4 Years of years old; **AND**
  - One of the following criteria below:
    - ≥ Three inhaled corticosteroid claims in the last 120 days; **OR**
    - ≥ Three oral steroid claims in the last 120 days; **OR**
    - Combination for ≥ three claims (as defined below) in the last 120 days:
      - One Inhaled Corticosteroid + 2 Oral Steroids
      - Two Inhaled Corticosteroids + 1 Oral Steroids

Non-Preferred Agents

- ~~AirDuo Digihaler® (fluticasone/salmeterol)~~---discontinued 6/1/2024
- Airsupra® (budesonide/albuterol)
- Breo Ellipta® (fluticasone furoate/vilanterol)
- Breyna® (budesonide/formoterol)
- Budesonide/formoterol (generic for Symbicort®)—GENERIC ONLY
- Fluticasone/salmeterol (generic for Advair® Diskus)—GENERIC ONLY
- Fluticasone/salmeterol HFA (generic for Advair® HFA)—GENERIC ONLY
- Fluticasone/salmeterol (generic for AirDuo® RespiClick)—GENERIC ONLY
- Fluticasone/vilanterol (generic for Breo Ellipta®)
- Wixela Inhub® (fluticasone/salmeterol)

Quantity Limits

- Symbicort® - #2 inhalers per month for 120 actuation size

If the beneficiary needs > 8 puffs per day, a PA can be submitted to approve an additional inhaler.

- Dulera® - #2 inhalers per month
- Advair Diskus® and Advair HFA® - #1 inhaler per month
- AirDuo RespiClick - #1 inhaler per month

(NOTE**** Advair Diskus®, Advair HFA® and AirDuo RespiClick® are not recommended for SMART therapy and should not be used for rescue.)

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Bronchodilators, Inhaled Combination Products (ICS/LAMA/LABA)

(Updated 1/1/2020)
(Updated 1/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL drugs may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- None

Non-Preferred Agents

- Breztri® Inhaler (budesonide/glycopyrrolate/formoterol)
- Trelegy Ellipta® (fluticasone furoate/umeclidinium/vilanterol)

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Budesonide EC 3mg Capsule (Entocort EC)

(Implemented 07/09/2013)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Submitted Diagnosis of Crohn's Disease in the past 2 years

Additional Criteria

- Quantity limits apply

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Budesonide Delayed Release Capsule (Tarpeyo®)

(Implemented 04/20/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥18 years of age; **AND**
- Must be prescribed by or in consultation with a nephrologist; **AND**
- Beneficiary must have a diagnosis of immunoglobulin A nephropathy (IgAN) with proteinuria **OR** a diagnosis consistent with the FDA approved indication; **AND**
- Beneficiary must have eGFR ≥35 mL/min/1.73 m2 and proteinuria (defined as either ≥1 g/day or UPCR ≥0.8 g/g) at baseline despite ACEi or ARB therapy; **AND**
- Beneficiary must be on a stable dose of maximally tolerated RAS inhibitor unless contraindicated for at least 90 days; **AND**
- Beneficiary must be prescribed in combination with an ACEi or ARB; **AND**
- Beneficiary must have trialed and failed corticosteroids; **AND**
- Beneficiary will take a maximum of 9 months of therapy at the maximum dose of 16 mg per day followed by 2 weeks of tapered dose at a maximum dose of 8 mg per day (unless new data supports continued use); **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Previous treatment; **AND**
  - Confirmation for the diagnosis of IgAN with renal biopsy and labs; **AND**
  - Current labs including eGFR, urine protein or UPCR; **AND**
  - Medical necessity over corticosteroids and immunosuppressants available without a PA; **AND**
- Initial PA for 3 months

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported on the official Compendia; **OR**
- Beneficiary has severe hepatic impairment; **OR**
- Prescriber orders for > 9 months of therapy (unless new data supports continued use)

Quantity Edits

- #124/31 days

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Burosumab-twza 10 mg, 20 mg, 30 mg injection (Crysvita®)

(Implemented 7/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Must be prescribed by on in consultation with a nephrologist or endocrinologist
- Beneficiary must be diagnosed with either:
  - X-linked hypophosphatemia (XLH); **OR**
  - FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO); **OR**
    - Must be a phosphaturic mesenchymal tumor
    - Tumor cannot be curatively resected or localized
  - Diagnosis consistent with any new FDA-approved indications
- Diagnosis must be confirmed by identifying at least **ONE** (1) of the following:
  - Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL
  - Phosphate regulating gene with homology to endopeptidases located on the X chromosome (PHEX-gene) mutations in the patient
  - Clinical, radiographic, and laboratory findings that support the diagnosis (e.g., evidence of Rickets, evidence of skeletal demineralization, low phosphate and high alkaline phosphatase activity for age)
- Beneficiary must have a baseline fasting serum phosphorus level with current hypophosphatemia, defined as a phosphate level below the lower limit of normal for patient's age
- Adults must have an inadequate response from oral phosphate and active vitamin D analogs
- Beneficiaries with TIO must have a tumor that cannot be curatively resected or localized
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Continues to take oral phosphate or active vitamin D analogs
  - Severe renal impairment (Glomerular Filtration Rate (GFR) < 30 mL/min)
- Prescriber must submit the following:
  - Current chart notes
  - Baseline labs including serum phosphorus, serum total alkaline phosphatase activity, and vitamin D
  - Baseline symptoms (e.g., pain, mobility, growth rate, rickets on radiographic evaluation (Rickets Severity Score))
  - Medical necessity for patients with closed epiphyses over oral phosphate and vitamin D supplementation
  - Attestation that patient has discontinued oral phosphate supplement and active vitamin D analogs

- Documentation of treatment plan
  - Where will dose be given (i.e., doctor's office, home health, infusion center etc.)
  - Where will labs be drawn
  - If this PA request originates outside of specialist clinic, provide a plan for consulting with specialist
- Information on tumor resection for TIO patient
- Clarification if this will be billed as a medical claim through "buy and bill" or billed as a pharmacy claim through a specialty pharmacy.

NOTE: If billing as a medical claim, contact AFMC for PA processing.

Renewal Requirements

- Beneficiary must be compliant with treatment (defined as 75% utilization)
- Beneficiary must not demonstrate unacceptable toxicity (e.g., severe hypersensitivity reactions, hyperphosphatemia or nephrocalcinosis, severe injection site reactions, etc.)
- Beneficiary must demonstrate a positive response with at least **ONE** (1) of the following:
  - Serum phosphate levels increased compared to baseline
  - Symptom improvement (e.g., pain, mobility, growth)
  - Radiographic imaging indicates improvement in Rickets/osteomalacia
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including serum phosphorus, serum total alkaline phosphatase activity, and vitamin D
  - Current symptoms (e.g., pain, mobility, growth, rickets on radiographic evaluation with RSS)
- Beneficiary with closed epiphyses must have documentation of medical necessity for continuation. Reassessment for efficacy with oral phosphate and active vitamin D analogs may be warranted.

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Butalbital Products

(Implemented 01/18/2011)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for these products may be faxed to the Prime Therapeutics State Government solutions pharmacy unit at 1-800-424-7976.

Drugs that do not require a manual PA

- Butalbital-Acetaminophen 50-325 mg **TABLET** (Marten-**Tab**)
- Butalbital-Acetaminophen-Caffeine 50-325-40 mg **TABLET** (Esgic**Tablet**)

Drugs that require a manual PA

- Butalbital-Acetaminophen 50-300 mg **TABLET** (Bupap 50-300 mg **Tablet**)
- Butalbital-Acetaminophen-Caffeine 50-300-40 mg **CAPSULE** (Fioricet **Capsule**)
- Butalbital-Acetaminophen-Caffeine 50-325-40 mg **CAPSULE** (Esgic **Capsule**)
- Butalbital-Aspirin-Caffeine 50-325-40 mg **CAPSULE** (Fiorinal **Capsule**)

Age Edit

- Beneficiary must be at least 12 years of age or greater

Quantity Edits

- Solid Oral dosage forms of butalbital products will be limited up to a maximum of 6 units per day
- Solid Oral dosage forms of butalbital products will have a cumulative quantity limit of 124 units per 31 days' supply
- The butalbital products that contain 750 mg acetaminophen per unit will be limited to a maximum of 5 units per day based on the maximum amount of acetaminophen allowed per day
- Oral liquid forms of butalbital will be limited to 60ml per day or up to 240ml per prescription

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C1 Esterase Inhibitor (Berinert®, Ruconest®)

(Implemented 4/17/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Patient must have a laboratory diagnosis of C1-INH deficient or dysfunctional HAE
- Must have ≥ 1 severe or life-threatening laryngeal attack or had 2-3 moderate attacks causing extremity, facial or abdominal swelling in the last year
- Provider must submit a proposed treatment plan for **both acute and prophylaxis** treatment (if meets prophylaxis criteria)
- Provider must verify that the patient or caregiver is appropriately trained on IV administration
- Documentation of expected angioedema triggers (Trigger avoidance is crucial)
- Must NOT be on an ACEi (or other possible drug causes such as estrogens and NSAIDs)
- Follow the package inserts for specific indicated age or contraindications
- Initial PA maximum of 3-month trial if approved
- Quantity limit of 2 doses per prescription fill

Denial Criteria

- History of allergic reaction for C1-INH or blood products
- Diagnosis of acquired angioedema
- Does not meet acute attack requirements for approval
- Beneficiary is not diagnosed with Type I or Type II HAE
- Failure to provide adequate records

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C1 Esterase Inhibitor (Cinryze®)

(Implemented 01/21/2011)
(Updated 4/17/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Patient must have a laboratory diagnosis of C1-INH deficient or dysfunctional HAE
- Must have ≥ 1 severe or life-threatening laryngeal attack per month or ≥ 4 moderate attacks causing extremity, facial or abdominal swelling despite treatment with medications for acute attacks
- Provider must submit a proposed treatment plan for **both acute attacks and prophylaxis** treatment
- Provider must verify that the caregiver is appropriately trained on IV administration
- Documentation of expected angioedema triggers (Trigger avoidance is crucial)
- Must NOT be on an ACEi (or other possible drug causes such as estrogens and NSAIDs)
- Follow the package inserts for specific indicated age or contraindications
- Documentation of attack frequency, comorbidities, and access to emergency care
- IF beneficiary has tried and had an insufficient response or contraindication to BOTH of the following classes of medication, provide that documentation.
  - 17α-alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
  - Antifibrinolytic agents (e.g. ε-aminocaproic acid, tranexamic acid)
- Initial PA maximum 3-month trial if approved

Denial Criteria

- History of allergic reaction for C1-INH or blood products
- Diagnosis of acquired angioedema
- < 1 severe or life-threatening laryngeal attack per month or < 4 moderate attacks per month causing extremity, facial or abdominal swelling
- Beneficiary is not diagnosed with Type I or Type II HAE (Type III would be considered separately)
- Failure to provide adequate records
- No therapeutic duplication of 2 or more agents

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C1 Esterase Inhibitor (Haegarda®)

(Implemented 4/17/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Patient must have a laboratory diagnosis of C1-INH deficient or dysfunctional HAE
- Must have ≥ 1 severe or life-threatening laryngeal attack per month or ≥ 4 moderate attacks causing extremity, facial or abdominal swelling despite treatment with medications for acute attacks
- Provider must submit a proposed treatment plan for **both acute attacks and prophylaxis** treatment
- Documentation of expected angioedema triggers (Trigger avoidance is crucial)
- Must NOT be on an ACEi (or other possible drug causes such as estrogens and NSAIDs)
- Follow the package inserts for specific indicated age or contraindications
- Documentation of attack frequency, comorbidities, and access to emergency care
- IF beneficiary has tried and had an insufficient response or contraindication to BOTH of the following classes of medication, provide that documentation.
  - 17α-alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
  - Antifibrinolytic agents (e.g. ε-aminocaproic acid, tranexamic acid)
- Initial PA maximum 3-month trial if approved

Denial Criteria

- History of allergic reaction for C1-INH or blood products
- Diagnosis of acquired angioedema
- < 1 severe or life-threatening laryngeal attack per month or < 4 moderate attacks per month causing extremity, facial or abdominal swelling
- Beneficiary is not diagnosed with Type I or Type II HAE (Type III would be considered separately)
- Failure to provide adequate records
- No therapeutic duplication of 2 or more agents

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Caplacizumab-yhdp (Cablivi®)

(*Implemented 10/16/2019*)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1- 800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Must be ≥ 18 years of age; **AND**
- Beneficiary has a clinical diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) (initial or recurrent); **AND**
- Provide the medical necessity over high dose glucocorticoids and rituximab with PEX; **AND**
- Beneficiary is currently taking immunosuppressive therapy; **AND**
- Beneficiary has initiated plasma exchange; **AND**
- Provide chart notes/hospitalization notes with treatment plan; **AND**
- Provide current labs with minimum of the following: CBCs with platelets, LFTs, and ADAMTS13 activity level (may not have immediately but should be drawn and pending results); **AND**
- Provide treatment plan if beneficiary has clinically significant bleeding; **AND**
- Beneficiary should not be pregnant or breastfeeding (until at least 2 months after last dose); **AND**
- Beneficiary considered high-risk and hospitalized and has at least one of the following (per UpToDate):
  - Neurologic abnormalities
  - Decreased level of consciousness
  - serum troponin level
  - Other signs of critical illness
- Approve 1 month at a time (max quantity would be 58 plus number of days getting PEX)

Denial Criteria

- Diagnosed with congenital thrombotic thrombocytopenic purpura or has other cause for thrombocytopenia; **OR**
- Pregnant or breastfeeding; **OR**
- Not receiving PEX or immunosuppressive therapy; **OR**
- Beneficiary is classified as standard risk and responds to PEX/glucocorticoids
- Interrupt treatment if clinically significant bleeding occurs; **OR**
- Concomitant use with anticoagulant?? (or require INR/PT and close monitoring); **OR**
- Discontinue if more than 2 recurrences of aTTP while on Cablivi®; **OR**
- ADAMTS13 activity level > 10%; **OR**
- Platelet count ≥ 100X109/L

Quantity Edits

- Maximum of 58 days after plasma exchange is complete

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Calcitrol (Vectical®), Calcipotriene (Dovonex®, Sorilux®)

(Implemented 06/19/2006)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Diagnosis of psoriasis in Medicaid history in previous 365 days; **AND**
- 2 paid claims of a topical corticosteroid in previous 27-60 days; **AND**
- At least one paid claim for a topical corticosteroid must be from the class 1 potency category.

Continuation Criteria

- Diagnosis of psoriasis in Medicaid history in previous 365 days; **AND**
- The incoming claim matches claim in history in the previous 45 days; **AND**
- At least two claims of a topical corticosteroid in previous 60 days in drug claim history with at least one topical corticosteroid claim 14-60 days back in history.

Denial Criteria for Calcipotriene (generic for Dovonex®)

- History of Vitiligo in previous two years

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Calcipotriene and Betamethasone Dipropionate (Taclonex®)

(Implemented 01/09/2008)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- ≥ 18 years of age; **AND**
- History of three paid claims in the past 90 days for Calcipotriene (DOVONEX); **AND**
- History of three paid claims in the past 90 days for a topical steroid

Denial Criteria

- < 18 years of age
- Concurrent use of a topical corticosteroid
- Failure to meet the approval criteria

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Calcium Channel Blockers

(Implemented 07/12/2005)
(Updated 07/20/2015)
(Updated 1/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Dihydropyridine and Combination Products

Preferred Agents

- Amlodipine besylate (generic for Norvasc®)
- Amlodipine/benazepril (generic for Lotrel®)
- Amlodipine/olmesartan (generic for Azor®)
- Amlodipine/valsartan (generic for Exforge®)
- Amlodipine/valsartan/hctz (generic for Exforge HCT®)
- Nifedipine IR (generic for Procardia®)
- Nifedipine ER (generic for Adalat CC®, Procardia XL®)

Non-Preferred Agents

- Amlodipine/atorvastatin (generic for Caduet®)
- Amlodipine/olmesartan/hctz (generic for Tribenzor®)
- Exforge® (amlodipine/valsartan)
- Exforge HCT® (amlodipine/valsartan/hctz)
- Felodipine ER (generic for Plendil®)
- Isradipine (generic for Dynacirc®)
- Isradipine ER (generic for Dynacirc CR®)
- Katerzia® suspension (amlodipine)
- Levamlodipine (generic for Conjupri®)
- Nicardipine (generic for Cardene®)
- Norliqva® (amlodipine suspension)
- Nimodipine (generic for Nymalize®)
- Nisoldipine er (generic for Sular®)
- Norvasc® (amlodipine)
- Nymalize® solution (nimodipine)
- Procardia XL® (nifedipine ER)

Non-Dihydropyridine and Combination Products

Preferred Agents

- Diltiazem ER capsule (generic for Dilacor XR®, Tiazac®)
- Diltiazem tablet (generic for Cardizem®)
- Verapamil tablet (generic for Calan®)
- Verapamil ER tablet (generic for Calan SR®)

Non-Preferred Agents

- Calan SR® (verapamil ER)
- Cardizem®, Cardizem CD®, LA® (diltiazem)
- Diltiazem CD, ER, LA, XR, XT (generic for Cardizem® and Matzim®)
- Matzim LA® (diltiazem ER)
- Tiazac® (diltiazem ER)
- Verapamil ER capsules (generic for Verelan®, Verelan PM®)
- Verelan® (verapamil ER)
- Verelan PM® (verapamil ER)

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Cannabidiol (CBD) extract – (Epidiolex®)

(Implemented 1/16/2019)
(Updated 4/4/2023)
(Updated 7/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary has documented history of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or Tuberous Sclerosis Complex (TSC)
- For Lennox-Gastaut Syndrome: Provider must submit written documentation of electroencephalogram (EEG) showing slow (<3.0 hertz [Hz]) spike-and-wave pattern;
- For Dravet Syndrome: Provider must submit written documentation showing convulsive status epilepticus, alternating hemiconvulsions, OR myoclonic seizures and include genetic testing results for Dravet Syndrome that shows mutations within SCN1A gene.
- For Tuberous Sclerosis Complex: Provider must provide documentation confirming the diagnosis
- Beneficiary is currently adherent to prescribed dose and frequency of antiepileptic drugs and was on stable dose(s) for at least 4 weeks
- Provider must submit chart notes and documentation that beneficiary is refractory to antiepileptic drugs with documented failures on more than 1 anticonvulsant drug (≥2 antiepileptic drugs)
- Provider must submit baseline liver function tests including liver enzyme test results (ALT AST) and total bilirubin
- Initial approval will be for 1 month
- Beneficiary is not pregnant, planning to become pregnant, or lactating

Denial Criteria

- Beneficiary does not meet approval criteria
- Beneficiary does not have seizures associated with Lennox-Gastaut syndrome or Dravet syndrome or Tuberous Sclerosis Complex
- Etiology of beneficiary's seizures is a progressive neurologic disease
- Beneficiary has significantly impaired hepatic function, defined as any of the following: alanine aminotransferase (ALT) or aspartate aminotransferase (AST) > 5 × upper limit of normal (ULN); ALT or AST > 3 × ULN and total bilirubin > 2 × ULN or international normalized ratio (INR) >1.5; ALT or AST > 3 × ULN with the presence of fatigue, nausea, vomiting, right upper quadrant pain or tenderness, fever, rash, and/or eosinophilia (> 5%)
- Female beneficiary is pregnant (positive pregnancy test), lactating or planning pregnancy for 3 months thereafter

Quantity Limits

- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Prescriber must submit beneficiary's weight and prescribed dose at every PA request
- Calculating the dose and the quantity limit for the number of 100 mL bottles per month will be entered at the time of PA approval
- Dose adjustment is recommended in patients with moderate (Child-Pugh B) hepatic impairment or severe (Child-Pugh C) hepatic impairment and the quantity limit of 100 ml bottles will be implemented at the time of PA approval
- Per the package insert, it may be necessary to have slower dose titration in patients with moderate or severe hepatic impairment than in patients without hepatic impairment, so quantity limit will be adjusted accordingly

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Capsaicin 8% kit (Qutenza®)

(Implemented 01/18/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Prescriber must be a specialist in treating neuropathic pain
- Beneficiary must be diagnosed with neuropathic pain associated with postherpetic neuralgia (PHN) or neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- QUTENZA may be purchased through buy and bill from specialty distributor or by prescription from specialty pharmacy. QUTENZA must be delivered to prescriber directly.
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or an official Compendia
- Application time must be consistent with the actual diagnosis (60 minutes for postherpetic neuralgia and 30 minutes for diabetic peripheral neuropathy)
- Beneficiaries being treated for PHN pain must have continued pain at least 6 months after healing of herpes zoster rash
- Beneficiary must have tried and failed at least 3 of the following prior to consideration for this medication:
  - Postherpetic neuralgia (PHN)
    - Topical capsaicin or lidocaine
    - Gabapentin and/or pregabalin
    - Tricyclic antidepressants (e.g., amitriptyline, nortriptyline)
    - Antiepileptic agents (e.g., valproic acid, carbamazepine, lamotrigine)
    - Serotonin-norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine)
  - Diabetic peripheral neuropathy (DPN)
    - Topical capsaicin or lidocaine
    - Gabapentin and/or pregabalin
    - Tricyclic antidepressants (e.g., amitriptyline, nortriptyline)
    - Antiepileptic agents (e.g., valproic acid, carbamazepine, lamotrigine)
    - Serotonin-norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine)
    - Electrical nerve stimulation
    - Spinal cord stimulation
    - Alpha-lipoic acid
- Prescriber must submit **ALL** of the following:
  - Current chart notes with documentation if treating PHN or DPN
  - Previous therapies tried
  - Medical necessity over other treatment options
  - Size of area to be treated. PA will be entered for a specific package size pertaining to the amount needed based on treatment area size.

  - If received from the specialty pharmacy as an outpatient prescription, prescriber must attest that the patient will not have access to this medication. The prescription must be delivered directly to the prescriber's office.
- If approved, PA will be entered for one (1) treatment at a time. Subsequent treatments will require additional PA review.
- PAs will be entered for one (1) treatment at a time and only one (1) treatment is allowed every 3 months

Renewal Requirements

- Prescriber must submit the following:
  - Current chart notes
  - Documented improvement in neuropathic pain

Quantity Edits

- 1 single use topical system per 90 days (carton can include 1, 2, or 4 systems)

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Cenegermin-bkbj (Oxervate®)

(Implemented 04/20/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 2 years of age; **AND**
- Beneficiary must have a diagnosis of neurotrophic keratitis **OR** a diagnosis consistent with FDA approved indication or Compendia support; **AND**
- Beneficiary must have stage 2 or stage 3 neurotrophic keratitis; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documented trials of the following; **AND**
    - Stage 2: Artificial tears, lubricant ointments, prophylactic antibiotic eye drops, and topical corticosteroids (if inflammation)
    - Stage 3: All products for stage 2 plus N-acetylcysteine, tetracycline, or medroxyprogesterone
- Stage of neurotrophic keratitis; **AND**
- Medical necessity over surgery with amniotic membrane; **AND**
- Medical necessity if requesting for > 8 weeks of therapy

Quantity Edits

- #1 vial per day per affected eye

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Cephalosporins

(Implemented 4/1/2023))

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Cefadroxil capsule and suspension (generic for Duricef®)
- Cefdinir capsule and suspension (generic for Omnicef®)
- Cefpodoxime tablet and suspension (generic for Vantin®)
- Cefprozil tablet and suspension (generic for Cefzil®)
- Cefuroxime tablet (generic for Ceftin®)
- Cephalexin capsule and suspension (generic for Keflex®)

Non-Preferred Agents

- Cefaclor capsule, ER tablet, and suspension (generic for Ceclor®)
- Cefadroxil tablet (generic for Duricef®)
- Cefixime capsule and suspension (generic for Suprax®)
- Cephalexin tablet (generic for Keflex®)
- Suprax® chew tablet, capsule, and suspension (cefixime)

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Cholic Acid capsule (Cholbam®)

(Updated 05/20/2015)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with **ONE** (1) of the following:
  - Bile acid synthesis disorders due to single enzyme defects (SEDs)
  - Peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption.
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Worsening liver function or cholestasis
  - Requested dose is not supported in the package insert
  - No liver improvement after 3 months of treatment
  - Develops complete biliary obstruction
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies with response
  - Liver function tests (AST, ALT, GGT, alkaline phosphatase, bilirubin, INR)
  - Serum or urinary bile acid levels
- Initial PA for 3 months

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response after 6 months of usage
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy

Quantity Edits

- #120 capsules/30 days

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Chronic GI Motility Agents

(Implemented 06/27/2007)
(Updated 07/17/2015)
(PDL Effective 4/1/18)
(Updated 4/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL drugs may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Linzess® (linaclotide)
- Lubiprostone (generic for Amitiza®)
- Movantik® (naloxegol)

Non-Preferred Agents

- Alosetron (generic for Lotronex®)
- Amitiza® (lubiprostone)
- Ibsrela® (tenapanor)
- Lotronex® (alosetron)
- Motegrity® (prucalopride)
- Prucalopride (generic for Motegrity®)
- Relistor® (methylnaltrexone)
- Symproic® (naldemedine)
- Trulance™ (plecanatide)
- Viberzi™ (eluxadoline)
- Zelnorm™ (tegaserod)

Approval Criteria for Lubiprostone (generic for Amitiza®)

Criterion 1:

- ≥ 18 years of age; **AND**
- Paid drug claim for LUBIPROSTONE within the past 60 days

Criterion 2:

- Beneficiary must be ≥ 18 years of age; **AND**
- Beneficiary's Medicaid profile must include at least one paid claim in the previous 14 to 60 days for polyethylene glycol (MIRALAX, GLYCOLAX) or lactulose; **AND**
- No Therapeutic Duplication (TD) allowed between MOTEGRITY tablet, LINZESS capsule, RELISTOR SQ, RELISTOR tablet, MOVANTIK tablet, SYMPROIC tablet, TRULANCE tablet, ZELNORM tablet, LUBIPROSTONE (generic AMITIZA) capsule of different strengths, or new agents to market.

Denial Criteria for Lubiprostone

- Absence of approval criteria
- History of mechanical gastrointestinal obstruction
- Age < 18 years of age

Approval Criteria for Linzess®

Criterion 1:

- Beneficiary must be ≥ 6 years old for Linzess 72mcg and ≥ 18 years old for Linzess 145mcg and 290mcg; **AND**
- Beneficiary's Medicaid profile must include a paid drug claim for LINZESS within the past 60 days

Criterion 2:

- Beneficiary must be ≥ 6 years of age for Linzess 72mcg and ≥ 18 years old for Linzess 145mcg and 290mcg; **AND**
- Beneficiary's Medicaid profile must include at least one paid claim in the previous 14 to 60 days for polyethylene glycol (MIRALAX, GLYCOLAX) or lactulose; **AND**
- No Therapeutic Duplication (TD) allowed between LUBIPROSTONE (generic AMITIZA), MOTEGRITY tablet, RELISTOR SQ, RELISTOR tablet, MOVANTIK tablet, SYMPROIC tablet, TRULANCE tablet, ZELNORM tablet, LINZESS capsule of different strengths, or new agents to market.

Denial Criteria for Linzess®

- Absence of approval criteria; **OR**
- Beneficiary has a history of mechanical gastrointestinal obstruction; **OR**
- Beneficiary is < 6 years of age; **OR**
- Beneficiary has a paid claim for an opioid in the last 60 days

Approval Criteria for Movantik®

Criterion 1:

- ≥ 18 years of age; **AND**
- Beneficiary's Medicaid profile must include a paid drug claim for MOVANTIK within the past 60 days

Criterion 2:

- Beneficiary must be ≥ 18 years of age; AND
- Beneficiary's Medicaid profile must include at least one paid claim in the previous 14 to 60 days for polyethylene glycol (MIRALAX, GLYCOLAX) or lactulose; **AND**
- No Therapeutic Duplication (TD) allowed between LUBIPROSTONE (generic AMITIZA), MOTEGRITY tablet, LINZESS capsule, RELISTOR SQ, RELISTOR tablet, SYMPROIC tablet, TRULANCE tablet, ZELNORM tablet, MOVANTIK tablet of different strengths, or new agents to market; **AND**
- Beneficiary has a paid claim for an opioid (includes buprenorphine) in the last 60 days.

Denial Criteria for Movantik®

- Absence of approval criteria; **OR**
- Beneficiary has a history of mechanical gastrointestinal obstruction; **OR**
- Beneficiary is < 18 years of age; **OR**

- Beneficiary does not have a paid claim for an opioid in the last 60 days

Additional Criteria

- Quantity limits apply

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Cinacalcet (Sensipar®)

(Implemented 05/23/2017)
(Updated 4/15/2020)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

Criterion 1: **POS PA approval criteria** for Treatment of Secondary Hyperparathyroidism (HPT) In Adult Patients with Chronic Kidney Disease (CKD) On Dialysis:

- Diagnosis in Medicaid medical history in previous 2 years of **BOTH** diagnosis codes for:
  - "Secondary HTP of renal origin" (ICD-10 code N25.81); **AND**
  - "ESRD CKD requiring Chronic Dialysis" (ICD-10 code N18.6 or Z99.2).

Manual review PA will be on a case-by-case basis if either diagnoses code is not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

Criterion 2: **POS PA approval criteria** for Treatment of Hypercalcemia in Adult Patients with Parathyroid Carcinoma:

- Diagnosis in Medicaid medical history in previous 2 years of **BOTH** diagnosis codes for:
  - "Cancer of the parathyroid gland" (ICD-10 code C75.0); **AND**
    - Diagnosis in medical history of "Hypercalcemia" (ICD-10 code E83.52); **OR**
    - Hypercalcemia level with Calcium > 10 mg/dL drawn in previous 30 days

Manual review PA will be on a case-by-case basis if either diagnosis code is not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

Criterion 3: **POS PA approval criteria** for treatment of hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated based on serum calcium levels, but who are unable to undergo parathyroidectomy:

- Absence of a Parathyroidectomy in the Patient's Medical History
- NO Procedure Code for Parathyroidectomy in the past 2 years; **AND**
  - Diagnosis in Medicaid medical history in previous 2 years
    - "Hypercalcemia" (ICD-10 code E83.52); **OR**
    - Hypercalcemia Level with calcium >10 mg/dL drawn in the previous 30 days

Manual review PA will be on a case-by-case basis if above criteria is not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found**.**

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Clindamycin phosphate 2% gel (Xaciato™)

(Implemented 10/19/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary is a female 12 years of age and older OR updated age allowance if indication changes
- Beneficiary has a confirmed diagnosis of bacterial vaginosis with the following:
  - Off-white vaginal discharge
  - Clue cells > 20% of total epithelial cells
  - Discharge pH >4.5
  - Positive whiff test
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Medical necessity over other treatment options available without a PA (e.g., oral or vaginal metronidazole, oral or vaginal clindamycin)

Quantity Edits

- 1 tube (8 gm)/30 days

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Clonidine and Guanfacine

(Implemented 07/11/2009)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

Patients ≥ 18 years of age

- All claims are approved

Patients < 18 years of age

- One therapeutic duplication with > 25% remaining on the last fill on different dates of service allowed per 93 days between two clonidine claims, two guanfacine claims, or one clonidine claim and one guanfacine claim
- Cumulative quantity edits will apply (Table 3)
- Maximum daily dose edits will apply (Table 3.1)

Table 3 – Cumulative Quantity Edits

Generic name	Cumulative qty < 18 y/o
Clonidine HCL 0.1mg tablet	124 per 31 days
Clonidine HCL 0.2mg tablet	62 per 31 days
Clonidine HCL 0.3mg tablet	31 per 31 days
Guanfacine 1mg tablet	93 per 31 days
Guanfacine 2mg tablet	62 per 31 days

Table 3.1 – Maximum Daily Dose Edits

Generic name	Dose < 18 y/o
Clonidine HCL 0.1mg tablet	4 tabs per day
Clonidine HCL 0.2mg tablet	2 tabs per day
Clonidine HCL 0.3mg tablet	1 tab per day
Guanfacine 1mg tablet	3 tabs per day
Guanfacine 2mg tablet	2 tabs per day

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Clonidine Vials

(Implemented 07/08/2014)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Clonidine HCl PF vials 5000 mcg/10 ml
- Clonidine HCl PF vials 1000 mcg/10 ml

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Colchicine 0.5 mg tablet (Lodoco®)

(Implemented 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with atherosclerotic disease or have multiple risk factors for cardiovascular disease
- Beneficiary is currently taking standard of care treatment for chronic coronary disease (e.g., antiplatelet, anticoagulant, lipid-lower agent, beta blocker, renin-angiotensin inhibitor)
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Renal failure (CrCl < 15 ml/minute); patients with renal impairment should be monitored
  - Severe hepatic impairment
  - Requires strong CYP3A4 inhibitors or P-gp inhibitors
  - Has pre-existing blood dyscrasias (i.e., myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, and aplastic anemia)
  - Develops neuromuscular toxicity or rhabdomyolysis
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including creatinine clearance and eGFR
  - Previous therapies for atherosclerotic disease
  - Letter of medical necessity over the use of colchicine 0.6 mg capsule or tablet

Renewal Requirements

- Beneficiary is compliant with therapy (defined as 75% utilization)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of any change to cardiovascular status

Quantity Edits

- #30/30 days

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Colony Stimulating Factors

(Reviewed 5/10/2018)
(Effective 7/1/2018)
(Effective 7/1/2021)
(Updated 1/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Preferred Agents

- Fylnetra® syringe (pegfilgrastim-pbbk)
- Neupogen® vial and syringe (filgrastim)

Non-Preferred Agents

- Fulphila® syringe (pegfilgrastim-jmbd)
- Granix® syringe (tbo-filgrastim)
- Leukine® vial (sargramostim)
- Neulasta® syringe (pegfilgrastim)
- Neulasta Onpro® Kit (pegfilgrastim)
- Nivestym® (filgrastim-aafi)
- Nyvepria™ (pegfilgrastim-apgf)
- Releuko® (filgrastim-ayow)
- Rolvedon® syringe (eflapegrastim-xnst)
- Ryzneuta® syringe (efbemalenograstim alfa-vuxw)
- Stimufend® (pegfilgrastim-fpgk)
- Udenyca® syringe and autoinjector (pegfilgrastim-cbqv)
- Zarxio® syringe (filgrastim-sndz)
- Ziextenzo® syringe (pegfilgrastim-bmez)

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Corticosteroids, Oral Inhaled (ICS)

(Implemented 08/11/2009)
(Updated 2/22/18)
(Effective 4/1/18)
(Updated 1/15/2020)
(Updated 1/1/2023)
(Updated 7/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Arnuity® Ellipta (fluticasone furoate) **– BRAND ONLY**
- Asmanex® HFA (mometasone furoate)
- Asmanex® Twisthaler (mometasone furoate)
- Pulmicort® Flexhaler (budesonide)
- QVAR® Redihaler (beclomethasone dipropionate)

Preferred Agents with Criteria

- Alvesco® HFA (ciclesonide)
- Budesonide ampules for nebulizer (generic for Pulmicort Respules®)

Non-Preferred Agents without Criteria

- ~~Armonair Digihaler® (fluticasone propionate)~~---discontinued 6/1/2024
- Fluticasone Diskus (generic for Flovent Diskus®)
- Fluticasone furoate (generic for Arnuity Ellipta®)
- Pulmicort Respules® (budesonide)

Non-Preferred Agents with Criteria

- Fluticasone HFA (generic for Flovent HFA®)

Approval Criteria for Alvesco® HFA

- Beneficiary must be ≥ 12 years of age or the minimum age recommended in the manufacturer's package insert
- Prescriber must submit documentation of the medical necessity for ALVESCO HFA over the preferred inhaled powder ICS formulation or preferred ICS/LABA product

Approval Criteria for Budesonide Respules Point-of-Sale (POS) Criteria

- **Criteria 1:** Beneficiary < 4 years of age (maximum dose is 2 mg/day)
  OR
- **Criteria 2:** Regardless of age, beneficiary has a billed diagnosis of Eosinophilic Esophagitis
  - Age < 10 years—maximum dose is 2 mg/day
  - Age ≥ 10 years—maximum dose is 4 mg/day

Approval Criteria for Fluticasone HFA Point-of-Sale (POS) Criteria

If one of the following criteria is not met, a prior authorization request will be required:

- **Criteria 1:**
  - Claim for beneficiary < 7 years of age for FLUTICASONE HFA will pay without a prior authorization
  - Beneficiaries < 7 years of age should transition to a preferred inhaled powder ICS formulation or preferred ICS/LABA product when possible

  OR
- **Criteria 2:**
  - Point-of-sale criteria for FLUTICASONE HFA for eosinophilic esophagitis (EoE)
    - Regardless of age, beneficiary with a billed diagnosis of EoE will not require a prior authorization
    - If there is no billed diagnosis of EoE, a prior authorization request must be submitted with documentation of medical necessity

Eosinophilic esophagitis (EoE) – Submit documentation supporting an EoE diagnosis.

Asthma – Beneficiaries ≥7 years of age with asthma should transition to an inhaled powder ICS formulation or ICS/LABA product that is available without a PA if possible (consider the GINA guidelines). If ICS HFA product is still needed, submit documentation of medical necessity over preferred powder ICS products or preferred ICS/LABA combination products. ASMANEX HFA is the preferred ICS HFA product when an ICS HFA formulation is deemed medically necessary.

NOTE: Consider SMART therapy with a preferred ICS-formoterol for use as an as needed (PRN) and regular daily treatment instead of a single agent inhaled corticosteroid (per GINA and EPR-3 Guidelines).

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Corticosteroids-Topical

(Implemented 03/26/2008)
(Updated 5/10/2017, Effective 7/1/2017)
(Updated 7/1/2020)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

The **QUANTITY LIMIT** for topical corticosteroids, in general, for each topical corticosteroid agent will be limited to ***one package size for the NDC*** (e.g., one 15 gm tube, one 30 gm tube, etc.), up to a 240 gm package size *if* the agent is available in a 240 gm size. Topical solutions and lotions will be limited to the *smaller* package size available for that drug entity.

Potency Class 1 – Superpotent, *Preferred Status* only for package sizes noted

- Clobetasol propionate 0.05% solution 25 ml, 50 ml
- Clobetasol propionate 0.05% cream 15 gm, 30 gm, 45 gm, 60 gm
- Clobetasol propionate 0.05% cream-emollient 15 gm, 30 gm, 60 gm
- Clobetasol propionate 0.05% ointment 15 gm, 30 gm, 45 gm, 60 gm
- Fluocinonide 0.1% cream 30 gm, 60 gm, 120 gm
- Halobetasol propionate 0.05% cream 15 gm, 50 gm

Potency Class 1 – Superpotent, *Non-Preferred Status* for all package sizes unless otherwise noted

- Betamethasone dipropionate augmented 0.05% gel
- Betamethasone dipropionate augmented 0.05% lotion
- Betamethasone dipropionate augmented 0.05% ointment (generic for Diprolene®)
- Bryhali® 0.1% lotion (halobetasol propionate)
- Clobetasol propionate 0.05% emollient foam
- Clobetasol propionate 0.05% foam
- Clobetasol propionate 0.05% gel
- Clobetasol propionate 0.05% lotion
- Clobetasol propionate 0.05% shampoo and spray (generic for Clobex®)
- Clobex® 0.05% shampoo and spray (clobetasol propionate)
- Clodan® 0.05% shampoo (clobetasol propionate)
- Desoximetasone 0.25% spray
- Diflorasone diacetate 0.05% ointment
- Diprolene® 0.05% ointment (betamethasone dipropionate augmented)
- Halobetasol propionate 0.05% foam (Lexette™)
- Halobetasol propionate 0.05% ointment 15 gm, 50 gm
- Tovet® 0.05% emollient foam (clobetasol propionate)
- Ultravate® 0.05% lotion (halobetasol propionate)
- Vanos® 0.01% cream (fluocinonide)

Potency Class 2 – Potent, *Preferred Status* only for package sizes noted

- Betamethasone dipropionate augmented 0.05% cream 15 gm, 50 gm
- Fluocinonide 0.05% cream 15 gm, 30 gm, 60 gm, 120 gm
- Fluocinonide 0.05% ointment 15 gm, 30 gm, 60 gm
- Triamcinolone 0.5% ointment 15 gm

Potency Class 2 – Potent, *Non-Preferred Status* for all package sizes unless otherwise noted

- Aplexicon® E 0.05% cream (diflorasone diacetate)
- Clobetasol propionate 0.025% cream
- Desoximetasone 0.25% cream
- Desoximetasone 0.05% gel
- Desoximetasone 0.25% ointment
- Diflorasone 0.05% cream
- Fluocinonide 0.05% gel
- Fluocinonide 0.05% solution
- Halcinonide 0.1% cream
- Halcinonide 0.01% solution
- Topicort® 0.25% cream (desoximetasone)
- Topicort® 0.05% gel (desoximetasone)

Potency Class 3 – Upper-Mid Strength, *Preferred Status* only for package sizes noted

- Betamethasone dipropionate 0.05% (not augmented) lotion 60 ml
- Betamethasone valerate 0.1% ointment 15 gm, 45 gm
- Mometasone furoate 0.1% ointment 15 gm, 45 gm
- Triamcinolone 0.5% cream 15 gm
- Triamcinolone 0.1% ointment 15 gm, 30 gm, 80 gm

Potency Class 3 – Upper-Mid Strength, *Non-Preferred Status* for all package sizes unless otherwise noted

- Amcinonide 0.1% cream
- Betamethasone dipropionate 0.05% cream (not augmented)
- Betamethasone dipropionate 0.05% ointment (not augmented)
- Betamethasone valerate 0.12% foam
- Fluocinonide 0.05% emollient cream
- Fluticasone propionate 0.005% ointment
- Triamcinolone 0.1% ointment 453.6 gm, 454 gm

Potency Class 4 – Mid Strength, *Preferred Status* only for package sizes noted

- Fluocinolone 0.025% ointment 15 gm, 60 gm
- Mometasone furoate 0.1% cream 15 gm, 45 gm
- Mometasone furoate 0.1% solution or lotion 30 ml, 60 ml
- Triamcinolone 0.1% cream 15 gm, 30 gm, 80 gm

Potency Class 4 – Mid Strength, *Non-Preferred Status* for all package sizes unless otherwise noted

- Clocortolone pivalate 0.1% cream
- Desoximetasone 0.05% cream
- Desoximetasone 0.05% ointment
- Flurandrenolide 0.05% ointment
- Hydrocortisone valerate 0.2% ointment
- Synalar® 0.025% ointment (fluocinolone)
- Triamcinolone 0.1% cream, 453.6 gm, 454 gm
- Triamcinolone acetonide 0.1% aerosol spray

Potency Class 5 – Lower-Mid Strength, *Preferred Status* only for package sizes noted

- Betamethasone valerate 0.1% cream 15 gm, 45 gm
- Fluocinolone 0.01% cream 15 gm, 60 gm
- Fluocinolone 0.025% cream 15 gm, 60 gm
- Fluticasone propionate 0.05% cream 15 gm, 30 gm, 60 gm
- Triamcinolone 0.025% lotion 60 ml
- Triamcinolone 0.025% ointment 15 gm, 80 gm
- Triamcinolone 0.1% lotion 60 ml

Potency Class 5 – Lower-Mid Strength, *Non-Preferred Status* for all package sizes unless otherwise noted

- Beser™ 0.05% lotion (fluticasone)
- Betamethasone valerate 0.1% lotion
- Capex® shampoo (fluocinolone)
- Desonide 0.05% lotion
- Desonide 0.05% ointment
- Flurandrenolide 0.05% lotion
- Fluticasone propionate 0.05% lotion
- Hydrocortisone butyrate 0.1% cream
- Hydrocortisone butyrate 0.1% lotion
- Hydrocortisone butyrate 0.1% ointment
- Hydrocortisone butyrate 0.1% solution
- Hydrocortisone valerate 0.2% cream
- Locoid Lipocream® (hydrocortisone butyrate emollient)
- Prednicarbate 0.1% cream emollient
- Prednicarbate 0.1% ointment

- Synalar® 0.025% cream (fluocinolone)
- Triamcinolone 0.025% ointment 454 gm, 430 gm
- Triamcinolone 0.05% ointment 430 gm

Potency Class 6 – Mild, *Preferred Status* only for package sizes noted

- Desonide 0.05% cream 15gm, 60gm
- Fluocinolone 0.01% solution 60 ml
- Triamcinolone 0.025% cream 15 gm, 80 gm

Potency Class 6 – Mild, *Non-Preferred Status* for all package sizes unless otherwise noted

- Alclometasone dipropionate 0.05% cream
- Alclometasone dipropionate 0.05% ointment
- Derma-Smooth FS® 0.01% body/scalp oil (fluocinolone)
- Fluocinolone scalp/body oil 0.01%
- Synalar® 0.1% solution (fluocinolone)
- Triamcinolone 0.025% cream 454 gm

Potency Class 7 – Least Potent, *Preferred Status* only for package sizes noted

- Hydrocortisone acetate 0.5% cream (covered OTC) 28.4 gm
- Hydrocortisone 0.5% cream (covered OTC) 28.4 gm, 28.35 gm
- Hydrocortisone 1% cream 28.35 gm 28.4 gm
- Hydrocortisone 1% ointment 28.35gm 28.4 gm
- Hydrocortisone 2.5% cream 20 gm, 28 gm, 28.35 gm, 30 gm
- Hydrocortisone 2.5% ointment 20 gm 28.35 gm, 28.4 gm

Potency Class 7 – Least Potent, *Non-Preferred Status* for all package sizes unless otherwise noted

- Hydrocortisone 1% cream 453.6 gm, 454 gm
- Hydrocortisone 1% ointment 453.6 gm
- Hydrocortisone 2.5% cream 453.6 gm
- Hydrocortisone 2.5% ointment 453.6 gm, 454 gm
- Hydrocortisone 2.5% lotion
- Hydrocortisone 2.5% solution
- Texacort® 2.5% solution (hydrocortisone)

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Corticotropin gel injection (Acthar HP®)

(Implemented 07/09/2013)
(Updated 10/26/2020)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≤ 2 years of age; **AND**
- Beneficiary must have a diagnosis for infantile spasms (West Syndrome) as indicated by:
  - Epileptic spasms; **AND**
  - Developmental problems; **AND**
  - Hypsarrhythmia on electroencephalography (EEG)
- Prior authorization request should be submitted prior to beginning ACTHAR if being hospitalized and sent again upon discharge; **AND**
- Provider must submit admission clinical notes with initial prior authorization request and discharge summary notes prior to discharge; **AND**
- Provider must submit current body surface area (BSA); **AND**
- Beneficiary has a history of previous vigabatrin (SABRIL) **and** corticosteroid usage with failure; **AND**
- Provider must complete the ACTHAR form with initial request and resubmit the form at time of discharge with specific taper directions; **AND**
- PA will be approved at the time of discharge for the amount needed for completion of the taper. Beneficiaries cannot fill ACTHAR as a pharmacy benefit and use during hospitalization.

Denial Criteria

- Beneficiary has not trialed vigabatrin (SABRIL) **and** corticosteroids; **OR**
- Provider has not submitted all of the required information as outlined on the ACTHAR form; **OR**
- Provider intends to use ACTHAR purchased as a pharmacy benefit during an inpatient stay

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Crinecerfont 25 mg, 50 mg, & 100 mg capsule and 50 mg/ml oral solution (Crenessity™)

(Implemented 4/16/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with classic congenital adrenal hyperplasia with 21-hydroxylase deficiency and meets **ONE** of the following:
  - Requires supraphysiological glucocorticoid doses and has normal androgen levels; **OR**
  - Glucocorticoids provide inadequate androgen control
- Prescribed by, or in consultation with, an endocrinologist
- Beneficiary must remain on glucocorticoid replacement therapy
- Beneficiary requiring concomitant moderate or strong CYP3A4 inducer (e.g., carbamazepine, phenobarbital, bosentan, modafinil) will need dose modification
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Has severe renal impairment or end-stage renal disease
  - Is not prescribed concomitant glucocorticoids
- Prescriber must submit the following:
  - Current chart notes with documentation to support the diagnosis
  - Previous therapies tried with doses
  - Current glucocorticoid dose
  - Current serum androgen levels
  - Current comprehensive lab panel
  - Current weight to confirm proper dosing
- Initial prior authorization will be for 3 months, subsequent approvals may be up to 6 months

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to treatment with a decrease in required glucocorticoid daily doses compared to baseline and decrease in androgen levels (if elevated at baseline)
- Prescriber must submit the following:
  - Current chart notes
  - Current glucocorticoid dose
  - Current serum androgen levels

Quantity Edits

- #60/30 days for each capsule strength (PA override for exceeding this quantity if requires a CYP3A4 inducer)
- #120 ml/30 days for oral solution (PA override for exceeding this quantity if requires a CYP3A4 inducer)

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Crofelemer tablet (Mytesi®)

(Implemented 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary diagnosed with HIV/AIDS and taking anti-retroviral therapy must be diagnosed with symptomatic non-infectious diarrhea
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Diarrhea is caused by an infection
  - Has not tried anti-diarrheal medication
- Prescriber must submit the following:
  - Current chart notes
  - Results of gastrointestinal biopsy, gastrointestinal culture, or stool test
  - Medical necessity over anti-diarrheal medication

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy

Quantity Edits

- #60/30 days

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Cromolyn sodium oral solution (Gastrocrom®)

(Implemented 09/21/2009)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Diagnosis of mastocytosis (congenital pigmentary anomalies or malignant mast cell tumors) in the past three years

Additional Criteria

- Age edit: > 2 years of age

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Cysteamine DR capsule and granules (Procysbi®)

(Implemented 03/18/2014)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with nephropathic cystinosis and be at least 1 year of age or older
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Develops skin or bone lesions (Ehlers-Danlos-like syndrome)—interrupt and start at lower dose
  - Develops severe skin rashes (e.g., erythema multiforme bullosa or toxic epidermal necrolysis)
  - Develops fibrosing colonopathy
  - Confirmed benign intracranial hypertension
  - Develops severe GI ulcers or bleeding—decrease dose
  - Develops leukopenia or elevated alkaline phosphatase levels—decrease dose or discontinue until values normalize
  - Dose requested is not supported in the package insert for patient body surface area
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC and alkaline phosphatase levels
  - Current body surface area for dose calculation
  - Medical necessity over CYSTAGON (cysteamine bitartrate IR)

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Current body surface area

Quantity Edits

- 25 mg capsules - #120/30 days
- 75 mg capsules - #800/30 days (based on max dose of 2000 mg per day)
- 75 mg granules - #800/30 days (based on max dose of 2000 mg per day)
- 300 mg granules - #210/30 days

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Cysteamine ophthalmic drops (Cystaran®, Cystadrops®)

(Implemented 12/10/2013)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with cystinosis and has corneal cystine crystal accumulation
- Prescribers must submit the following:
  - Current chart notes
  - Baseline description of corneal cystine crystals
  - Test results confirming the diagnosis
  - If requested drug is CYSTADROPS, provide the medical necessity of CYSTADROPS over CYSTARAN

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with a decrease in corneal cystine crystals
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy

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Cystic Fibrosis Transmembrane Conductance Regulator Agents (CFTR) – Alyftrek™, Kalydeco®, Orkambi®, Symdeko®, and Trikafta®

(Implemented 7/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Point-Of-Sale (POS) Edits

Criterion 1:

- Beneficiary has a billed diagnosis of Cystic Fibrosis in the last 2 years
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for the specific requested medication
- Beneficiary is prescribed a maximum dose based on support in manufacturer's package insert

OR

Criterion 2:

- Beneficiary Medicaid profile includes a claim for either ALYFTREK, KALYDECO, ORKAMBI, SYMDEKO, OR TRIKAFTA in the last 90 days

Beneficiaries not meeting the POS edits will require a prior authorization. The prescriber must submit a request with current chart notes documenting a Cystic Fibrosis diagnosis.

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Danicopan 50 mg, 100 mg tablet (Voydeya™)

(Implemented 7/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with paroxysmal nocturnal hemoglobinuria (PNH) and require treatment for extravascular hemolysis (EVH) and concomitant therapy with ravulizumab or eculizumab OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must be vaccinated against encapsulated bacteria, including *Streptococcus pneumoniae* and *Neisseria meningitidis* types A, C, W, Y, and B, at least 2 weeks prior to initiation of VOYDEYA, and beneficiary must be provided antibiotics if vaccines were administered less than 2 weeks before starting therapy
- Prescriber and pharmacy must be enrolled in the REMS program
- The medication is prescribed by or in consultation with a hematologist
- Beneficiary must have clinically significant EVH defined as anemia with hemoglobin ≤ 9.5 g/dL and absolute reticulocyte count ≥120 X 10^9/L with or without transfusion support
- Beneficiary must have been on a stable dose of either ravulizumab or eculizumab for at least the previous 6 months.
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Severe hepatic impairment (Child-Pugh C)
  - Not on a stable dose of a C5 inhibitor
  - Treatment plan does not include continuation of a C5 inhibitor
  - Active infections caused by an encapsulated bacteria (such as *Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae* type b)
  - If no vaccinations against encapsulated bacteria (such as *Streptococcus pneumoniae* and *Neisseria meningitidis*) at least 2 weeks prior to initiation of Fabhalta® and no antibiotic drug prophylaxis
  - Pregnant or breastfeeding
- Prescriber must submit the following:
  - Current chart notes
  - Documented symptoms as a baseline
  - Documentation of previous therapies
  - Current labs including complete blood count (CBC), comprehensive metabolic panel (CMP)
  - Recent history of blood transfusions
  - Pregnancy test results (if applicable)
  - Dose requested

Renewal Requirements

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary remains on C5 inhibitor
- Beneficiary has an improvement in hemoglobin and/or reticulocyte count compared to baseline
- Beneficiary has an improvement in overall clinical presentation (e.g., fatigue, dyspnea, reduction in transfusions)
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC and CMP

Quantity Edits

- 150 mg dose (100 mg + 50 mg taken three times daily) - #180 tablets per 30 days
- 200 mg dose (two 100 mg taken three times daily) - #180 tablets per 30 days

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Deferasirox tablet and sprinkle granules (Jadenu®)

(Implemented 04/13/2015)
Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with **ONE** of the following:
  - Chronic iron overload due to blood transfusions (Transfusional Iron Overload) with both of the following:
    - Transfusion of at least 100 mL/kg of packed reb blood cells (e.g., at least 20 units of packed red blood cells for a 40 kg person or more in individuals weighing more than 40 kg)
    - Serum ferritin consistently greater than 1,000 mcg/L
  - Chronic iron overload in non-transfusion-dependent thalassemia syndromes with both of the following:
    - Liver Iron Concentration (LIC) of at least 5 mg Fe/g dw
    - Serum ferritin greater than 300 mcg/L
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has eGFR ≤ 40 mL/min/1.73 m^2
  - Has suspected GI ulceration or hemorrhage
  - Has severe hepatic impairment; dose reduction in moderate hepatic impairment
  - Has high-risk myelodysplastic syndrome
  - Has advanced malignancies
  - Has platelet counts ≤ 50 x 10^9/L
  - Serum ferritin falls below 500 mcg/L in transfusional iron overload patient and less than 300 mcg/L in thalassemia patient (must interrupt and monitor)
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried with response
  - Baseline renal function with eGFR and serum creatinine
  - Baseline serum ferritin level and liver iron concentration (LIC) in thalassemia patient
  - Other current labs including liver function tests and platelets
  - Current weight
  - Medical necessity over EXJADE which is available without a PA

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response (i.e., decrease in liver iron concentration (LIC) and/or serum ferritin)
- Prescriber must submit the following:

- Current chart notes
- Documentation of response to therapy
- Updated labs (i.e., renal function, LFTs, platelets, serum ferritin, LIC)

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Deferiprone tablet (Ferriprox®)

(Implemented 07/09/2012)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with thalassemia syndromes, sickle cell disease or other anemias and need treatment for transfusional iron overload
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has myelodysplastic syndrome
  - Has Diamond Blackfan anemia
  - Develops agranulocytosis with ANC < 0.5 x 10^9/L **OR** neutropenia with ANC < 1.5 x 10^9/L and > 0.5 x 10^9/L
  - Interrupt therapy if neutropenic with ANC < 1.5 x 10^9/L
  - Pregnancy
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies with response
  - Current labs including absolute neutrophil count (ANC), serum ferritin, liver function tests (LFTs), zinc
  - Current weight

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with decrease in liver iron concentration (LIC) and/or serum ferritin
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Updated labs (i.e., LFTs, serum ferritin, ANC)

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Delafloxacin tablet and vial (Baxdela®)

(Implemented 03/14/2018)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with **ONE** of the following:
  - Acute Bacterial Skin and Skin Structure Infections - **BAXDELA** is indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Staphylococcus haemolyticus, Staphylococcus lugdunensis, Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), *Streptococcus pyogenes*, *Enterococcus faecalis*, *Escherichia coli, Enterobacter cloacae, Klebsiella pneumoniae,* and *Pseudomonas aeruginosa.*
  - Community-Acquired Bacterial Pneumonia - **BAXDELA** is indicated in adults for the treatment of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus* (methicillin-susceptible [MSSA] isolates only), *Klebsiella pneumoniae*, *Escherichia coli, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae*, *Chlamydia pneumoniae*, *Legionella pneumophila,* and *Mycoplasma pneumoniae.*
- Beneficiary should not be approved or continue this therapy with any of the following:
  - End Stage Renal Disease (ESRD) (< 15 mL/min/1.73 m^2), including patients on hemodialysis (HD)
  - Infection does not culture with a bacteria listed in the indications
- Prescriber must submit the following:
  - Current chart notes
  - Confirmation of diagnosis with culture
  - Medical necessity over other fluoroquinolones or one of the many other available antibiotics available without a PA

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Denosumab vial (Xgeva®)

(Implemented 01/21/2011)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with **ONE** of the following:
  - Multiple myeloma and bone metastasis from solid tumors
  - Giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
  - Hypercalcemia of malignancy refractory to IV bisphosphonate therapy
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Pre-existing hypocalcemia—therapy delayed until corrected
  - Takes Prolia®
  - Pregnancy
- Prescriber must submit the following:
  - Current chart notes with diagnosis
  - Previous therapies tried
  - Current labs including calcium and vitamin D
- If approved, Xgeva® is preferred over its biosimilars.

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response without intolerable side effects
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Current labs including calcium and vitamin D

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Desmopressin nasal spray and solution (DDAVP®)

(Implemented 03/26/2008)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Diagnosis in Medicaid history of diabetes insipidus in the past three years.

Denial Criteria

- Diagnosis in Medicaid history of nocturnal enuresis in the past three years.
- Diagnosis in Medicaid history of urinary incontinence in the pastthree years.

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Desmopressin acetate tablet (Nocdurna®)

(Implemented 1/16/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Provider must provide documentation to explain and substantiate the medical necessity of the beneficiary receiving NOCDURNA SL tablet over the generic desmopressin tablets that do not require prior authorization
- Beneficiary is adult ≥18 years of age
- Provider must submit gender of the beneficiary at birth as the dose is gender-based because for women is lower than for men because women are more sensitive to the effects of NOCDURNA and women have a higher risk of hyponatremia with the higher dose; approval dose is 27.7 mcg for women; 55.3 mcg for men
- Provider must submit results of confirmed diagnosis of nocturnal polyuria using data from a 24-hour urine collection
- Provider must submit baseline serum sodium concentration
- Beneficiary is not pregnant or lactating
- Initial approval is 1 month

Denial Criteria

- Beneficiary has an eGFR below 50 mL/min/1.73 m2
- Beneficiary is < 18 years of age
- Beneficiary does not meet approval criteria
- Beneficiary diagnosed with heart failure
- Beneficiary currently prescribed loop diuretics or systemic or inhaled glucocorticoids
- Beneficiary has hyponatremia or a history of hyponatremia
- Beneficiary has syndrome of inappropriate antidiuretic hormone secretion (SIADH)
- Beneficiary has illnesses that can cause fluid or electrolyte imbalance
- Female beneficiary is pregnant

Quantity Limits

- 1 tablet daily

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Dexchlorpheniramine maleate (Ryclora™)

(*Implemented 1/16/2019)*

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Provider must submit explanation and documentation of medical necessity of beneficiary receiving this antihistamine over other antihistamines with anticholinergic (drying) and sedative side effects, OTC or legend, (e.g., chlorpheniramine syrup, carbinoxamine liquid, or diphenhydramine liquid) that are covered by AR Medicaid without prior authorization criteria AND over the preferred status non-sedating antihistamines listed on the Medicaid PDL
- Beneficiary is ≥ 2 years of age and ≤ 6 years of age
- Length of PA approval determined at the time of PA approval

Denial Criteria

- Beneficiary is < 2 years of age or > 6 years of age
- Beneficiary has not tried other sedating antihistamines covered by AR Medicaid without prior authorization and available in liquid form
- Beneficiary has not tried the preferred non-sedating antihistamines on the PDL

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Dexamethasone Dose Pack (TaperDex®)

(Implemented 10/11/2011)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that do not require manual review for prior authorization

- Dexamethasone 1.5 mg tablet

Drugs that require manual review for prior authorization

- Dexamethasone dose pack
- TaperDex® dose pack

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Dextromethorphan and Quinidine capsule (Nuedexta®)

(Implemented 06/21/2011)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with pseudobulbar affect (PBA) secondary to a neurological condition (e.g., ALS, MS, Parkinson's disease, stroke, traumatic brain injury)
- Prescribed by or in consultation with a neurologist or psychiatrist
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Requires concomitant quinidine, quinine, or mefloquine
  - Requires concomitant monoamine oxidase inhibitors (MAOI) therapy or stopped the MAOI in the last 14 days (e.g., phenelzine and selegiline)
  - Requires concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimozide)
  - History of prolonged QT interval, congenital long QT syndrome, torsades de pointes, heart failure, or has high risk of complete AV block
  - Pregnancy
- Prescriber must submit the following:
  - Current chart notes
  - Rationale for diagnosis of PBA
  - Baseline number of PBA laughing or crying episodes per day
- Initial PA for 60 days

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with a documented decrease in PBA laughing or crying episodes
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Current PBA episodes per day (laughing and crying)

Quantity Edits

- #60/30 days

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Dichlorphenamide tablet (Keveyis® and Ormalvi™)

(Implemented 02/16/2016)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis or related variants
- Beneficiary must have a trial and failure of acetazolamide along with the appropriate diuretic needed for the patient's diagnosis
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Requires concomitant high dose aspirin
  - If metabolic acidosis develops or persists, consider reducing the dose or discontinuing
  - If hypokalemia develops or persists, consider reducing the dose or discontinuing
- Prescriber must submit the following:
  - Current chart notes
  - Baseline labs including serum potassium and sodium bicarbonate
  - Baseline symptoms with description of muscle weakness attack frequency and severity
- Initial PA for 2 months

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with reduced frequency and severity of attacks
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Current description of frequency and severity of muscle weakness attacks

Quantity Edits

- #120/30 days

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Digoxin 62.5 mcg (Lanoxin®)

(Implemented 7/23/2016)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with heart failure or atrial fibrillation
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Medical necessity over other digoxin strengths that are available without a PA
- Initial PA for 6 months

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Disopyramide CR (Norpace CR®)

(Implemented 04/08/2014)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- >/= 90 days of Disopyramide CR therapy in the past 120 days

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Dornase Alfa inhalation Solution (Pulmozyme®)

(Implemented 01/09/2008)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Diagnosis of cystic fibrosis in medical history

Additional Criteria

- Quantity limits apply

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Doxepin 5% cream (Zonalon®, Prudoxin®)

(Implemented 09/21/2009)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- History of > 2 claims for a steroidal product (Class 5 or higher) in the past 60 days

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Doxycycline/Minocycline

(Implemented 06/19/2008)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851

Drugs that do not require a manual PA

Generic MAC'd solid dosage forms of doxycycline and minocycline including:

- Doxycycline hyclate 20 mg tablet (generic for Periostat®)
- Doxycycline hyclate 50 mg capsule (generic for Vibramycin®)
- Doxycycline hyclate 100 mg capsule (generic for Vibramycin®)
- Doxycycline hyclate 100 mg tablet (generic for Vibra-tab®)
- Doxycycline monohydrate 50 mg capsule (generic for Monodox®)
- Doxycycline monohydrate 100 mg capsule (generic for Monodox®)
- Minocycline HCl 50 mg capsule (generic for Minocin®)
- Minocycline HCl 75 mg capsule (generic for Dynacin®)
- Minocycline HCl 100 mg capsule (generic for Minocin®)

Drugs that require a manual PA

- Doxycycline hyclate 75 mg delayed-release capsule & tablet (generic for Doryx®)
- Doxycycline hyclate 100 mg delayed-release capsule & tablet (generic for Doryx®)
- Doxycycline hyclate 200 mg delayed-release tablet (generic for Doryx®)
- Doxycycline monohydrate 40 mg extended-release capsule (generic for Oracea®)
- Doxycycline hyclate 75 mg tablet
- Doxycycline hyclate 150 mg tablet
- Doxycycline monohydrate 75 mg capsule (generic for Monodox®)
- Doxycycline monohydrate 150 mg capsule (generic for Adoxa®)
- Doxycycline monohydrate 50 mg tablet (generic for Adoxa®)
- Doxycycline monohydrate 75 mg tablet (generic for Adoxa®)
- Doxycycline monohydrate 100 mg tablet (generic for Adoxa®)
- Doxycycline monohydrate 150 mg tablet (generic for Adoxa®)
- Minocycline HCl 50 mg tablet (generic for Dynacin®)
- Minocycline HCl 75 mg tablet (generic for Dynacin®)
- Minocycline HCl 100 mg tablet (generic for Dynacin®)

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Doxylamine succinate/Pyridoxine (Diclegis DR®)

(Implemented 09/18/2013)
(Updated 4/20/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Point-of-Sale (POS) Approval Criteria

- Beneficiary has a billed diagnosis of pregnancy or a lab value confirming pregnancy within the last 9 months without documentation of delivery or pregnancy termination.
- Beneficiary not meeting point-of-sale criteria will require a PA request with documentation of current pregnancy.

Quantity Edits

- #124/31 days

Top of the document

Doxylamine succinate/Pyridoxine (Bonjesta®)

Updated 4/20/2022

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Confirmation of pregnancy
- Medical necessity over DICLEGIS

Quantity Edits

- #62/31 days

Top of the document

Dronabinol (Marinol®)

(Implemented 06/27/2007)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

Criterion 1:

- Age > 18 years of age; **AND**
- Submitted diagnosis HIV within the past 730 days; **AND**
- Submitted diagnosis for cachexia within the past 730 days; **AND**
- At least three paid drug claims in history identifying antiretrovirals (either assingle entity or combo drug) within the past 31 days; **AND**
- Paid claim for megestrol acetate (MEGACE) within the past 31 days (four weeks) (Showing concomitant treatment)

Criterion 2:

- Age > 18 years of age; **AND**
- Submitted diagnosis malignant cancer within the past 365 days; **AND**
- Procedure code indicating radiation treatment within the past 45 days; **AND**
- Paid drug claim in history within the past 45 days for an oral 5-HT3 (serotonin) receptor antagonist; **OR**
- Paid drug claim in history within the past 45 days for a NK1 (neurokinin-1) receptor antagonist

Denial Criteria

- Absence of approval criteria
- Submitted diagnosis of bipolar in medical history.
- Submitted diagnosis of depression in medical history.
- Submitted diagnosis of schizophrenia in medical history.
- Submitted diagnosis of substance or alcohol abuse in medical history.

Additional Criteria

- Quantity limits apply

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Duchenne Muscular Dystrophy Agents

(Added to PDL 4/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents with Criteria (Manual Review)

- Emflaza® suspension (deflazacort) - **BRAND ONLY**
- Emflaza® tablet (deflazacort) - **BRAND ONLY**

Non-Preferred Agents

- Agamree® suspension (vamorolone)
- Deflazacort suspension (generic for Emflaza®)
- Deflazacort tablet (generic for Emflaza®)
- Duvyzat™ suspension (givinostat)

Approval Criteria for Emflaza®

- Beneficiary has a confirmed genetic diagnosis of Duchenne muscular dystrophy (DMD
- Age ≥ 2 years old
- Provide documentation of the mutation in the dystrophin gene
- Prescribed by a provider who specializes in the treatment of DMD and/or neuromuscular disorders
- Provide a letter of medical necessity with a significant reason specific to the beneficiary that EMFLAZA is needed over other glucocorticosteroids, such as prednisone or prednisolone
- Prescriber must submit documentation to substantiate the medical necessity request of EMFLAZA over other glucocorticoid agents, including submitting chart notes, data on all previous glucocorticosteroid(s) tried, and include explanation of failure or explanation of an adverse effect caused by prednisone or prednisolone that is not also caused by EMFLAZA
- Provide documentation of current weight and dosage requested
- Provide documentation that beneficiary has received a baseline eye examination
- Provide documentation that the beneficiary is currently receiving, or planning to receive, physical therapy and provide physical therapy notes
- Provide documentation of Child-Pugh Score (no clinical experience in patients with severe hepatic impairment)

Denial Criteria for Emflaza®

- Beneficiary is < 2 years of age
- Beneficiary does not meet above approval criteria
- Beneficiary has not received prednisone or prednisolone
- Beneficiary did not receive the weight-based dose on a daily schedule of prednisone or prednisolone (0.75 mg/kg/day)

- Beneficiary is classified as Child Pugh C

Approval Criteria for Agamree®

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with Duchenne Muscular Dystrophy (DMD) OR a diagnosis consistent with any new FDA-approved indication. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary has received all appropriate immunizations according to current ACIP guidelines at least two weeks prior to initiation (at least 4 to 6 weeks prior for live attenuated or live vaccines)
- Dose modifications
  - Mild to moderate hepatic impairment – 2 mg/kg once daily with a maximum of 100 mg for beneficiaries more than 50 kg (Severe hepatic impairment will be denied)
  - Coadministration with CYP3A4 inhibitors – 4 mg/kg once daily with a maximum of 200 mg for beneficiaries more than 50 kg
- Prescriber must specialize in the treatment of DMD and/or neuromuscular disorders
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of the mutation in the dystrophin gene
  - Information on previous glucocorticosteroids tried including explanation of failure or adverse effect caused by the steroid that is not also caused by AGAMREE
  - Letter of medical necessity with a significant reason specific to the beneficiary that AGAMREE is needed over other glucocorticosteroids (e.g., prednisone, prednisolone, deflazacort)
  - Current weight and dose requested
  - Documentation that the beneficiary is currently receiving, or planning to receive, physical therapy and provide physical therapy notes
  - A baseline assessment of ambulatory function using the Time to Stand Test (TTSTAND) has been documented prior to initiating AGAMREE therapy
- Requests for non-preferred agents require the medical necessity over brand name EMFLAZA.

Renewal Requirements for Agamree®

- Beneficiary demonstrates a positive response to vamorolone treatment with clinical improvement in ambulatory function as measured by the Time to Stand Test (TTSTAND) compared to baseline after 24 weeks
- Beneficiary lacks clinically significant or intolerable adverse effects related to treatment
- Prescriber must submit the following:
  - Current chart notes
  - Current weight and dose requested

Quantity Edits for Agamree®

- 3 bottles per 30 days

Approval Criteria for Duvyzat™

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with Duchenne Muscular Dystrophy (DMD) **OR** a diagnosis consistent with any new FDA-approved indication. Any off-label requests will be reviewed on a case-by-case basis.
- Prescribed by a provider who specializes in the treatment of DMD and/or neuromuscular disorders
- Beneficiary must have been stable on prednisone, deflazacort, or vamorolone for at least 6 months unless there is a documented contraindication
- Beneficiary will continue corticosteroid therapy concomitantly unless contraindicated
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Baseline platelet count less than 150 x 10^9/L
  - Triglycerides remain elevated despite adequate dietary intervention and dosage adjustment
  - Previous gene therapy for the treatment of DMD (e.g., Elevidys®)
  - Currently non-ambulatory
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of the mutation in the dystrophin gene
  - Previous therapies tried with timeframe and response
  - Current labs including platelets and lipids
  - Baseline ECG results if has underlying cardiac disease or taking concomitant medications that cause QT prolongation
  - Current weight
  - Dose requested
  - Baseline assessment of ambulatory function to be used throughout treatment for consistent monitoring (e.g., Time to Stand Test (TTSTAND), 4-stair climb (4SC) time, North Star Ambulatory Assessment (NSAA)
  - Documentation that the beneficiary is currently receiving, or planning to receive, physical therapy and provide physical therapy notes
  - Letter of medical necessity with a significant clinical reason specific to the beneficiary that DUVYZAT is needed over the preferred medications and of medications available as a medical claim (i.e., eteplirsen, golodirsen, casimersen, and viltolarsen)
- Requests for non-preferred agents require the medical necessity over brand name EMFLAZA.

Renewal Requirements for Duvyzat™

- Beneficiary must be compliant with therapy (defined as 75% utilization)
- Beneficiary demonstrates a positive response with either clinical improvement or a decrease in the rate of function decline compared to baseline
- Beneficiary lacks clinically significant or intolerable adverse effects related to treatment (i.e., platelets remain >150 x 10^9/L)
- Prescriber must submit the following:
  - Current chart notes with documentation of response to therapy

- Current labs including platelets and lipids
- Attestation that the beneficiary continues physical therapy

Quantity Edits for Duvyzat™

- 420 mL (3 bottles)/35 days

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Droxidopa capsule (Northera®)

(Implemented 01/13/2015)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy
- Beneficiary must have tried and failed at least two of the following medications (unless contraindication to all medications):
  - Midodrine
  - Fludrocortisone
  - Pyridostigmine
- Prescriber must submit the following:
  - Current chart notes
  - Document of previous therapies with response
  - Baseline documentation of symptoms
- Initial request should be for 2 weeks

Renewal Requirements

- Prescriber must submit documentation of positive response to treatment with decreased symptoms to continue with authorization.

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Elafibranor tablet (Iqirvo®)

(Implemented 10/16/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with primary biliary cholangitis (PBC) confirmed by **TWO** of the following:
  - An alkaline phosphatase (ALP) level of at least 1.67 times (1.67X) the upper limit of normal
  - Presence of antimitochondrial antibodies (AMA) at a titer of 1:40 or higher
  - Histologic evidence of PBC (nonsuppurative destructive cholangitis and destruction of interlobular bile ducts)
- Must be prescribed by or in consultation with a hepatologist or gastroenterologist
- Beneficiary must have had an inadequate response to ursodeoxycholic acid (UDCA) without improvement in LFTs and documented PBC related symptoms after a 1-year trial or the beneficiary must demonstrate intolerance to UDCA (e.g., Ursodiol)
- Beneficiary with an inadequate response to UDCA alone must take IQIRVO concomitantly with UDCA unless intolerant to UDCA
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
  - Pregnant
  - Complete biliary obstruction
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Documentation of previous therapies tried with response
  - Baseline description of muscle pain or myopathy (evaluate periodically for new onset or worsening muscle pain, myopathy, or rhabdomyolysis)
  - Labs including liver function tests with baseline alkaline phosphatase
  - Current treatment plan
  - Medical necessity over UDCA taken as monotherapy

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to IQIRVO with an improvement in symptoms and corresponding labs while experiencing no intolerable side effects
- Beneficiary must remain on ursodeoxycholic acid (UDCA) concomitantly unless there are tolerability issues

- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy with summary of current symptoms
  - Current labs including liver function tests with alkaline phosphatase
  - Description of muscle pain or myopathy

Quantity Edits

- #30 per 30 days

Top of the document

Eliglustat capsule (Cerdelga®)

(Implemented 01/13/2015)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with Gaucher disease type 1 (GD1) and either be CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs)
- Beneficiary should not be approved or continue the medication if meets one of the following based on CYP2D6 metabolizer status:
  - Extensive metabolizers
    - Taking strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor
    - Moderate or severe hepatic impairment
    - Mild hepatic impairment and taking a strong or moderate CYP2D6 inhibitor
    - End-stage renal disease (CrCl < 15 mL/min)
  - Intermediate metabolizers
    - Taking a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor
    - Taking a strong CYP3A inhibitor
    - Any degree of hepatic or renal impairment
  - Poor metabolizers
    - Taking a strong CYP3A inhibitor
    - Any degree of hepatic or renal impairment
  - Any metabolizer status
    - pre-existing cardiac disease (congestive heart failure, recent acute myocardial infarction, bradycardia, heart block, ventricular arrhythmia)
    - long QT syndrome
    - in combination with Class IA (e.g., quinidine, procainamide) or Class III (e.g., amiodarone, sotalol) antiarrhythmic medications
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Test results confirming type of metabolizer
  - Baseline spleen and liver volume
  - Current labs for kidney and liver function, hemoglobin, and platelets

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with reduction in spleen and/or liver size and increase in hemoglobin and/or platelets
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy

Quantity Edits

- CYP2D6 EMs and IMs—#56/28 days
- CYP2D6 PMs—#28/28 days

Top of the document

Ensifentrine inhalation suspension (Ohtuvayre™)

(Implemented 10/16/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 40 years of age
- Beneficiary must be diagnosed with chronic obstructive pulmonary disease with severity defined by
  - Pre- and Post-bronchodilator FEV1/FVC ratio of < 0.70; **AND**
  - Post-bronchodilator FEV1 ≥ 30% and ≤ 70% predicted normal; **AND**
  - History of ≥ 2 moderate or ≥ 1 severe exacerbation(s) requiring hospitalization within the past 12 months
- Beneficiary has exacerbation(s) while compliant for at least 3 months on **ONE** of the following with continued pulmonary function tests meeting the defined severity listed above:
  - LAMA/LABA combination if blood eosinophil count < 300 cells/µL (drawn in the last 12 months)
  - LAMA/LABA/ICS combination if blood eosinophil count ≥ 300 cells/µL (drawn in the last 12 months)
- Beneficiary must remain on standard maintenance therapy and use this medication as add-on therapy
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Current smoker that refuses to start a cessation plan
- Prescriber must submit the following:
  - Current chart notes with previous and current therapies
  - Current pulmonary function tests as baseline
  - Documentation of smoking history
  - If currently smoking, provide smoking cessation plan
  - Medical necessity over Daliresp® (roflumilast) tablet

Renewal Requirements

- Beneficiary is compliant with therapy (defined as 50% utilization or 90 days of therapy in 186 days)
- Beneficiary must demonstrate a positive response to therapy as indicated by at least **ONE** (1) of the following:
  - Decrease in quantity and/or severity of exacerbations; **OR**
  - Improvement in lung function/FEV1 over baseline; **OR**
  - Improvement in COPD-related symptoms and/or quality of life
- Beneficiary must remain a non-smoker
- Prescriber must submit the following:
  - Current chart notes

- Current PFTs
- Attestation that the beneficiary continues to refrain from smoking

Quantity Edits

- #60 ampules (1 carton)/30 days

Top of the document

Entecavir (Baraclude®)

(Implemented 09/24/2008)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- No history of HIV/AIDS diagnosis in medical history; **OR**
- HIV/AIDS diagnosis in medical history; **AND**
- At least one paid Medicaid drug claim for antiretroviral in past 45 days

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Eosinophilic Esophagitis

(Implemented 7/20/2022)
(Updated 7/19/2023)
(Updated 7/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851

Point-of-Sale (POS) Approval Criteria for Corticosteroids

- Fluticasone HFA (generic for Flovent®) - no point-of-sale criteria required for EoE
- Budesonide Respules
  - **Criteria 1:** Beneficiary < 4 years of age (maximum dose is 2 mg/day); **OR**
  - **Criteria 2:** Regardless of age, beneficiary has a billed diagnosis of EOE in the last 2 years:
    - Age < 10 years - maximum dose is 2 mg/day
    - Age ≥ 10 years - maximum dose is 4 mg/day
- Dose recommendations for budesonide slurry
  - 1-2 mg once daily for patients < 10 y/o
  - 2 mg once daily for patients ≥ 10 y/o; may titrate to 4 mg daily
  - Documentation suggests the use of 0.5 mg/2 mL to ensure enough liquid volume to coat the esophagus.
- Eohilia™ (budesonide) 2 mg/10 mL suspension
  - Beneficiary must have a billed diagnosis of eosinophilic esophagitis (EoE) in the last 2 years
  - Beneficiary must be ≥ 11 years of age or meet the minimum age recommended in the manufacturer's package insert for this FDA approved indication
  - Beneficiary must be prescribed no more than 4 mg per day
  - Beneficiary will be allowed up to 12 weeks of treatment (request for more than 12 weeks will require a prior authorization)
- Renewal Requirements for Eohilia™:
  - Currently, data for treatment with EOHILIA beyond 12 weeks has not been shown to be safe and effective for the treatment of EoE.
  - If beneficiary is positively responding to EOHILIA, continuation may be considered after EGD at 12 weeks.
  - Prescriber must submit the following:
    - Current chart notes
    - EGD report after 12 weeks of therapy
    - Medical necessity over fluticasone HFA and budesonide respules
- Quantity Edit for Eohilia™: #60 doses (1 carton) per 30 days

Manual Review Approval Criteria for Dupixent® (dupilumab)

- Beneficiary must be aged 1 year and older, weighing at least 15 kg, **OR** the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must have a confirmed diagnosis of eosinophilic esophagitis (EOE) with an esophageal biopsy that indicates ≥15 eosinophils per high-power field (eos/hpf) and **ONE** of the following:
  - Symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, chest pain); **OR**
  - Endoscopy features consistent with eosinophilic esophagitis (e.g., stacked circular rings, esophageal strictures, linear furrows)
- Beneficiary must have at least a 12-week trial and failure of swallowed corticosteroids (e.g., fluticasone or budesonide)
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies including dietary restrictions, procedures, or pharmacological treatment
  - Baseline eos/hpf after corticosteroid and PPI trials
  - Baseline beneficiary determined Dysphagia Symptom Questionnaire (DSQ) score

Continuation Criteria for Dupixent® (dupilumab)

- Beneficiary demonstrates a positive response with one of the following after 6 months of treatment:
  - Achieved remission with ≤ 6 eos/hpf; **OR**
  - Decrease in DSQ score from baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current beneficiary determined DSQ score
  - Current eos/hpf

Top of the document

Eplontersen sodium 45 mg/0.8 mL injection (Wainua™)

(Implemented 4/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1- 800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary with multisystem symptoms and/or family history with the diagnosis confirmed with **ONE** of the following:
  - Confirmation of a transthyretin (TTR) variant by genetic testing
  - Tissue biopsy confirming the presence of amyloid deposits
- This medication must be prescribed by or in consultation with a neurologist
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Severe renal impairment or end-stage renal disease
  - Moderate or severe hepatic impairment
- Prescriber must submit the following:
  - Current chart notes
  - Medical necessity over preferred neuropathic pain agents
  - Attestation that Vitamin A is being monitored for possible supplementation
  - Baseline modified Neuropathy Impairment Score +7 (mNIS+7) and Norfolk Quality of Life-Diabetic neuropathy (QoL-DN) total score
  - Previous therapies tried
  - Current labs including liver function tests (LFTs) and basic metabolic panel (BMP)

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75%)
- Beneficiary must demonstrate a positive response with either reduced or stable mNIS+7 and/or QoL-DN scores with improvement in neuropathy
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including LFTs and BMP

Quantity Edits

- #1/30 days

Top of the document

Esketamine solution (Spravato®)

(Implemented 5/1/2020)
(Updated 5/10/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with **ONE** of the following:
  - Treatment resistant depression (TRD) with Spravato® to be used as monotherapy or in conjunction with an oral antidepressant
  - Depressive symptoms with major depressive disorder with acute suicidal ideation or behavior with Spravato® used in conjunction with an oral antidepressant
  - Diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary must have failed treatment with a minimum of **THREE** separate therapeutic trials including antidepressants from at least **TWO** different drug classes (SSRI, SNRI and bupropion) as well as at least **ONE** trial of augmentation therapy with one of the following:
  - Atypical antipsychotic
  - Lithium
  - Antidepressant from a different class
- Beneficiary's profile will be reviewed for compliance on previous therapies with at least **EIGHT** weeks each for the nonconcurrent monotherapies at maximally tolerated doses
- Prescriber must be enrolled as a Spravato® REMS-certified provider and must make arrangements with the beneficiary's pharmacy for delivery of the medication
- Beneficiary must be enrolled in the Spravato® REMS program
- Medication must be administered under the direct supervision of a healthcare provider with post-administration observation for a minimum of 2 hours
- Prescriber must review the beneficiary's PDMP for evidence of abuse potential and attest that the beneficiary will be monitored for signs of abuse or misuse
- Beneficiary must not be pregnant or breastfeeding
- Beneficiary must not have active moderate or severe substance or alcohol use disorder
- Beneficiary must not have aneurysmal vascular disease, a history of intracerebral hemorrhage or a hypersensitivity to esketamine/ketamine
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Documentation of previous failed therapies
  - If beneficiary tried IV Ketamine, provide documentation of trial and response
  - Baseline depression assessment using a validated depression rating scale
  - Treatment plan for possible serious cardiac adverse events during treatment session (i.e., access to emergency care)
- Initial approval for 4 weeks only for twice weekly dosing. If twice weekly dosing is required for longer than 4 weeks, an additional prior authorization request will need to be submitted.

Quantity Edits

- Initial PA (weeks 1-4)—2 kits/week
- Renewal PA (week 5 and after)—1 kit/week

Top of the document

Erythropoiesis Stimulating Agents

(Implemented 03/26/2008)
(Re-review 5/10/18)
(Effective 7/1/18)
(Updated 4/15/2020)
(Updated 4/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Aranesp® syringe (darbepoetin alfa in polysorbate)
- Epogen® vial (epoetin alfa)
- Retacrit® vial (epoetin alfa)

Non-Preferred Agents

- Aranesp® vial (darbepoetin alfa in polysorbate)
- Mircera® syringe (methoxy peg-epoetin beta)
- Procrit® vial (epoetin alfa)
- Reblozyl® vial (luspatercept)

Approval Criteria for Preferred Agents with Criteria

- The Prime system reviews lab results for the previous 30 days for a hemoglobin (Hgb) level.
- If a Hgb level is available and ≤ 10 g/dL, a claim will process at point-of-sale without a prior authorization.
- If hemoglobin level is not available in the Prime system or the beneficiary does not meet the above lab requirement, a prior authorization request must be submitted.

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Estrogen-Replacement Agents

(Implemented 07/11/2008)
(Updated 10/31/2015)
(Updated 4/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Climara® Pro patch (estradiol/levonorgestrel)
- Estradiol oral tablet (generic for Estrace®)
- Estradiol once weekly transdermal (generic for Climara®)
- Estradiol twice weekly transdermal (generic for Alora®, Vivelle-Dot®, Minivelle® Dotti®, Lyllana®)
- Premarin® tablet (conjugated estrogen)
- Prempro® tablet (conjugated estrogen/medroxyprogesterone)

Non-Preferred Agents

- Activella® tablet (estradiol/norethindrone acetate)
- Alora® patch (estradiol)
- Amabelz® tablet (estradiol/norethindrone acetate)
- Bijuva® capsule (estradiol/progesterone)
- Climara® patch (estradiol)
- Combipatch® patch (estradiol/norethindrone acetate)
- DivigeL® topical gel (estradiol)
- Dotti® patch (estradiol)
- Duavee® tablet (estrogens, conjugated/Bazedoxifene)
- Elestrin® gel (estradiol)
- Estrace® tablet (estradiol)
- Estradiol gel (generic for Estrogel®)
- Evamist® spray (estradiol)
- Fyavolv® tablet (ethinyl estradiol/norethindrone)
- Jinteli® tablet (ethinyl estradiol/norethindrone)
- Lopreeza® tablet (estradiol/norethindrone acetate)
- Lyllana® patch (estradiol)
- Menest® tablet (estrogens, esterified)
- Menostar® patch (estradiol)
- Mimvey® tablet (estradiol/norethindrone acetate)
- Minivelle® patch (estradiol)
- Vivelle-Dot® patch (estradiol)

Non-Preferred Agents with Criteria

- Angeliq® (Estradiol/drospirenone)

- Estradiol/norethindrone (generic for Activella®, Amabelz®, Lopreeza®, Mimvey®)
- Ethinyl estradiol/norethindrone acetate (Femhrt®, Jintelli®, Fyavolv®)
- Prefest® (estradiol/norgestimate)
- Premphase® (estrogens, conjugated/medroxyprogesterone)

Approval Criteria for Non-Preferred Agents with Criteria

- ≥ 120 days of therapy in the previous 180 days for the same drug, strength, and dosage form

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Everolimus Tablet (Zortress®)

(Implemented 04/10/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Point-of-Sale (POS) Approval Criteria

- Beneficiary is age 18 years or greater; **AND**
- Diagnosis in Medicaid history of kidney transplant (Z94.0) **OR** liver transplant (Z94.4) in previous 2 years; **AND**
- No therapeutic duplication between different strengths of ZORTRESS or between other brand names of everolimus (e.g., AFINITOR)

Quantity Edits

- 2 tablets per day **AND** #60 for 30-day supply

Top of the document

Famotidine 40mg/5ml oral suspension (Pepcid®)

(Implemented 09/24/2008)
(Updated 11/1/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- < 7 years of age; **OR**
- NPO (Appendix A) within the past 365 days

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Fecal Microbiota Spores, Live-brpk capsule (Vowst™)

(Effective 7/19/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with *Clostridioides difficile* infection (CDI) following antibacterial treatment for recurrent CDI (rCDI) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have at least 3 separate confirmed *C difficile* infections within 12 months (definition of recurrent CDI) and given prior therapy with vancomycin and/or fidaxomicin. *C difficile* should be diagnosed based on positive diagnostic laboratory assay and typical manifestations with ≥ 3 loose stools in 24 hours.
- Beneficiary must have completed antibacterial treatment for recurrent CDI 2-4 days before initiating treatment with VOWST
- Beneficiary must be prescribed magnesium citrate to take the day prior to beginning VOWST
- Beneficiary should not be approved if any of the following:
  - Prescribed concomitant antibacterial therapy
  - Does not meet the requirements for recurrent CDI
  - Has not been treated with either vancomycin or fidaxomicin
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of treatment for previous CDI episodes
  - Previous laboratory assay results noting *C difficile*
  - Medical necessity over vancomycin and fidaxomicin if have not been tried and failed
- PA for 1 claim

Quantity Edits

- #12 per claim

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Fenfluramine Solution (Fintepla®)

(Implemented 10/21/2020)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 2 and ≤ 18 years of age; **AND**
- Beneficiary has a diagnosis of seizures associated with Dravet syndrome **OR** a diagnosis consistent with FDA indications; **AND**
- Provider must submit written documentation showing convulsive status epilepticus, alternating hemiconvulsions, **OR** myoclonic seizures and include genetic testing results for Dravet Syndrome that shows mutations within SCN1A gene.
- Prescriber, pharmacy and beneficiary must all be enrolled in the FINTEPLA REMS program; **AND**
- Beneficiary must have inadequately controlled seizures while on at least one anti-epileptic drug (Trials required a minimum of 6 convulsive seizures in a 6-week baseline period while stable on current AEDs.); **AND**
- Maximum dose for beneficiaries NOT taking stiripentol is 0.35 mg/kg twice daily (26 mg per day), and maximum dose for beneficiaries taking stiripentol is 0.2 mg/kg twice daily (17 mg per day); **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of weight and blood pressure; **AND**
  - Current list of medications with doses and all other therapies tried; **AND**
  - Current baseline seizure activity; **AND**
  - Current labs including CBC, BMP and LFTs; **AND**
  - Results from echocardiogram (must evaluate for valvular heart disease and pulmonary arterial hypertension); **AND**
  - Current dose needed based on weight and stiripentol usage

Denial Criteria

- Beneficiary does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Beneficiary has moderate or severe renal impairment; **OR**
- Beneficiary has hepatic impairment; **OR**
- Beneficiary has valvular heart disease or pulmonary arterial hypertension; **OR**
- Beneficiary requires concomitant monoamine oxidase inhibitors; **OR**
- Beneficiary develops acute decrease in visual acuity or ocular pain; **OR**
- Prescriber orders dosing not consistent with FDA approved labeling.

Quantity Edits

- 360 mL bottle: 1 bottle/30 days - gives maximum dose of 26 mg per day.

Top of the document

Ferric maltol 30 mg capsule (Accrufer®)

(Implemented 04/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with iron deficiency **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have a baseline hemoglobin less than 12 mg/dL and baseline ferritin < 30 mcg/L
- Beneficiary must have tried and failed other ferrous products (i.e., sulfate, gluconate, or fumarate) or have a contraindication
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC and ferritin panel
  - Expected cause of iron deficiency

Renewal Requirements

- Beneficiary continues to be at risk for iron deficiency (e.g., chronic kidney disease, inflammatory bowel disease)
- Beneficiary had a positive response with increased ferritin and/or hemoglobin
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC and ferritin panel

Quantity Edits

- #60/30 days

Top of the document

Fezolinetant 45 mg tablet (Veozah™) *(Effective 7/19/2023)*

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with menopause and experiencing moderate to severe vasomotor symptoms **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Documentation that moderate to severe vasomotor symptoms have been disruptive to daily life must be provided (e.g., sleep disruption, night sweats, daytime hot flashes, palpitations)
- Beneficiary must be confirmed as menopausal with 1 of the following:
  - Spontaneous amenorrhea for ≥ 12 consecutive months
  - Spontaneous amenorrhea for ≥ 6 months with biochemical criteria of menopause (follicle-stimulating hormone [FSH] > 40 IU/L); **OR**
  - Having had bilateral oophorectomy ≥ 6 weeks prior to the screening visit.
- Beneficiary must have tried and failed hormone replacement therapy or have a contraindication to hormone replacement therapy
- Beneficiary should not be approved if any of the following:
  - Has cirrhosis
  - Has severe renal impairment or end-stage renal disease (eGFR < 30 mL/min/1.73 m^2)
  - Requires concomitant use with CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Current labs including FSH level, LFTs, and CMP
  - Duration of symptoms
  - Medical necessity over hormone replacement therapy and other options supported in literature (i.e., SSRIs, SNRIs, anti-epileptics, clonidine)
- Initial PA for 3 months

Renewal Requirements

- Beneficiary has a documented improvement in symptoms
- Beneficiary is compliant on the medication (defined as 75% utilization)
- Prescriber must submit current chart notes with documentation of response
- Renewal PAs can be approved for 6 months

Quantity Edits

- #31/31 days

Finerenone (Kerendia®)

(Implemented 1/19/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 18 years of age; **AND**
- Beneficiary must have a diagnosis of Type 2 diabetes mellitus and chronic kidney disease **OR** a diagnosis consistent with FDA indications; **AND**
- Beneficiary must have one of the following to confirm the diagnosis of CKD with T2D:
  - UACR of 30-300 mg/g, eGFR 25-60 mL/min/1.73m^2 and diabetic retinopathy **OR**
  - UACR of ≥ 300 mg/g and eGFR 25-75 mL/min/1.73m^2
- Beneficiary must have been treated with an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) unless contraindicated and receiving treatment for diabetes based on treatment guidelines; **AND**
- Beneficiary must have tried and failed an aldosterone inhibitor unless contraindicated; **AND**
- Beneficiary must be a non-smoker or participating in a tobacco cessation program; **AND**
- Beneficiary must have controlled diabetes (HbA1c <9%) and blood pressure (BP < 130/85); **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of previous therapies; **AND**
  - Current labs including Urinary Albumin-to-Creatinine Ratio (UACR), eGFR, and potassium level; **AND**
  - Medical necessity over other mineralocorticoid receptor antagonists available without a PA
- Initial approval for 3 months

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported on the official
- Compendia; **OR**
- Beneficiary has eGFR < 25 mL/min/1.73m^2; **OR**
- Beneficiary's baseline serum potassium is > 5 mEq/L; **OR**
- Beneficiary is receiving concomitant strong CYP3A4 inhibitors (e.g., fluconazole) and strong or moderate CYP3A4 inducers (e.g., efavirenz, rifampicin); **OR**
- Beneficiary has been diagnosed with adrenal insufficiency (Addison's disease)

Quantity Edits

- 20 mg - #31/ 31 days
- 10 mg - #31/ 31 days

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Fidaxomicin (Dificid®)

(Implemented 01/12/2012)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- At least 1 paid claim in Medicaid history for VANCOMYCIN (oral or injectable compounded for oral use) in the previous 10 to 30 days.

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Flouride toothpaste (Fraiche 5000 PREVI, Fraiche 5000 Sensitive, Fraiche 5000, Fraiche 5000 Kids Plus)

(Implemented 7/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- For FRAICHE 5000 PREVI and FRAICHE 5000 Sensitive, beneficiary must have documented tooth sensitivity with necessity of a fluoride toothpaste
- Prescriber must submit the following:
  - Current visit notes
  - Documentation of the medical necessity over fluoride products which are available without a prior authorization

Quantity Edit

- 1 tube per 31 days

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Fluorouracil solution/cream (Efudex®)

(Implemented 06/21/2011)
(Updated 01/17/2017)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria for Fluorouracil 2% Solution

- Diagnosis of Actinic Keratosis in Medicaid history in the past 2 months; **AND**
- No therapeutic duplication with Diclofenac Sodium 3% gel (SOLARAZE); **OR**
- No therapeutic duplication with other strengths of Fluorouracil cream or solution (CARAC, EFUDEX); **OR**
- No therapeutic duplication with Imiquimod cream (ALDARA, ZYCLARA)

Approval Criteria for Fluorouracil 5% Cream or Solution

- Diagnosis of Actinic Keratosis or Basal Cell Carcinoma in Medicaid history in the past 2 months; **AND**
- No therapeutic duplication with Diclofenac Sodium 3% gel (SOLARAZE); **OR**
- No therapeutic duplication with other strengths of Fluorouracil cream or solution (CARAC, EFUDEX); **OR**
- No therapeutic duplication with Imiquimod cream (ALDARA, ZYCLARA)

Additional Criteria

- Quantity limits may apply

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Fluorouracil cream (Carac® 0.5%)

(Updated 01/17/2017)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Diagnosis of Actinic or Solar Keratosis in Medicaid history in the past 2 months; **AND**
- No therapeutic duplication with Diclofenac Sodium 3% gel (SOLARAZE); **OR**
- No therapeutic duplication with other strengths of Fluorouracil cream or solution (EFUDEX); **OR**
- No therapeutic duplication with Imiquimod cream (ALDARA, ZYCLARA)
- PA for 1 month only
- Max quantity of 1 tube per claim

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Foscarbidopa/foslevodopa 120 mg/2400 mg injection (Vyalev®)

(Implemented 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with advanced Parkinson's disease and experiencing continued motor fluctuations despite compliance on carbidopa/levodopa **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have demonstrated a previous response to levodopa but continue to have motor fluctuations with a minimum of 2.5 hours of "Off" time per day
- Prescriber must attest that patient/caregivers have been counseled on potential adverse effects that require monitoring that could require a dose reduction or discontinuation (i.e., impulsive behaviors, infusion site reactions, dyskinesia, and glaucoma)
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Requires non-selective monoamine oxidase (MAO) inhibitor
  - Has a major psychiatric disorder
- Prescriber must submit the following:
  - Current chart notes
  - Current symptoms of Parkinson's Disease
  - Average number of "Off" hours per day
  - Medical necessity over increasing the dose on long and short acting oral carbidopa/levodopa products

Renewal Requirements

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary demonstrates a decrease in "Off" hours compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Attestation that patient continues to be monitored for potential adverse reactions (i.e., impulsive behaviors, infusion site reactions, dyskinesia, and glaucoma

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Furosemide 80 mg/ml injection (Furoscix®)

(Implemented 1/17/2024)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with fluid overload and with **ONE** of the following:
  - New York Heart Association (NYHA) Class III chronic heart failure; **OR**
  - Chronic Kidney Disease (CKD); **OR**
  - Diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Must be prescribed by or in consultation with a cardiologist
- Beneficiary must have tried and failed oral furosemide (160 mg) **AND** one of the following:
  - Torsemide (40 mg)
  - Bumetanide (4 mg)
- Beneficiary must be adherent to CHF therapies (i.e., ACE/ARB, beta blockers, salt restrictions) or medications for CKD (i.e., SGLT-2 inhibitors, diuretics)
- Beneficiary must have documented recent weight gain and increased edema or other symptoms of extracellular volume expansion (e.g., jugular venous distention, pulmonary congestion or rales)
- Prescriber must submit ALL the following:
  - Current chart notes
  - Current and previous therapies for heart failure
  - Medical necessity over oral and IV furosemide and other diuretics class
  - Current and baseline weight
  - Confirmation that beneficiary has a history of at least one prior hospitalization or emergency department visit due to heart failure or chronic kidney disease exacerbations and/or fluid overload, and the beneficiary is stable enough to avoid hospitalization at the time of administration
  - Current labs
  - Attestation that FUROSCIX will be used short-term then transitioned back to oral diuretics as soon as practical.

Renewal Requirements

- Beneficiary continues to have fluid overload
- Prescriber must submit the following:
  - Current chart notes
  - Continued treatment plan for fluid overload
  - Current weight and description of edema

Quantity Edits

- #2 per claim

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Gabapentin Quantity Edits

(Effective 7/15/2020)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for these products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

December 19, 2019--The U.S. Food and Drug Administration (FDA) is warning that serious breathing difficulties may occur in patients using gabapentin (NEURONTIN, GRALISE, HORIZANT) or pregabalin (LYRICA, LYRICA CR) who have respiratory risk factors. These include the use of opioid pain medicines and other drugs that depress the central nervous system, and conditions such as chronic obstructive pulmonary disease (COPD) that reduce lung function. The elderly are also at higher risk.

Approval Criteria

- For Neurontin® (gabapentin), limit to 3600 mg per day.
- For Gralise®, limit to 1800 mg per day
- For Horizant®, limit to 1200 mg per day.

Quantity Edits

- Gabapentin 100 mg capsule -- 248/31 days
- Gabapentin 250 mg/5 ml -- 3 bottles (1410 ml) per 30 days
- Gabapentin 300 mg capsule -- 372/31 days
- Gabapentin 400 mg capsule -- 279/31 days
- Gabapentin 600 mg tablet -- 186/31 days
- Gabapentin 800 mg tablet -- 140/31 days
- Gralise® 300 mg tablet -- 155/31 days
- Gralise® 450 mg tablet -- 93/31 days
- Gralise® 600 mg tablet -- 93/31 days
- Gralise® 750 mg tablet -- 62/31 days
- Gralise® 900 mg tablet -- 62/31 days
- Horizant® 300 mg tablet -- 31/31 days
- Horizant® 600 mg tablet -- 62/31 days

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Ganaxolone (Ztalmy®)

(Effective 10/19/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥2 years of age
- Beneficiary must have a diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) OR a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Beneficiary's seizures are refractory to current antiepileptic therapy with at least 2 previous trials with different MOA
- Beneficiaries requiring a CYP3A4 inducer should avoid this medication. If unavoidable, the ZTALMY dose should be increased.
- Prescriber must order a dose titration and should not order a dose that exceeds the dose supported in the FDA approved package insert or MicroMedex®:
  - Weight ≤ 28 kg: maximum dose is 63 mg/kg/day
  - Weight > 28 kg: maximum dose is 1,800 mg/day
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Current weight
  - Genetic testing results confirming the presence of the CDKL5 mutation
  - Previous therapies tried with response
  - Baseline average daily seizure count
  - Attestation that the beneficiary/caregiver has been educated on titration schedule

Quantity Edits

- For max dose of 1800 mg daily = 36 mL per day (1116 mL per 31 days)

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Glaucoma Agents

(Implemented 7/1/17)
(Updated 7/1/2020)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Status only for strengths and package sizes noted

- Alphagan P® 0.15% drops 5 ml, 10 ml, 15 ml (brimonidine) – **BRAND ONLY**
- Carteolol 1% solution drops 5 ml, 10 ml, 15 ml (generic for Ocupress®)
- Combigan® solution drops 5 ml, 10 ml, 15 ml (brimonidine 0.2%/ timolol 0.5%) - **BRAND ONLY**
- Dorzolamide 2% drops 10 ml (generic for Trusopt®)
- Dorzolamide/timolol 22.3-6.8 mg/ml drops 10 ml (generic for Cosopt®)
- Latanoprost 0.005% solution drops 2.5 ml (generic for Xalatan®)
- Levobunolol 0.5% solution drops 5 ml (generic for Betagan®)
- Lumigan® 0.01% solution drops 2.5 ml, 5 ml (bimatoprost)
- Rhopressa® 0.02% drops (netarsudil)
- Rocklatan® 0.02%/0.005% drops 2.5 ml (netarsudil/latanoprost)
- Timolol 0.25%, 0.5% solution drops 5 ml, 10 ml, 15 ml (generic for Timoptic®)
- Travatan Z® 2.5 ml, 5 ml solution drops (travoprost) - **BRAND ONLY**

Non-Preferred Status, all package sizes unless otherwise noted

- Alphagan P® 0.1% drops (brimonidine)
- Apraclonidine 0.5%solution drops (generic for Iopidine®)
- Azopt 1% drops (brinzolamide)
- Betaxolol 0.5% solution drops (generic for Betoptic®)
- Betimol® 0.25%, 0.5% drops (timolol)
- Betoptic S® 0.25% drops (betaxolol)
- Bimatoprost 0.03% solution drops (generic for Lumigan®)
- Brimonidine 0.1%, 0.15%, 0.2% drops (generic for Alphagan®/Alphagan P®)
- Brimonidine 0.2%/timolol 0.5% (generic for Combigan®)
- Brinzolamide 1% suspension drops (generic for Azopt®)
- Cosopt® 2%/0.5% drops (dorzolamide/timolol)
- Cosopt® PF 2%/0.5% drops (dorzolamide 2%/timolol)
- Dorzolamide 2%/timolol 0.5% solution drops (generic for Cosopt® PF)
- Istalol® 0.5% drops (timolol maleate)
- Iyuzeh® 0.005% drops (latanoprost)
- Phospholine Iodide® 0.125% drops (echothiopate)
- Pilocarpine 1%, 2%, 4% solution drops (generic for Pilocar®)
- Simbrinza® suspension drops (brimonidine 1%/brinzolamide 0.2%)
- Tafluprost 0.0015% drops (generic for Zioptan®)
- Timolol 0.25%, 0.5% gel forming solution (generic for Timoptic-XE®)

- Timolol 0.5% drops (generic for Betimol®)
- Timolol maleate 0.5% drops (generic for Istalol®)
- Timolol preservative free 0.25%, 0.5% (generic for Timoptic Ocudose®)
- Timoptic Ocudose® 0.25%, 0.5% (timolol)
- Travoprost 0.004% (generic for Travatan Z®)
- Vyzulta® 0.024% drops (latanoprostene bunod)
- Xalatan® 0.005% drops (latanoprost)
- Xelpros™ 0.005% solution/drops (latanoprost)
- Zioptan® 0.0015% drops (tafluprost)

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Glutamine powder (Endari®)

(Implemented 03/01/2018)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with sickle cell disease and is at least 5 years of age
- Beneficiary must be compliant on hydroxyurea for a minimum of 6 months prior to prior authorization request unless discontinued for failed response while compliant or experiences intolerable toxicity
- Beneficiary must experience at least 2 painful sickle cell crises in the previous 12 months while compliant on hydroxyurea with ER or hospital admissions requiring parentally-administered narcotics or ketorolac
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Not compliant on hydroxyurea for a minimum of 6 months unless discontinued by prescriber due to intolerance or lack of efficacy while compliant
  - Pregnancy
  - Dose not supported in package insert for weight
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried with treatment duration and response including current hydroxyurea dose
  - If hydroxyurea has been discontinued, provide documentation of either failure (with supporting labs/documentation of sickle cell crises compared with prior to trial of hydroxyurea) or intolerable toxicity with required intervention
  - Provide baseline summary pf painful crises, blood transfusions, and hospitalizations with documentation and medical records for hospitalizations and ER visits
  - Current weight
  - Treatment plan for handling acute complications of sickle cell disease
  - Letter of medical necessity for adding ENDARI to treatment plan
  - Current labs including
    - INR
    - Serum albumin
    - Baseline fetal hemoglobin (HbF) level prior to hydroxyurea
    - Current HbF while on hydroxyurea
- Initial PA for 3 months unless an adult with stable weight then can be approved for 6 months

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization) for both ENDARI and hydroxyurea
- Beneficiary must demonstrate a positive response with any of the following by 6 months of treatment (beneficiary's Medicaid profile will be reviewed along with submitted documentation):
  - Decreased chronic pain with decreased opioid use
  - Reduction of painful sickle cell crises compared with prior to starting ENDARI
  - Decrease in ER admissions or hospitalizations for sickle cell anemia or related pain requiring transfusions and/or parenteral pain treatment
  - Reduction in occurrence of Acute Chest Syndrome or fewer cumulative day as in-patient in hospital
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Current weight
  - Current labs
  - Summary of transfusions, ER visits, or hospitalizations since previous approval

Quantity Edits

- Maximum of 6 packets per day; 180 packets/30 days

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Glycopyrrolate 0.2 mg/ml vial

(Implemented 07/08/2014)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that do not require prior authorization

- Glycopyrrolate 1 mg/5 ml oral solution (generic for Cuvposa®)

Drugs that require manual review for prior authorization

- Glycopyrrolate 0.2 mg/ml vial

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Glycopyrrolate tablet (Dartisla ODT® 1.7 mg and Glycate® 1.5 mg)

(Implemented 03/18/2014)
(Updated 5/10/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with peptic ulcer disease and used as an adjunct to other treatment to reduce symptoms **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary should not be approved if at risk for anticholinergic toxicity (e.g., glaucoma, obstructive uropathies, mechanical obstructive diseases of GI tract, GI motility disorders, active inflammatory or infectious colitis, history of or current toxic megacolon, myasthenia gravis)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous and current therapies
  - Medical necessity of DARTISLA ODT or GLYCATE over regular glycopyrrolate tablets which are available without a PA

Renewal Requirements

- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy (if asymptomatic, provider rationale for continued use)
  - Continued medical necessity of DARTISLA ODT or GLYCATE (over glycopyrrolate tablets)

Quantity Edits

- #124/31 days

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Growth Hormone

(Implemented 01/24/2007)
(Updated10/01/2016)
(Updated1/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents that require manual review for prior authorization

- Genotropin® (somatropin)
- Norditropin® (somatropin)

Non-Preferred Agents

- Humatrope® (somatropin)
- Ngenla® pen (somatrogon-ghla)
- Nutropin AQ® pen® (somatropin)
- Omnitrope® (somatropin)
- Skytrofa® (lonapegsomatropin-tcgd))
- Sogroya® (somapacitan-beco)
- Zomacton® (somatropin)

Approval Criteria for Preferred Agents

In children, we may need to question continuation when growth velocity is ≤ 2.5 cm/year.

Criterion 1:

- Beneficiary < 18 years of age
- Beneficiary has one of the following diagnoses:
  - Diagnosis of Prader-Willi Syndrome (PWS) with the following exceptions
    - Severe obesity (>225% of IBW)
    - Untreated severe obstructive sleep apnea
    - History of severe respiratory impairment
    - Untreated or uncontrolled diabetes, hypothyroidism, or adrenal insufficiency
  - Diagnosis of Turner Syndrome
  - Diagnosis of Noonan Syndrome
  - Diagnosis of chronic renal insufficiency or end-stage renal disease awaiting transplant
- Provocative GH stimulation test is not required
- Epiphyses should remain open during treatment and should be monitored beginning at 13-14 years of age. Bone age should be done at least yearly to verify that the epiphyses are open. Growth velocity can be taken into consideration to determine efficacy. If the growth velocity has slowed regardless of epiphyses status, use your best judgement on continuation.

Criterion 2:

- Beneficiary < 18 years of age
- Beneficiary has one of the following diagnoses:
  - Panhypopituitarism
  - Craniopharyngioma
  - Septo-optic dysplasia
- Provocative GH stimulation test and bone age are not required

Criterion 3:

- Beneficiary < 18 years of age
- Beneficiary has abnormal growth velocity and height below the mean for gender and age
- Beneficiary has one of the following diagnoses:
  - Growth Hormone Deficiency/Pituitary Dwarfism
  - Iatrogenic Pituitary Disorder
  - Unspecified disorder of the pituitary gland
- Epiphyses should remain open during treatment and should be monitored beginning at 12-14 years of age. Bone age should be done at least yearly to verify that the epiphyses are open. Growth velocity can be taken into consideration to determine efficacy. If the growth velocity has slowed regardless of epiphyses status, use your best judgement on continuation.
- Expected tests/labs for initial approval
  - Low growth hormone
  - Low IGF-1 and/or IFGBP-3 in addition to stim tests
  - Thyroid function test to rule out hypothyroidism
  - Delayed bone age—typically determined from x-ray of hand and wrist
  - MRI or CT scan to rule out pituitary gland issues
  - Provocative GH stimulation test unless beneficiary has one of the following:
  - Pituitary abnormality (pituitary anomaly, tumor, or irradiation)
    - Newborn with congenital pituitary abnormality, hypoglycemia, and GH < 5 mcg/L
    - Extreme short stature (e.g., height < -3 SD), normal nutrition, significantly reduced IGF-1 and/or IGFBP-3, and delayed bone age

Criterion 4:

- Beneficiary > 18 years of age and diagnosed with child onset GHD
- Has one of the following diagnoses:
  - Growth Hormone Deficiency/Pituitary Dwarfism
  - Iatrogenic Pituitary Disorder
  - Unspecified disorder of the pituitary gland
- Expected tests/labs
  - Failure of 2 provocative GH stimulation tests as an adult or after documented epiphyses closure
  - Low IGF-1 and/or IGFBP-3

Criterion 5:

- Beneficiary > 18 years of age
- Has one of the following diagnoses
  - Panhypopituitarism
  - Craniopharyngioma

- Septo-optic dysplasia
- Continued symptoms with low GH and IGF-1. Labs should be measured yearly to determine GH dose.

Denial Criteria

- History of the following diagnoses
  - Age > 65 years
  - History of malignancy in the past 365 days
  - History of renal transplant in the past 365 days
  - Pregnancy

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Hemophilia A/B Products

(Implemented 03/01/2018)
(Updated 8/16/2019)
(Updated 7/20/2022)
(Updated 1/15/2025)
(Updated 4/16/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require a manual review for prior authorization

- Alhemo®
- Feiba®
- Hemlibra®
- Hympavzi™
- NovoSeven RT®
- Sevenfact®

Approval Criteria for Alhemo®

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary requires routine prophylaxis to prevent or reduce the frequency of bleeding episodes and is diagnosed with **ONE** of the following:
    - hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors, **OR**
    - hemophilia B (congenital factor IX deficiency) with factor IX inhibitors.
- Beneficiary must meet **ONE** of the following:
    - High factor VIII or IX inhibitor titer (≥ 5 Bethesda units per mL (BU)); **OR**
    - Factor VIII or IX inhibitor titer < 5 BU/ml with inadequate response to high dose factor;
- Beneficiary must have been prescribed, or need, treatment with bypassing agents •
- Beneficiaries must meet **ONE** of the following for confirming disease severity:
    - Severe disease with < 1% of factor VIII or factor IX in blood while on factor products; **OR**
    - Moderate disease with 1-5% of factor VIII or factor IX in blood while on factor products with **ONE** of the following (prescriber must submit letter of medical necessity and chart notes to support):
        - History of spontaneous bleeding episodes into the central nervous system or other serious life-threatening bleed; **OR**
        - At least two (2) joint bleeds causing hemophilia-related joint damage; **OR**
        - Poor venous access; **OR**
        - High Factor VIII or Factor IX dose
- Beneficiary should not be approved or continue the medication if meets one of the

following:
  - Continues to receive prophylaxis bypassing agents (e.g., rFVIIa or aPCC)
  - ALHEMO is ordered for breakthrough bleeding
  - Pregnant
- Request must be submitted by, or in consultation with, a hemophilia specialist or hemophilia treatment center
- Prescriber must submit the following:
  - Chart notes for the last 24 weeks with summary of bleeding events
  - Previous therapies tried with episodic or prophylactic bypassing agents (e.g., Feiba®, NovoSeven RT®, or Sevenfact®)
  - Documentation of **ONE** of the following:
    - Inadequate response to Immune Tolerance Induction (ITI); **OR**
    - Rationale why the beneficiary is not a candidate for ITI;
  - Current factor activity and annualized bleeding rate
  - Current labs including CBC
  - Negative pregnancy test results if applicable
  - Attestation that female beneficiary of reproductive potential has been counseled on the importance of effective contraception
  - Attestation that beneficiary has been counseled on proper technique on episodic treatment with bypassing agents as needed for breakthrough bleeding episodes
  - Medical necessity over prophylaxis factor products and Hemlibra® for hemophilia A
- Initial PA will be for 3 months, renewal PAs may be approved for up to 6 months.

Renewal Requirements for Alhemo®

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a decrease in annualized bleeding rate compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC
  - Summary of bleeds since last PA

Approval Criteria for Feiba®

- Beneficiary must have a diagnosis of hemophilia A or B with high factor VIII or factor IX titer inhibitors (≥ 5 Bethesda Units) requiring treatment for **ONE** of the following:
  - Control and prevention of bleeding episodes; **OR**
  - Peri-operative management; **OR**
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; **AND**
- Beneficiary has a documented trial and failure of Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation) and emicizumab-kxwh (HEMLIBRA) (FEIBA may be taken as breakthrough for patients taking emicizumab) – **Hemophilia A only**
- Beneficiary has a documented trial and failure of the combination of highly immunosuppressive regimens and Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation). – **Hemophilia B only**
- Prescriber must submit the following:
  - If doses above 100 units/kg or daily doses of 200 units/kg are required, provide the

treatment plan to monitor for Disseminated Intravascular Coagulation (DIC) or signs of ischemia and thromboembolic events; **AND**
- Chart notes with history of bleeds and treatment for the last 24 weeks; **AND**
- Current labs; **AND**
- Current weight for dosing; **AND**
- Provide requested dose as PA will be entered for specific dosing requirements

Approval Criteria for Hemlibra® for Hemophilia A WITH Inhibitors

- Beneficiary must have a diagnosis of congenital hemophilia A **WITH** inhibitors **AND ONE** of the following:
  - High factor VIII inhibitor titer (≥ 5 Bethesda units per mL (BU)); **OR**
  - Factor VIII inhibitor titer < 5 BU/mL with inadequate response to high dose factor;
- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; **AND**
- Prescriber must submit the following:
  - Chart notes for the last 24 weeks; **AND**
  - Current labs including CBCs and LFTs; **AND**
  - Documentation that HEMLIBRA is prescribed for the prevention of bleeding episodes (not acute treatment); **AND**
  - Documentation of any previous treatment with episodic and prophylactic bypassing agents (FEIBA, NOVOSEVEN RT, or SEVENFACT); **AND**
  - Documentation of one of the following:
    - Inadequate response to Immune Tolerance Induction (ITI); **OR**
    - Rationale why the beneficiary is not a candidate for ITI;
  - Attestation that beneficiary will NOT be receiving concurrent prophylactic treatment with bypassing agents or has possibility of receiving ITI while taking HEMLIBRA; **AND**
  - Attestation that the beneficiary has been counseled on proper technique on episodic treatment with bypassing agents as needed for breakthrough bleeding episodes; **AND**
  - Current weight; **AND**
- Initial PA will be for 1 month for the FDA-approved loading dose of 3mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis

Approval Criteria for Hemlibra® for Hemophilia A WITHOUT Inhibitors

- Beneficiary must have a diagnosis of congenital hemophilia A **WITHOUT** inhibitors **AND ONE** of the following:
- Severe disease with < 1% of factor VIII in blood while on factor VIII products; **OR**
- Moderate disease with 1-5% of factor VIII in blood while on factor VIII products with **ONE** of the following (prescriber must submit letter of medical necessity and chart notes to support):
  - History of spontaneous bleeding episodes into the central nervous system or other serious life-threatening bleed; **OR**
  - At least two (2) joint bleeds causing hemophilia-related joint damage; **OR**
  - Poor venous access; **OR**
  - High Factor VIII dose
- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; **AND**
- Prescriber must submit the following:
  - Chart notes for the last 24 weeks; **AND**

- Current labs including SBOL and LFTs; **AND**
- Documentation that HEMLIBRA is prescribed for the prevention of bleeding episodes (not acute treatment); **AND**
- Documentation of any previous prophylactic and/or episodic FVIII infusions; **AND**
- Attestation that beneficiary will NOT be receiving concurrent prophylaxis factor VIII; **AND**
- Attestation that beneficiary has been counseled on proper technique on episodic treatment with factor VIII products as needed for breakthrough bleeding episodes; **AND**
- Current weight; **AND**

- Initial PA will be for 1 month for the FDA-approved loading dose of 3 mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis

Denial Criteria for Hemlibra®

- Beneficiary does not have a diagnosis of congenital hemophilia A; **OR**
- Beneficiary continues to receive prophylaxis doses (e.g., FVIII, FIX, or bypassing agents); **OR**
- If approved and the beneficiary is not compliant on prescribed Hemlibra® dose; **OR**
- Prescriber requests dose above FDA-approved dose or prescribes the use of HEMLIBRA for PRN dosing; **OR**
- If approved and the beneficiary has no positive response with the decrease of bleeding episodes and/or decrease of episodic agent use

Approval Criteria for Hympavzi™

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary requires routine prophylaxis to prevent or reduce the frequency of bleeding episodes and is diagnosed with **one** of the following:
  - hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors; **OR**
  - hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.
- Beneficiaries must meet **one** of the following for confirming disease severity:
  - Severe disease with < 1% of factor VIII or factor IX in blood while on factor products; **OR**
  - Moderate disease with 1-5% of factor VIII or factor IX in blood while on factor products with **ONE** of the following (prescriber must submit letter of medical necessity and chart notes to support):
    - History of spontaneous bleeding episodes into the central nervous system or other serious life-threatening bleed; **OR**
    - At least two (2) joint bleeds causing hemophilia-related joint damage; **OR**
    - Poor venous access; **OR**
    - High Factor VIII or Factor IX dose
- Request must be submitted by, or in consultation with, a hemophilia specialist or hemophilia treatment center
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Continues to receive prophylaxis Factor doses (e.g., FVIII, FIX, or bypassing agents)
  - HYMPAVZI is ordered for breakthrough bleeding
  - Pregnant

- Prescriber must submit the following:
  - Chart notes for the last 24 weeks with summary of bleeding events
  - Previous therapies tried with timeline and response (prophylaxis and acute treatment)
  - Current factor activity and annualized bleeding rate
  - Current labs including CBC
  - Negative pregnancy test results if applicable
  - Attestation that female beneficiary of reproductive potential has been counseled on the importance of effective contraception
  - Attestation that beneficiary has been counseled on proper technique on episodic treatment with factor VIII or factor IX products as needed for breakthrough bleeding episodes
  - Medical necessity over prophylaxis factor products and HEMLIBRA for hemophilia A

Renewal Requirements for Hympavzi™

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a decrease in annualized bleeding rate compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC
  - Summary of bleeds since last PA

Quantity Edits for Hympavzi™

- #8/28 days

Approval Criteria for NovoSeven RT® and Sevenfact®

Hemophilia A and B with Inhibitors (NovoSeven RT® or Sevenfact®)

- Beneficiary must have a diagnosis of congenital or acquired hemophilia A or B with inhibitors confirmed by blood coagulation testing that requires treatment of bleeding episodes or peri-operative management; **AND**
- Request must be submitted by or in consultation with a hemophilia specialist or hemophilia treatment center; **AND**
- Beneficiary has a documented trial and failure of Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation) and emicizumab-kxwh (HEMLIBRA) (NOVOSEVEN or SEVENFACT may be taken as breakthrough for patients taking emicizumab) – **Hemophilia A** only
- Beneficiary has a documented trial and failure of the combination of highly immunosuppressive regimens and Immune Tolerance Induction (ITI) therapy (If not a candidate for ITI, provide documentation). – **Hemophilia B only**
- Prescriber must submit the following:
  - Chart notes with history of bleeds and treatment for the last 24 weeks; **AND**
  - Current labs; **AND**
  - Current weight for dosing; **AND**
  - Provide requested dose as PA will be entered for specific dosing requirements

Congenital Factor VII Deficiency (NovoSeven RT®)

- Beneficiary has a diagnosis of congenital factor VII deficiency confirmed by blood

coagulation testing requiring treatment of bleeding episodes or peri-operative management; **AND**

- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of prothrombin time and factor VII coagulant activity prior to administration as baseline

Glanzmann's Thrombasthenia (NovoSeven RT®)

- Beneficiary has a diagnosis of Glanzmann's thrombasthenia and condition is refractory to platelet transfusions; **AND**
- Used for the treatment of one of the following:
  - Control of bleeding episodes; **OR**
  - Peri-operative management

Acquired Hemophilia (NovoSeven RT®)

- Beneficiary has a diagnosis of Acquired Hemophilia; **AND**
- Used for the treatment of one of the following:
  - Control of bleeding episodes; **OR**
  - Peri-operative management

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Hemorrhoid Preparations

(Implemented 01/12/2010)
(Updated 08/14/2015)
(Updated to PDL10/1/2021)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Hydrocortisone 1% cream
- Hydrocortisone 2.5% cream
- Hydrocortisone-Pramoxine 1%-1% cream
- Proctofoam-HC® 1-1% (hydrocortisone-pramoxine)
- Procto-Med HC™ 2.5% cream (hydrocortisone)
- Procto-Sol HC® 2.5% cream (hydrocortisone)

Non-Preferred Agents

- Anu-Sol HC® 2.5% cream (hydrocortisone)
- Cortifoam® 10% foam (hydrocortisone)
- Proctozone-HC® 2.5% cream (hydrocortisone)

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Hepatitis C Medications

(Implemented 10/21/2009)
(Updated 2/22/2018) (Effective 4/1/18)
(Updated 4/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents that require manual review for prior authorization

- Mavyret™ tablet (glecaprevir and pibrentasvir)
- Sofosbuvir/velpatasvir tablet (generic for Epclusa®)
- Zepatier® tablet (elbasvir/grazoprevir)
- Ribavirin capsule 200 mg
- Ribavirin tablet 200 mg

Non-Preferred Agents

- Epclusa® tablet (sofosbuvir/velpatasvir)
- Harvoni® tablet (ledipasvir-sofosbuvir)
- Pegasys® pen, vial (peginterferon alpha-2a)
- PegIntron® vial kit (peginterferon alpha-2b)
- Sovaldi®tablet (sofosbuvir)
- Viekira Pak™ tablet dosepak (ombitasvir-paritaprevir-ritonavir & dasabuvir)
- Vosevi® tablet, film-coated (sofosbuvir, velpatasvir, and voxilaprevir)

Link to Hepatitis C prior authorization form—Portable Document Format (.pdf):
Arkansas Medicaid Hepatitis C Prescription Drug Program (ar.primetherapeutics.com)

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HMG-CoA Reductase Inhibitors

(Implemented 06/10/2008)
(Update to PDL Effective 7/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Atorvastatin calcium (generic for Lipitor®)
- Lovastatin (generic for Mevacor®)
- Pravastatin (generic for Pravachol®)
- Rosuvastatin (generic for Crestor®)
- Simvastatin (generic for Zocor®)

Non-Preferred Agents

- Altoprev® (lovastatin ER)
- Atorvaliq® suspension (atorvastatin)
- Atorvastatin/amlodipine (generic for Caduet®)
- Caduet® (atorvastatin/amlodipine)
- Crestor® (rosuvastatin)
- Fluvastatin (generic for Lescol®)
- Lipitor® (atorvastatin)
- Livalo® (pitavastatin)
- Pitavastatin (generic for Livalo®)
- Simvastatin/ezetimibe(generic for Vytorin®)
- Vytorin® (simvastatin/ezetimibe)
- Zocor® (simvastatin)

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Human Immunodeficiency Virus (HIV)

(Implemented 10/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Abacavir tablet and solution (generic for Ziagen)
- Abacavir/lamivudine tablet (generic for Epzicom)
- Atazanavir capsule (generic for Reyataz)
- Biktarvy tablet (bictegravir/emtricitabine/tenofovir)
- Cimduo tablet (lamivudine/tenofovir)
- Complera tablet (emtricitabine/rilpivirine/tenofovir) **– BRAND ONLY**
- Darunavir ethanolate 600 mg, 800 mg tablets (generic for Prezista)
- Delstrigo tablet (doravirine/lamivudine/tenofovir)
- Descovy tablet (emtricitabine/tenofovir alafenam)
- Dovato tablet (dolutegravir/lamivudine)
- Edurant tablet (rilpivirine)
- Efavirenz tablet (generic for Sustiva)
- Efavirenz/emtricitabine/tenofovir disoproxil fumarate tablet (generic for Atripla)
- Emtricitabine/tenofovir disoproxil fumarate tablet (generic for Truvada)
- Emtriva solution (emtricitabine)
- Evotaz tablet (atazanavir/cobicistat)
- Fosamprenavir tablet (generic for Lexiva)
- Genvoya tablet (elvitegravir/cobicistat/emtricitabine/tenofovir)
- Isentress powder, chew, tablet, and HD tablet (raltegravir potassium)
- Juluca tablet (dolutegravir/rilpivirine)
- Lamivudine tablet and solution (generic for Epivir)
- Lamivudine/zidovudine tablet (generic for Combivir)
- Lexiva suspension (fosamprenavir)
- Lopinavir/ritonavir solution and tablet (generic for Kaletra)
- Nevirapine tablet, suspension, and ER tablet (generic for Viramune)
- Norvir powder (ritonavir)
- Odefsey tablet (emtricitabine/rilpivirine/tenofovir)
- Pifeltro tablet (doravirine)
- Prezcobix tablet (darunavir/cobicistat)
- Prezista suspension (darunavir ethanolate)
- Prezista 75 mg, 150 mg tablets
- Reyataz powder (atazanavir)
- Ritonavir tablet (generic for Norvir)
- Stribild tablet (elvitegravir/cobicistat/emtricitabine/tenofovir)
- Symfi Lo tablet (efavirenz/lamivudine/tenofovir) - **BRAND ONLY**

- Symfi tablet (efavirenz/lamivudine/tenofovir) - **BRAND ONLY**
- Symtuza tablet (darunavir/cobicistat/emtricitabine/tenofovir)
- Tenofovir disoproxil fumarate tablet (generic for Viread)
- Tivicay PD tablet for suspension and Tivicay tablet (dolutegravir sodium)
- Triumeq PD tablet for suspension and Triumeq tablet (abacavir/dolutegravir/lamivudine)
- Tybost tablet (cobicistat)
- Zidovudine tablet and syrup (generic for Retrovir)

Non-Preferred Agents

- Aptivus capsule (tipranavir)
- Atripla tablet (efavirenz/emtricitabine/tenofovir)
- Combivir tablet (lamivudine/zidovudine)
- Didanosine capsule (generic for Videx EC)
- Edurant Ped tablet for suspension (rilpivirine)
- Efavirenz capsule (generic for Sustiva)
- Efavirenz/lamivudine/tenofovir disoproxil fumarate tablet (generic for Symfi and Symfi Lo)
- Emtricitabine capsule (generic for Emtriva)
- Emtricitabine/rilpivirine/tenofovir tablet (generic for Complera)
- Emtriva capsule (emtricitabine)
- Epivir solution and tablet (lamivudine)
- Epzicom tablet (abacavir/lamivudine)
- Etravirine tablet (generic for Intelence)
- Fuzeon vial (enfuvirtide)
- Intelence tablet (etravirine)
- Kaletra solution and tablet (lopinavir/ritonavir)
- Lexiva tablet (fosamprenavir)
- Norvir tablet (ritonavir)
- Prezista 600 mg. 800 mg tablet (darunavir)
- Retrovir syrup (zidovudine)
- Reyataz capsule (atazanavir)
- Rukobia tablet (fostemsavir tromethamine)
- Stavudine capsule (generic for Zerit)
- Sustiva capsule (efavirenz)
- Temixys tablet (lamivudine/tenofovir)
- Trizivir tablet (abacavir/lamivudine/zidovudine)
- Truvada tablet (emtricitabine/tenofovir)
- Viracept tablet (nelfinavir)
- Viramune XR tablet (nevirapine)
- Viread tablet and powder (tenofovir)
- Ziagen solution and tablet (abacavir)
- Zidovudine capsule (generic for Retrovir)

Non-Preferred Agents with Criteria

- Apretude* vial (cabotegravir)
- Cabenuva* vial (cabotegravir and rilpivirine)
- Maraviroc* tablet (generic for Selzentry)
- Selzentry* solution and tablet (maraviroc)

• Sunlenca* tablet and vial (lenacapavir sodium)
• Yeztugo* tablet and vial (lenacapavir sodium)
Note: Trogarzo is available as a medical claim only. Prior authorization criteria may apply.

Approval Criteria for Cabenuva

• Beneficiary meets the minimum age and weight recommended in the manufacturer's package insert for this FDA approved indication (As of 7/27/2023, minimum age is 12 years old and weight is 35 kg).
• Beneficiary has a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection and is virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure or suspected resistance to cabotegravir or rilpivirine **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
• Beneficiary should not be approved or continue on this therapy if requires coadministration with any of the following:
    o Anticonvulsants: Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
    o Antimycobacterials: Rifabutin, rifampin, rifapentine
    o Glucocorticoid (systemic): Dexamethasone (more than a single-dose treatment)
    o Herbal product: St John's wort (Hypericum perforatum)
• Prescriber must submit **ALL** of the following:
    o Current chart notes
    o Labs including current RNA documenting viral suppression
    o Attestation that beneficiary has been counseled on the importance of compliance
    o Confirmation whether beneficiary will start with oral lead in doses or move directly to the injection
    o Medical necessity over current oral therapy
• Prior authorization will be approved for 12 months.

Renewal Requirements

• Beneficiary remains compliant on all antiretroviral medications
• Beneficiary has a demonstrated continued virological suppression
• Prescriber must submit **ALL** of the following:
    o Current chart notes
    o Current labs including viral load

Quantity Edits

600 mg/ 900 mg kit—1 per 30 days
400 mg/ 600 mg kit—1 per 30 days

Approval Criteria for Apretude

• Beneficiary meets the minimum age and weight recommended in the manufacturer's package insert for this FDA approved indication (As of 7/27/2023, minimum age is 12 years old and weight is 35 kg).
• Beneficiary must be considered at-risk for sexually acquired HIV-1 infections requiring pre-exposure prophylaxis (PrEP)
• Beneficiary must have a current negative HIV-1 test

• Beneficiary should not be approved or continue on this therapy with any of the following:
  o Has a positive HIV-1 test either prior to initiating Apretude® or during treatment
  o Medical necessity over oral PrEP options was not provided
• Prescriber must submit **ALL** of the following:
  o Current chart notes
  o Current HIV test results
  o Medical necessity over oral PrEP options (e.g., generic Truvada® or Descovy®)
  o Document if beneficiary will have the 28-day oral lead-in therapy or begin with Apretude®
  o Attestation that the prescriber has counseled the patient about the importance of compliance
• Prior authorization will be approved for 12 months.

Quantity Edit

• 1 injection every 2 months (quantity override will be needed for first 2 months loading dose)

Information from the Selzentry Form

Part 1: Initial Approval Criteria

Use of maraviroc for treatment-experienced or treatment-naïve patient (Please check all that apply; all must be true for patient to be eligible):
1. Under the care of an experienced HIV practitioner
2. Evidence of virologic failure (documented by viral load > 1,000 copies/mL not related to non-adherence to prescribed ARV)
3. Unable to construct a multi-drug regimen from preferred°, alternative*, or acceptable^ regimens as defined by the Department of Health and Human Services Guidelines for Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents that includes at least two additional active antiretroviral drug in addition to maraviroc.

°Preferred Regimens (Regimens with optimal and durable efficacy, favorable tolerability and toxicity profile, and ease of use)
*Alternative Regimens (Regimens that are effective and tolerable but have potential disadvantages compared with preferred regimens. An alternative regimen may be the preferred regimen for some patients.)
^Acceptable Regimens (CI) (Regimens that may be selected for some patients but are less satisfactory than preferred or alternative regimens)

Part 2: Medicaid Approval Requirements for Trofile® Assay Test: This section to be completed by AR Medicaid only. Patient meets criteria stated in Part 1 above.

If patient meets Part 1 criteria, Medicaid Utilization Review will be notified that patient meets Medicaid criteria for proceeding with Trofile® Assay Test.

• A highly sensitive tropism assay at baseline is required prior to initiation of maraviroc; the results of the tropism assay may take approximately 3 weeks and a prescription for maraviroc should not be written until the results indicate only CCR5 tropism.

• Prior approval from Medicaid is required for a repeat tropism assay. A repeat tropism assay should only be performed if the provider is considering a change of treatment due to increasing VL and/or decreasing CD4 count. If CXCR4 or DM virus is detected during therapy, the PA for maraviroc will be discontinued. In failing patients who have CCR5 virus, a maraviroc resistance assay may also be necessary.

Part 3: Approval or Denial for Selzentry® (maraviroc):

1. Does patient have confirmed infection with only CCR5 tropic virus as determined by Trofile® Assay Test result screening prior to maraviroc initiation? (Copy of lab test results required as part of the manual review process)
2. The prior approval is NDC and dose specific. AR Medicaid will allow up to a maximum of 1200 mg/day in the following dosing regimens. Please indicate intended dose*:
    - o 150 mg tablet, 1 tablet twice daily
    - o 300 mg tablet, 1 tablet twice daily
    - o 300 mg tablet, 2 tablets twice daily

*Caution and/or dosing adjustments may be warranted in patients with renal or hepatic impairment. Please refer to prescribing information in manufacturer's package insert for dosing and contraindications.

Approval Criteria for Sunlenca

• Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication

• Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia

• Beneficiary must be diagnosed with HIV-1 infection and heavily treatment-experienced with multidrug resistant disease failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations OR a diagnosis consistent with any new FDA-approved indications or support on the official Compendia

• Multidrug resistance is defined as resistance to =2 agents from =3 of the 4 main classes of ARV

• ARV classes include nucleoside reverse transcriptase inhibitors (NRTI), non-nucleoside reverse transcriptase inhibitors (NNRTI), protease inhibitors (PI) and integrase strand transfer inhibitor (INSTI)

• Beneficiary should not be approved with any of the following:
    - o Concomitant administration of strong CYP3A inducers is required
    - o Baseline HIV-1 RNA levels < 400 copies/mL
    - o Prior to starting SUNLENCA, there is no current antiretroviral therapy
    - o Not prescribed a concomitant optimized background regimen

• Prescriber must submit ALL of the following:
    - o Current chart notes
    - o Documentation of previous therapies tried
    - o Current labs including viral load
    - o Documentation of which regimen prescribed
    - o Documentation of concomitant antiretrovirals prescribed

• PA will be approved for 1 year

Renewal Requirements

• Beneficiary remains compliant on all antiretroviral medications

• Beneficiary has a demonstrated improvement in viral load

- Prescriber must submit **ALL** of the following:
    - Current chart notes
    - Current labs including viral load

Quantity Edits

- #1 oral tablet pack per year (qty 4 or 5 depending on regimen chosen)
- 1 injection kit (2 vials) every 6 months

Top of the document

Hydrochlorothiazide 10 mg/ml suspension (Inzirqo™)

(Implemented 4/16/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

POINT-OF-SALE (POS) EDITS:

- Patients under 7 years of age or have a diagnosis of NPO **(Appendix A)** in the last 365 days; **AND**
- Billed diagnosis of hypertension or edema in the last 2 years

PATIENTS NOT MEETING POS CRITERIA:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with hypertension or edema associated with congestive heart failure, hepatic cirrhosis, or renal disease **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must submit the following:
  - Current chart notes
  - Baseline blood pressure or description of edema
  - Medical necessity over hydrochlorothiazide tablets and capsules
  - For patients 7 years of age and older, attestation of NPO status will be required every 6 months (effective 8/1/2025)

Renewal Requirements

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary should have an improvement with underlying diagnosis
- Prescriber must submit the following:
  - Current chart notes
  - Current blood pressure or description of edema
  - Continued medical necessity of Inzirqo™ suspension over oral solid dosage forms

Quantity Edits

- 2 bottles per month (If patient requires a higher dose, a quantity override can be entered.)

Top of the document

Hydrocortisone sprinkle (Alkindi®)

(Implemented 10/16/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary does not exceed the maximum age recommended in the manufacturer's package insert (< 18 years of age)
- Beneficiary must be diagnosed with adrenocortical insufficiency
- Prescriber must submit the following:
  - Current chart notes
  - Dose requested
  - Medical necessity over hydrocortisone tablets or prednisolone solution which are available without prior authorization

Renewal Requirements

- Beneficiary continues to demonstrate the medical necessity of the sprinkle formulation

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Hydroxyurea 100 mg film coated tablet (Siklos®)

(Implemented 01/01/2019)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with sickle cell anemia with moderate to severe painful crises
- Beneficiary should not be approved or continue this therapy with any of the following:
    - Medical necessity over hydroxyurea 500 mg and DROXIA has not been established
    - Dose must be reduced by 50% in patients with creatinine clearance of less than 60 mL/min or with end-stage renal disease (ESRD)
- Prescriber must submit the following:
    - Current chart notes
    - Current labs
    - Current weight
    - Baseline summary of pain crises with documentation of hospitalizations, ER visits, and transfusions for sickle cell diagnosis for the past 12 months
    - Letter of medical necessity for SIKLOS over hydroxyurea 500 mg capsule or DROXIA which are both available without prior authorization. Products have the same black-box warnings.

Top of the document

Hydrodroxyurea 100 mg/ml solution (Xromi®)

(Implemented 4/16/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

POINT-OF-SALE (POS) EDITS:

- Patients under 7 years of age or have a diagnosis of NPO in the last 365 days; **AND**
- Billed diagnosis of sickle cell disease in the last 2 years

PATIENTS NOT MEETING POS CRITERIA:

- Beneficiary must be diagnosed with moderate to severe, painful crises associated with sickle cell anemia
- Prescribed by, or in consultation with, a specialist in the treatment of sickle cell.
- Prescriber must submit the following:
  - Current chart notes with documentation of pain crises and blood transfusion frequency
  - Medical necessity for the use of solution over capsules which are available without prior authorization
  - For patients 7 years of age and older, attestation of NPO status will be required every 6 months (effective 8/1/2025)
  - Negative pregnancy test if a female of reproductive potential
  - Attestation that female patients of reproductive potential will be using effective contraception
  - Attestation that labs will be monitored throughout treatment

Renewal Requirements

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate an improvement in frequency of pain crises and transfusions
- Prescriber must submit the following:
  - Current chart notes
  - Continued medical necessity for the use of oral solution over capsules
  - Attestation that female patients of reproductive potential will continue to use effective contraception

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Glucagon Agents

(Implemented 10/15/2019)
(Updated 4/1/2020)
(Updated 7/1/2023)
(Updated 4/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Baqsimi® intranasal powder (glucagon)
- Proglycem® suspension (diazoxide) – **BRAND ONLY**
- Zegalogue® pre-filled syringe and autoinjector (dasiglucagon)

Preferred Agent with Criteria

- Gvoke® pre-filled syringe and autoinjector (glucagon)

Point-of-Sale (POS) Approval Criteria for Gvoke® PFS and autoinjector

- Beneficiary is 2-5 years of age.
- If the beneficiary does not meet the age limitation, a prior authorization request is needed from the prescriber.

Non-Preferred Agents

- Diazoxide suspension (generic for Proglycem®)
- Glucagon 1mg emergency kit
- Gvoke® (glucagon) vial

Quantity Edits

- 2 doses per prescription fill

Age Edits

- FDA approved minimum requirements apply

Top of the document

GnRH Receptor Antagonists – Uterine Disorders

(New PDL Class 04/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for these products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents with Criteria (Manual Review)

- Myfembree® tablet (relugolix, estradiol, and norethindrone acetate)
- Oriahnn® capsule (elagolix, estradiol, and norethindrone acetate & elagolix)
- Orilissa® tablet (elagolix)

Non-Preferred Agents

- None

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be prescribed **ONE** of the following medications with corresponding indications:
  - ORILISSA
    - Moderate to severe pain associated with endometriosis
  - ORIAHNN
    - Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
  - MYFEMBREE
    - Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
    - Moderate to severe pain associated with endometriosis in premenopausal women
- Attestation that beneficiary of reproductive potential will use effective non-hormonal contraception during treatment and for 1 week after discontinuing therapy
- Beneficiary must have tried and failed at least 2 of the following treatment options with at least a 3-month history (unless documentation of contraindication is provided):
  - NSAIDs and/or acetaminophen usage (for endometriosis associated pain)
  - Contraceptives (i.e., combined estrogen-progestin treatments include combined oral contraceptive pills, transdermal patches, and vaginal rings)
  - Progesterone-only therapy (e.g., medroxyprogesterone, norethindrone, dienogest)
  - Intrauterine device
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Postmenopausal
  - Pregnant
  - Known osteoporosis because of risk for further bone loss (T-score < -1.0 SD)
  - Severe hepatic impairment (Child-Pugh C); dose modifications may be needed for moderate hepatic impairment

- Requires concomitant organic anion transporting polypeptide (OATP) 1B1 (a hepatic uptake transporter) (e.g., cyclosporine and gemfibrozil)
- History of major depression or PTSD in the last 2 years **OR** history of a major psychiatric disorder (i.e., schizophrenia or bipolar) **OR** history of suicide attempt in the last year
- Exceeds the following dosing:
  - ORILISSA
    - 150 mg once daily for 24 months-- no hepatic impairment or dyspareunia
    - 200 mg twice daily for 6 months—has dyspareunia
    - 150 mg once daily for 6 months—has moderate hepatic impairment (Child-Pugh B)
  - MYFEMBREE—1 tablet daily for maximum of 24 months
  - ORIAHNN—1 capsule twice daily for maximum of 24 months
- Request for ORILISSA
  - Chronic pelvic pain that is not caused by endometriosis (e.g., pelvic inflammatory disease, inflammatory bowel disease, ovarian cysts)
- Request for ORIAHNN or MYFEMBREE
  - High risk of arterial, venous thrombotic, or thromboembolic disorders which is defined as having at least one of the following
    - woman over 35 years of age who smoke
    - current or history of deep vein thrombosis or pulmonary embolism
    - vascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease)
    - thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
    - inherited or acquired hypercoagulopathies
    - uncontrolled hypertension
    - headaches with focal neurological symptoms or have migraine headaches with aura if over age 35
  - Current or history of breast cancer or other hormonally-sensitive malignancies, and with increased risk of hormonally-sensitive malignancies
  - Undiagnosed abnormal uterine bleeding
  - History of heavy bleeding associated with uterine fibroids that has not caused anemia (hemoglobin level ≤ 12 g/dL)
  - Concomitant use with oral P-gp inhibitors for MYFEMBREE

- Prescriber must submit the following:
  - Name of the medication being requested
  - Current chart notes with symptom history
  - Documentation of previous therapies tried with duration and response
  - Confirmation of diagnosis with pelvic exam results and imaging/biopsy results (e.g., transvaginal US, MRI, laparoscopy, CT scan)
  - Current labs including CBCs and LFTs
  - Confirmation of negative pregnancy status (i.e., current negative pregnancy test, beginning medication within 7 days of onset of menses, or tubal ligation)
  - Letter of medical necessity outlining the need for one of these medications over other treatment options ((i.e., OTC pain medications, hormonal contraception, progestin therapy, and surgery)

- If requesting a non-preferred medication, provide the necessity of the chosen medication over the preferred option(s).

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate improvement of symptoms (i.e., reduction in endometriosis related pain, decrease in heavy menstrual bleeding and/or improvement in hemoglobin)
- Beneficiary remains free from hepatic impairment, osteoporosis, psychiatric disorders, and pregnancy
- Beneficiary has not surpassed the maximum treatment duration as noted in the package insert
- Beneficiary of reproductive potential remains on non-hormonal contraception
- Prescriber must submit the following:
  - Current chart notes with documentation of current symptoms
  - Current labs including CBCs and LFTs
  - Documentation of negative pregnancy status

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Ibrexafungerp (Brexafemme®)

(Updated 10/20/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be post-menarchal; **AND**
- Beneficiary must have a diagnosis of vulvovaginal candidiasis (VVC) OR a diagnosis consistent with FDA approved indication; **AND**
- Beneficiary must have failed (non-clearance of initial infection) after vaginal antifungal treatment AND fluconazole unless cannot tolerate azole antifungals; **AND**
- Prescriber must submit current chart notes

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported on the official Compendia; **OR**
- Prescriber requests total dose greater than 600 mg; **OR**
- Prescriber has not tried an azole antifungal if no contraindication; **OR**
- Beneficiary is pregnant

Quantity Edits

- #4 tablets /30 days

Top of the document

Icatibant (Firazyr®)

(Implemented 01/12/2012)
(Updated 4/17/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Patient must have a laboratory diagnosis of C1-INH deficient or dysfunctional HAE
- Must have ≥ 1 severe or life-threatening laryngeal attack or had 2-3 moderate attacks causing extremity, facial or abdominal swelling in the last year
- Provider must submit a proposed treatment plan for **both acute and prophylaxis** treatment (if meets prophylaxis criteria)
- Documentation of expected angioedema triggers (Trigger avoidance is crucial)
- Must **NOT** be on an ACEi (or other possible drug causes such as estrogens and NSAIDs)
- Follow the package inserts for specific indicated age or contraindications
- Initial PA maximum of 3-month trial if approved
- Quantity limit of 2 doses per prescription fill

Denial Criteria

- History of allergic reaction for C1-INH or blood products
- Diagnosis of acquired angioedema
- Does not meet acute attack requirements for approval
- Beneficiary is not diagnosed with Type I or Type II HAE
- Failure to provide adequate records

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Imiquimod (Aldara®)

(Implemented 06/27/2007)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- > 12 years of age; **AND**
- Submitted diagnosis for superficial basal cell carcinoma (sBCC) within past two months; **OR**
- Submitted diagnosis for actinic keratosis (AK) within past two months; **OR**
- Submitted diagnosis for Condyloma Acuminata (or commonly known as external genital or perianal warts) within past two months; **AND**
- No Therapeutic Duplication with Diclofenac sodium 3% gel
- No Therapeutic Duplication with Fluorouracil cream/solution topical
- No Therapeutic Duplication with other strengths of Imiquimod cream topical
- No Therapeutic Duplication with Ingenol gel topical

Additional Criteria

- Quantity limits apply

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Imiquimod (Zyclara®)

(Implemented 04/27/2010)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- > 12 years of age; **AND**
- Submitted diagnosis for actinic keratosis (AK) within past two months; **OR**
- Submitted diagnosis for Condyloma Acuminata (commonly known as external genital or perianal warts) within past two months; **AND**
- No Therapeutic Duplication with Diclofenac sodium 3% gel
- No Therapeutic Duplication with Fluorouracil cream/solution topical
- No Therapeutic Duplication with other strengths of Imiquimod cream topical
- No Therapeutic Duplication with Ingenol gel topical

Additional Criteria

- Quantity limits apply

Top of the document

Immune Globulins (IVIG)

(Implemented on 4/1/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Gammagard® Liquid vial
- Gamunex-C® vial
- Hizentra®

Point-of-Sale (POS) Approval Criteria for Preferred Agents

- All IVIG and SCIG products will be subject to point-of-sale edits
- For a claim to process at POS, the beneficiary must have a billed diagnosis for an indication found in Table A in the last 2 years
- Beneficiaries without a billed diagnosis from Table A will require a prior authorization request to be submitted by the prescriber. Each PA request will be reviewed on a case-by-case basis. The prescriber must submit the following:
  - Current chart notes
  - Diagnosis requiring immune globulin
  - Criteria does not pertain to medically billed claims; only pertains to pharmacy claims

Non-Preferred Agents

- Alyglo™ vial
- Asceniv™ vial
- Bivigam® vial
- Cutaquig® vial
- Cuvitru® vial
- Cytogam® vial
- Flebogamma Dif® vial
- Gamastan® S-D vial
- Gamastan® vial
- Gammagard® S-D vial
- Gammaked™ vial
- Gammaplex® vial
- HyperRHO® S-D syringe
- Hyqvia® vial
- Hyqvia IG Component® vial
- MICRhoGAM® Ultra-filtered plus syringe
- Octagam® vial
- Panzyga® vial
- Privigen® vial

Non-Preferred Agents (continued)

- RhoGAM® Ultra-filtered plus syringe
- Rhophylac® syringe
- WinRho® SDF vial
- Xembify® vial

Table A—From DailyMed and MicroMedex (9/20/2021)

FDA approved and non-FDA supported immune globulin indications
FDA approved indications
Primary Humoral Immunodeficiency
•Common variable immunodeficiency •X-linked agammaglobinemia •Congenital agammaglobinemia •Wiskott-Aldrich syndrome •Severe combined immunodeficiency
Chronic Immune Thrombocytopenic Purpura
Chronic Inflammatory Demyelinating Polyneuropathy
Kawasaki Syndrome
Multifocal Motor Neuropathy
B-cell Chronic Lymphocytic Leukemia
Dermatomyositis
Supported non-FDA approved indications
Acquired epidermolysis bullosa
Autoimmune hemolytic anemia
Autoimmune neutropenia
Bone marrow transplant
Bullous pemphigoid
Cytomegalovirus Infection (Treatment and prophylaxis)
Disseminated encephalomyelitis
Guillain-Barre Syndrome
Herpes gestationis
Kidney disease (Severe IgA nephropathy)
Linear IgA dermatosis
Lumbosacral radiculoplexus neuropathy
Lymphoproliferative disorder following transplantation
Myasthenia gravis
Ocular cicatricial pemphigoid
Pemphigus vulgaris
Polyarteritis nodosa
Pyoderma gangrenosum
Renal Transplant
Respiratory Syncytial Virus Infection
Stiff-person syndrome
Toxic shock syndrome
Uveitis
von Willebrand disorder

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Immunologic Agents (Multiple Sclerosis)

(Implemented 09/27/2011)
(Updated 06/18/2015)
(Updated 1/1/17)
(Updated 1/1/2020)
(Updated 1/1/2023)
(Updated 1/18/2023)
(Updated 10/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents without Criteria

- Ampyra® ER tablet (dalfampridine ER)
- Avonex® injection (interferon beta – 1A)
- Copaxone® **20 mg** injection- **Brand Only**
- Dalfampridine ER tablet (generic for Ampyra® ER)
- Dimethyl fumarate capsule (generic for Tecfidera®)
- Fingolimod capsule (generic for Gilenya®)
- Teriflunomide tablet (generic for Aubagio®)

Preferred Agent with Criteria

- Kesimpta® pen (ofatumumab)

Non-Preferred Agents

- Aubagio® tablet (teriflunomide)
- Bafiertam® capsule (monomethyl fumarate)
- Betaseron® injection (interferon Beta – 1B)
- Copaxone® 40 mg injection (glatiramer)
- Extavia® injection (Interferon Beta – 1B)
- Glatiramer acetate injection (generic for Copaxone®)
- Glatiramer acetate injection (generic for Glatopa®)
- Glatopa® injection (glatiramer)
- Gilenya® capsule (fingolimod)
- Mavenclad® tablet (cladribine)
- Mayzent® tablet (siponimod)
- Plegridy® pen and syringe (peginterferon beta – 1A)
- Ponvory® tablet (ponesimod)
- Rebif®/Rebif Rebidose (interferon beta – 1A/albumin)
- Tascenso® ODT (fingolimod)

- Tecfidera® capsule (dimethyl fumarate)
- Vumerity® capsule (diroximel fumarate)
- Zeposia® capsule (ozanimod)

Briumvi®, Lemtrada®, Ocrevus®, and Tysabri® are excluded from the pharmacy program.

Point-of-Sale (POS) Approval Criteria for Kesimpta®

Beneficiary must meet **ONE** of the following:

Criteria 1:

- Medicaid prescription history contains at least 6 claims for preferred multiple sclerosis medication(s) (Ampyra® ER and dalfampridine ER are not included) in the previous year (6 months total with multiple drugs or all with single drug)

Criteria 2:

- Medicaid prescription history contains a claim for Kesimpta® in the last 2 months

Non-Preferred Medications Approval Criteria

All Non-Preferred Medications:

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary has a confirmed diagnosis of a relapsing form of multiple sclerosis (MS) including clinically isolated syndrome, relapsing-remitting disease, or active secondary progressive disease
- Initial request must be submitted by or in consultation with a neurologist or other appropriate specialist
- Beneficiary with moderately active disease must have tried and failed multiple preferred products with different mechanisms of action. If tried Kesimpta®, beneficiary must have taken for at least 6 months. Failure is defined by any of the following:
  - At least one relapse during therapy with preferred medications
  - MRI indicates additional lesions compared to baseline
  - Beneficiary demonstrates an increased disability as measured by the Expanded Disability Status Scale (EDSS) compared to baseline
  - Documented adverse effects to the preferred agents
- Beneficiary with highly active or rapidly evolving aggressive disease will be reviewed on a case-by-case basis
- Beneficiary is not prescribed other Disease-Modifying Therapies (DMTs) for the treatment of MS to be used concomitantly
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous therapies with response
  - Letter of medical necessity over the preferred medications
  - Baseline MRI with documentation of lesions
  - Baseline Expanded Disability Status Scale (EDSS)
- See additional criteria noted below for specific medications

FUMARATES: Bafiertam®, Vumerity®

- Beneficiary does **NOT** have any of the following:
  - Moderate to severe renal impairment
  - Moderate to severe hepatic impairment
  - Previous failure with any fumarate product
- Prescribed concomitant fumarate therapies
- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Current labs including a CBC including lymphocyte count and LFTs
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive potential
  - Medical necessity over dimethyl fumarate

INTERFERONS: Betaseron®, Extavia®, Plegridy®, Rebif®/Rebif Rebidose®

- Prescriber must submit **ALL** of the following (in addition to the info requested above):
  - Current labs including CBC with differential and LFTs
  - Attestation that patient has been counseled about depression
  - Medical necessity over Avonex®

GLATIRAMER: Copaxone® 40 mg, Glatopa® 20 mg or 40 mg

- Prescriber must submit the necessity over Copaxone® 20mg daily (convenience would not be considered medically necessary)

SPHINGOSINE 1-PHOSPHATE RECEPTOR MODULATORS: Mayzent®, Ponvory®, Tascenso ODT®, Zeposia®

- Beneficiary does **NOT** have any of the following:
  - Current systemic or clinically significant infection
  - Use of any other antineoplastic, immunosuppressive or immunomodulator drugs to treat other conditions
  - Baseline heart rate ≤ 55 bpm
  - Moderate to severe hepatic impairment (Child-Pugh class B or C)
  - MI, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class II or IV heart failure in the last 6 months
  - Presence of Mobitz type II second-degree, third-degree AV block, sick sinus syndrome, or sino-atrial block, unless have a pacemaker
  - Previous treatment with alemtuzumab
- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Current labs including a CBC including lymphocyte count and LFTs
  - Documentation of CYP2C9 genotype to determine dose for Mayzent®
  - Documentation of cardiac evaluation with ECG if beneficiary has preexisting conditions (Contraindicated in recent MI, angina, stroke, TIA, severe HF, baseline QTc interval ≥ 500 msec, or cardiac arrhythmias requiring therapy).
  - Baseline eye exam report
  - Vaccinate for varicella zoster virus before initiation if VZV antibody negative

  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive potential
  - Medical necessity over fingolimod
- Mayzent® beneficiary must NOT have a CYP2C9 *3/*3 genotype (homozygous)

PURINE ANTIMETABOLITE: Mavenclad®

- Beneficiary should **NOT** have a diagnosis of clinically isolated syndrome
- Beneficiary does **NOT** have any of the following:
  - Human immunodeficiency virus (HIV), hep B or C, TB or other current systemic or clinically significant infection
  - Current malignancy
  - Use of any other antineoplastic, immunosuppressive or immunomodulator drugs to treat other conditions
  - Moderate to severe renal impairment (CrCl < 60mL/min)
  - Moderate to severe hepatic impairment (Child-Pugh score > 6)
- Prescriber must submit **ALL** of the following (in addition to info request above):
  - Medical necessity over all other DMTs
  - Treatment plan after two years of therapy
  - Current labs including a CBC with differential including lymphocyte count and LFTs
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive potential
  - Reports for screening Hepatitis B and C, HIV, and tuberculosis
  - Vaccinate for varicella zoster virus before initiation if VZV antibody negative

Renewal Requirements

- Prescriber must submit current chart notes with documentation of response to therapy
- Beneficiary must have a positive response to therapy which may include any of the following:
  - Decrease in the number of relapses
  - Improvement or no decline in Expanded Disability Status Scale (EDSS)
  - Improvement in MRI findings since initiating therapy

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Immunomodulators, Monoclonal Antibodies

(Implemented 8/1/2003)
(Updated criteria 7/19/2023)
(Updated PDL 10/1/2023)
(Updated criteria 4/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents with Criteria

- Dupixent® pen and syringe (dupilumab)
- Fasenra® pen and syringe (benralizumab)
- Xolair® syringe and autoinjector (omalizumab)

Non-Preferred Agents

- Nemluvio® injection (nemolizumab-ilto)
- Nucala® auto-inject, syringe, vial (mepolizumab)
- Tezspire® (tezepelumab-ekko)
- Xolair® vial (omalizumab)

FDA Approved Indications

- **DUPIXENT:**
  - Moderate to severe atopic dermatitis
  - Chronic rhinosinusitis with nasal polyposis
  - Chronic Spontaneous Urticaria
  - Moderate to severe asthma (either eosinophilic phenotype or oral steroid dependent)
  - Eosinophilic Esophagitis
  - Prurigo Nodularis
  - Eosinophilic phenotype chronic obstructive pulmonary disease (COPD)

- **FASENRA:**
  - Severe asthma with an eosinophilic phenotype

- **XOLAIR:**
  - Moderate to severe asthma with positive skin test or in vitro reactivity to allergen
  - Nasal polyps
  - Chronic Spontaneous Urticaria
  - IgE-Mediated Food Allergies

- **NEMLUVIO:**
  - Moderate to severe atopic dermatitis
  - Prurigo Nodularis

- **NUCALA:**
  - Eosinophilic phenotype chronic obstructive pulmonary disease (COPD)

- Hypereosinophilic Syndrome
- Maintenance treatment of chronic rhinosinusitis with nasal polyps
- Severe asthma with an eosinophilic phenotype
- Eosinophilic Granulomatosis with Polyangiitis

- **TEZSPIRE:**
  - Severe asthma

Approval Criteria for Asthma (Dupixent®, Fasenra®, Nucala®, Tezspire®, and Xolair®)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Prescribed by or in consultation with specialist in pulmonology, allergy or immunology
- Beneficiary must have a diagnosis consistent with FDA indications.
  - **NUCALA** - add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype
  - **FASENRA** - add-on maintenance treatment of patients with severe asthma aged 6 years and older and with an eosinophilic phenotype
  - **DUPIXENT** - add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma
  - **TEZSPIRE** - add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma
  - **XOLAIR** - adults and pediatric patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids
- Beneficiary must have moderate to severe asthma as defined by at least **TWO** of the following:
  - 1 or more exacerbations defined as:
    - Requires treatments with systemic corticosteroids; **OR**
    - Requires medical treatment (e.g., emergency room visits or hospitalizations)
  - Beneficiary must be compliant on at least **TWO** asthma maintenance medications with one being an inhaled corticosteroid at a maximized dose (ICS/LABA combination products count as two medications). Compliance will be reviewed on a case-by-case basis
  - Beneficiary has oral corticosteroid dependent asthma
- Beneficiary has no therapeutic duplication with any other monoclonal antibodies
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried for asthma with response
  - Baseline labs (must fall within the manufacturer's requirements in the package insert)
    - Baseline blood eosinophil count for FASENRA, NUCALA, and DUPIXENT (if eosinophilic type) with eosinophils ≥ 150
    - Baseline serum IgE levels, body weight, and completed form for XOLAIR
  - Baseline Asthma Control Questionnaire (ACQ-5) for all patients **OR** Asthma Quality of Life Questionnaire (AQLQ) scores for adults only

  - Current Pulmonary Function Test results
  - If the request is for a non-preferred product, provide a letter of medical necessity for requested product over a preferred monoclonal antibody and other therapies outlined in treatment guidelines
- Beneficiary is compliant on asthma controller medication (ICS or ICS/LABA) and immunomodulator injection
- Prescriber must submit the following:
  - Current chart notes with documentation of response to therapy after 12 months of treatment
  - Current PFTs
  - Current blood eosinophil count for FASENRA, DUPIXENT (if eosinophilic type), and NUCALA
  - Current serum IgE level and body weight for XOLAIR
  - Current Asthma Control Questionnaire (ACQ-5) for all patients **OR** Asthma Quality of Life Questionnaire (AQLQ) scores for adults only
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy as indicated by at least ONE (1) of the following:
  - Beneficiary must have an improvement in FEV1 over baseline after 12 months
  - Beneficiary must have fewer exacerbations
  - Beneficiary must have a decrease in blood eosinophil count OR serum IgE OR decrease in oral corticosteroid usage (depending on medication)
  - Beneficiary must have improved asthma control and quality of life scores

Approval Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA) (Nucala®)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must be diagnosed with EGPA for at least 6 months based on the presence of asthma plus eosinophilia (>1.0x10^9/Liter and/or >10% of leucocytes)
- Beneficiary has a history of relapsing or refractory disease with at least one confirmed EGPA relapse within the last 2 years while taking oral corticosteroids
- Beneficiary must be on a stable dose of oral prednisolone or prednisone of ≥ 7.5 mg/day for at least four (4) weeks
- If Beneficiary is receiving immunosuppressive therapy (excluding cyclophosphamide), the dosage must be stable for four (4) weeks
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Beneficiary has no therapeutic duplication with any other monoclonal antibodies
- Beneficiary does not have life-threatening EGPA. Life-threatening EGPA would be defined as:
  - Severe alveolar hemorrhage or hemoptysis requiring transfusion or ventilation, or hemoglobin is < 8 g/dL
  - Rapidly progressive glomerulonephritis with creatinine > 2.5 mg/dL
  - Severe cardiac involvement including life-threatening arrhythmia, LVEF <20%, NUHA Class III/IV or acute myocardial infarction
- Prescriber must submit the following:
  - Current chart notes

- Current labs including CBCs and LFTs if on methotrexate or azathioprine
- Baseline Birmingham Vasculitis Activity Score (BVAS)
- Medical necessity over corticosteroids and/or immunosuppressive therapy

Continuation Criteria for EGPA

- Beneficiary must be compliant on this medication
- Beneficiary must show a positive response to therapy with at least **ONE** of the following:
  - BVAS = 0 (no vasculitis); **OR**
  - Corticosteroid dose has been decreased to ≤ 4 mg/day
- Prescriber must submit the following:
  - Current chart notes
  - Current corticosteroid dose
  - Current BVAS

For complete Atopic Dermatitis criteria, please see Immunomodulators, Atopic Dermatitis

Approval Criteria for Atopic Dermatitis (Dupixent®)

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating atopic dermatitis
- Beneficiary has a documented diagnosis of moderate to severe atopic dermatitis with at least **ONE** of the following (baseline at time of biologic request):
  - Baseline impacted body surface area (BSA) ≥ 10%
  - Baseline Eczema Area and Severity Index (EASI) total score of ≥ 16
  - Baseline weekly averaged peak pruritis Numeric Rating Scale (NRS) ≥ 7
  - Baseline Investigator's Global Assessment (IGA) score ≥ 3
  - Baseline Scoring Atopic Dermatitis (SCORAD) score ≥ 25
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in the official Compendia
- Beneficiary has no therapeutic duplication with monoclonal antibodies or cytokine & CAM antagonists
- Beneficiary must have a trial and failure of topical therapy and at a minimum must include
  - At least **ONE** topical corticosteroid entity over a minimum of 60 days use with topical corticosteroids being "high" potency (Class-2) or superpotent (Class-1) for adults **OR** medium potency for children (unless contraindicated); **AND**
  - At least **ONE** trial of a topical calcineurin inhibitor (TCI) over a minimum of 30 days (i.e., pimecrolimus or tacrolimus)
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Documentation of previous therapies with trial length of each medication
  - BSA prior to topical/systemic therapies and current impacted BSA
  - Baseline EASI, NRS, IGA and/or SCORAD and updated score with previous treatment
  - Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
  - Letter of medical necessity over other treatment options for atopic dermatitis

Continuation Criteria for Atopic Dermatitis

- Beneficiary is compliant on this medication
- Beneficiary must show continued positive treatment response with each PA request for continued prior approval with at least one of the following compared to baseline:
  - Decrease in severity scores; **OR**
  - Decrease in BSA impacted; **OR**
  - Decrease in need for systemic or topical rescue treatment
- Prescriber must submit:
  - Current chart notes
  - Current BSA and EASI, NRS, IGA or SCORAD (compared to baseline severity score)

Approval Criteria for Chronic Spontaneous Urticaria (Dupixent® and Xolair®)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with chronic spontaneous urticaria (CSU) with wheals/hives with or without angioedema for > 6 consecutive weeks
- Must be prescribed by, or in consultation with, a dermatologist, allergist, or immunologist
- Beneficiary must minimize factors that can exacerbate CSU (i.e., NSAIDs, alcohol, stress, and friction from clothing)
- Beneficiary must have at least **ONE** of the following despite treatment listed below:
  - Baseline Urticaria Activity Score-7 (UAS7) must be ≥ 16
  - Baseline Itch Severity Score-7 (ISS7) must be ≥ 8
  - Baseline Urticaria Control Test (UCT) must be < 12
- Beneficiary must have tried and failed the following unless there is a contraindication to their use:
  - Non-sedating H1-antihistamine (nsAH) for a minimum of 2 weeks; **AND**
  - nsAH at 4 times the normal daily dose for a minimum of 4 weeks
- Prescriber must submit the following:
  - Current chart notes
  - Baseline description of urticaria
  - Baseline UAS7 and/or ISS7 and/or UCT scores
  - Previous therapies that were tried with treatment duration

Continuation Criteria for Chronic Idiopathic Urticaria

- Beneficiary has been compliant with therapy (defined as: 75% utilization)
- Beneficiary must have a positive response with a decrease in urticaria symptoms and an improvement in **ONE** of the following (must use same test as baseline):
  - UAS7
  - ISS7
  - UCT
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of current symptoms
  - Current CSU test with at least **ONE** of the following (must use the same test as baseline):

- Urticaria Activity Score-7 (UAS7)
- Itch Severity Score-7 (ISS7) score
- Urticaria Control Test (UCT)

Approval Criteria for Nasal Polyps (Dupixent®, Nucala®, and Xolair®)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must have a diagnosis of chronic rhinosinusitis with nasal polyposis
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Prescribed by or in consultation with specialist in pulmonology, allergy, immunology, or otolaryngology
- Beneficiary must have a trial and failure of three (3) months of nasas corticosteroids (e.g., fluticasone, beclomethasone, budesonide)
- Beneficiary must have met one (1) of the following:
  - Previous treatment with oral corticosteroids for nasal polyps in the last 2 years; **OR**
  - Previous nasal surgery for nasal polyps
- Prescriber must submit the following:
  - Current chart notes with description of size/quantity of nasal polyps
  - Documentation of previous therapies tried
  - Requested dose
  - Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
  - Current IgE and weight for XOLAIR request
  - Medical necessity over nasal corticosteroids, antileukotrienes, and surgery
  - Documentation that concomitant nasal corticosteroids are prescribed

Continuation Criteria for Nasal Polyps

- Beneficiary must demonstrate an improvement in size/quantity of polyps with an improvement of symptoms compared to baseline
- Beneficiary must be compliant on this medication and nasal corticosteroids
- Prescriber must submit the following:
  - Current chart notes with description of polyps
  - Current body weight for dose determination for XOLAIR
  - Requested dose

For complete Eosinophilic Esophagitis (EOE) criteria, please see Eosinophilic Esophagitis

Approval Criteria for Eosinophilic Esophagitis (EOE) (Dupixent®)

- Beneficiary must be aged 1 year and older, weighing at least 15 kg, **OR** the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must have a confirmed diagnosis of eosinophilic esophagitis (EOE) with an esophageal biopsy that indicates ≥ 15 eosinophils per high-power field (eos/hpf) and **ONE** of the following:

  - Symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, chest pain); **OR**
  - Endoscopy features consistent with eosinophilic esophagitis (e.g., stacked circular rings, esophageal strictures, linear furrows)
- Beneficiary must have at least a 12 week trial and failure of swallowed corticosteroids (e.g., fluticasone or budesonide)
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies including dietary restrictions, procedures, or pharmacological treatment
  - Baseline eos/hpf after corticosteroid and PPI trials
  - Baseline beneficiary determined Dysphagia Symptom Questionnaire (DSQ) score

Continuation Criteria for Eosinophilic Esophagitis

- Beneficiary demonstrates a positive response with one of the following after 6 months of treatment:
  - Achieved remission with ≤ 6 eos/hpf; **OR**
  - Decrease in DSQ score from baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current beneficiary determined DSQ score
  - Current eos/hpf

Approval Criteria for COPD (Dupixent® and Nucala®)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Prescribed by or in consultation with a pulmonologist
- Beneficiary has been diagnosed with eosinophilic phenotype chronic obstructive pulmonary disease (COPD) that is inadequately controlled on maintenance therapy with moderate to severe airflow limitation defined by the following:
  - Post-bronchodilator FEV1/FVC ratio < 0.7; **AND**
  - Post-bronchodilator FEV1 of 30% to 70% predicted; **AND**
  - History of ≥ 2 moderate or ≥ 1 severe exacerbations(s) within the past 12 months
- Beneficiary must have a trial and failure of maintenance triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (unless contraindicated) with a trial lasting for at least 3 months
- Beneficiary must have a blood eosinophilic count of at least 300 cells/µL as a baseline drawn in the last 12 months
- Beneficiary must remain on standard maintenance therapy and use this medication as add-on therapy
- Prescriber must submit the following:
  - Current chart notes with description of COPD symptoms and history of exacerbations for the last 12 months
  - Documentation of previous therapies tried
  - Current pulmonary function tests
  - Baseline labs including CBC with differential
  - Documentation of smoking history

Continuation Criteria for COPD

- Beneficiary remains compliant on COPD maintenance therapy (inhalers and immunomodulator injection)
- Beneficiary must demonstrate a positive response to therapy as indicated by at least **ONE** (1) of the following:
  - Decrease in quantity and/or severity of exacerbations; **OR**
  - Improvement in lung function/FEV1 over baseline; **OR**
  - Improvement in COPD-related symptoms and/or quality of life
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy compared to previous baseline with information on any exacerbations since last PA review
  - Current PFTs

Approval Criteria for Hypereosinophilic Syndrome (Nucala®)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must have a diagnosis of hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Beneficiary has documented at least 2 HES flares within the past 12 months while on stable HES therapy with at least **TWO** of the following:
  - Chronic or episodic corticosteroids
  - Immunosuppressants
  - Cytotoxic therapy
- Beneficiary has a baseline blood eosinophil count of at least 1000 cells/µL
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried and response
  - Current labs including CBCs and LFTs if on methotrexate or azathioprine

Continuation Criteria for Hypereosinophilic Syndrome

- Beneficiary must be compliant on this medication
- Beneficiary has a positive response with a decrease in HES flares and a decrease in blood eosinophil count
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBCs
  - Documentation of HES flares since beginning treatment

Approval Criteria for Prurigo Nodularis (Dupixent® and Nemluvio®)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must have a diagnosis of prurigo nodularis with widespread or recalcitrant disease **OR** has a comorbidity of moderate to severe atopic dermatitis
- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist

treating atopic dermatitis/prurigo nodularis
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- If the request is for a non-preferred medication, the beneficiary must have tried and failed the preferred biologic(s) with this indication before non-preferred options can be approved unless there is a patient specific contraindication to the preferred options(s)
- Beneficiary must have a trial and failure of topical medications and at a minimum must include (unless contraindicated or inappropriate for the patient's age):
  - At least **ONE** topical corticosteroid entity over a minimum of 60 days use with topical corticosteroids being "high" potency (Class-2) **OR** superpotent (Class-1) **OR** medium potency for children; **AND**
  - At least **ONE** trial of a topical calcineurin inhibitor (TCI) with either pimecrolimus or tacrolimus over a minimum of 30 days
- Prescriber must submit the following:
  - Current chart notes
  - Description of current status for baseline (i.e., BSA of nodules, peak pruritis Numeric Rating Scale (NRS), Investigator's Global Assessment (IGA)
  - Previous therapies tried
  - If no history of atopic dermatitis, provide documentation that other systemic causes for pruritis have been ruled out (i.e., chronic kidney disease, liver disease)

Continuation Criteria for Prurigo Nodularis

- Beneficiary must show continued positive treatment response with each PA request for continued prior approval with at least one of the following compared to baseline:
  - Decrease in pruritis; **OR**
  - Decrease in BSA impacted; **OR**
  - Decrease in need for systemic or topical rescue treatment
- Prescriber must submit:
  - Current chart notes
  - Current BSA and pruritis test scores (i.e., NRS, IGA)

Approval Criteria for IgE-Mediated Food Allergies (Xolair®)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with one or more IgE-mediated food allergies **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must be an Allergy and Immunology specialist
- Beneficiary has no therapeutic duplication with any other monoclonal antibodies
- Prescriber must attest that the beneficiary has been counseled to continue to avoid the foods that cause allergic reactions as this medication is for accidental exposure only
- Beneficiary must continue to have injectable epinephrine on hand with a pharmacy claim within the last year
- Prescriber must submit the following:
  - Current chart notes
  - Baseline serum IgE level

- Current weight
- Dose requested (must be supported by the dosing chart in the package insert)
- Skin prick test results confirming food allergies

Continuation Criteria for IgE-Mediated Food Allergies

- Beneficiary remains compliant based on pharmacy claims (defined as 75%). If not compliant, the medical necessity for restarting therapy should be provided.
- Prescriber must submit the following:
  - Current chart notes
  - Serum IgE level is not required for compliant beneficiaries or those with a dose in the last year; dose interruptions lasting one year or more require a new serum IgE level
  - Current weight
  - Dose requested (must be supported by the dosing chart in the package insert)

Quantity Edits

- FASENRA - #1 pen/vial per 8 weeks (will need quantity override for first 3 months)
- DUPIXENT - #5 syringes per 50 days
- NUCALA - #3 prefilled syringes/autoinjectors per 28 days
- TEZSPIRE - #1 syringe/vial per 28 days
- XOLAIR - #4 300 mg prefilled syringe/autoinjector per 28 days;
  #2 150 mg prefilled syringe/autoinjector per 28 days;
  #4 150 mg vial per 28 days;
  #2 75 mg prefilled syringe/autoinjector per 28 days

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Inhaled Antibiotics

(Updated 10/01/2016)
(Updated 1/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Bethkis® (Tobramycin)
- Kitabis Pak® (Tobramycin)
- Tobramycin (generic for Tobi®)

Non-Preferred Agents

- Arikayce® (amikacin liposome) – Criteria for Arikayce
- Aztreonam (generic for Cayston®)
- Cayston® (Aztreonam)
- Tobi® (Tobramycin)
- Tobi Podhaler® (Tobramycin)
- Tobramycin (generic for Bethkis®)
- Tobramycin pak (generic for Kitabis Pak®)

Approval Criteria for Preferred Agents

- Diagnosis of cystic fibrosis in medical history

Denial Criteria for Preferred Agents

- History of Cayston® in the past 50 days
- History of J-Code for Tobramycin Injection in the past 60 days

Additional Criteria

- Quantity limits apply

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Insulins

(Implemented 04/08/2014)
(Updated 11/27/17, Effective 1/1/18)
(Effective 10/1/2020)
(Updated 5/15/2023)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents – Rapid-Acting Insulin

- Insulin aspart cartridge/FlexPen/vial (generic for Novolog®)
- Insulin lispro Jr. KwikPen (generic for Humalog®)
- Insulin lispro KwikPen/vial (generic for Humalog®)

Non-Preferred Agents – Rapid-Acting Insulin

- Admelog® SoloStar pen/vial (insulin lispro)
- Afrezza® inhalation powder (insulin human)
- Apidra® SoloStar pen/vial (insulin glulisine)
- Fiasp® vial/FlexTouch pen/penfill/pumpcart (insulin aspart)
- Humalog® Tempo pen (insulin lispro)
- Humalog® U-100 cartridge (insulin lispro)
- Humalog® U-100 Jr. KwikPen (insulin lispro)
- Humalog® U-100 KwikPen/vial (insulin lispro)
- Humalog® U-200 KwikPen (insulin lispro)
- Lyumjev™ KwikPen/vial (insulin lispro-aabc)
- Lyumjev™ U-200 KwikPen (insulin lispro-aabc)
- Lyumjev™ Tempo pen (insulin lispro-aabc)
- Merilog™ U-100 SoloStar pen/vial (insulin aspart-szjj)
- Novolog® U-100 cartridge/FlexPen/vial (insulin aspart)

Preferred Agents – Rapid/Intermediate-Acting Combinations

- Insulin aspart mix pen/vial (generic for Novolog® Mix)
- Insulin lispro mix pen (generic for Humalog® Mix)

Non-Preferred Agents – Rapid/Intermediate-Acting Combinations

- Humalog® Mix KwikPen (insulin lispro/lispro protamine)
- Humalog® Mix vial (insulin lispro/lispro protamine)
- Novolog® Mix FlexPen (insulin aspart/aspart protamine)
- Novolog® Mix vial (insulin aspart/aspart protamine)

Preferred Agents – Regular Insulin

- Humulin® R U-100 vial (OTC)
- Humulin® R U-500 KwikPen/vial

Non-Preferred Agents – Regular Insulin

- Novolin® R U-100 FlexPen/vial (OTC)

Preferred Agents – Intermediate Insulin

- Humulin® N U-100 vial (OTC)

Non-Preferred Agents – Intermediate Insulin

- Humulin® N U-100 KwikPen (OTC)
- Novolin® N U-100 FlexPen/vial (OTC)

Preferred Agents – Regular/Intermediate-Acting Combinations

- Humulin® 70/30 KwikPen (OTC)
- Humulin® 70/30 vial (OTC)

Non-Preferred Agents – Regular/Intermediate-Acting Combinations

- Novolin® 70/30 vial (OTC)
- Novolin® 70/30 FlexPen (OTC)

Preferred Agents – Long-Acting Insulin

- Lantus® SoloStar pen (insulin glargine)
- Lantus® vial (insulin glargine)

Non-Preferred Agents – Long-Acting Insulin

- Basaglar® KwikPen (insulin glargine)
- Basaglar® Tempo pen (insulin glargine)
- Insulin degludec U-100 and U-200 pen (generic for Tresiba®)
- Insulin degludec vial (generic for Tresiba®)
- Insulin glargine Max SoloStar pen (generic for Toujeo®)
- Insulin glargine SoloStar pen (generic for Toujeo®)
- Insulin glargine-yfgn pen/vial (generic for Semglee®)
- Levemir® FlexTouch (insulin detemir) – while product is still available
- Levemir® vial (insulin detemir) – while product is still available
- Rezvoglar® KwikPen (insulin glargine-aglr)
- Semglee™ pen/vial (insulin glargine-yfgn)
- Soliqua® injection (insulin glargine/lixisenatide)
- Toujeo® Max SoloStar pen (insulin glargine)
- Toujeo® SoloStar pen (insulin glargine)
- Tresiba® U-100 and U-200 FlexTouch (insulin degludec)
- Tresiba® vial (insulin degludec)
- Xultophy® injection (insulin degludec/liraglutide)

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Intranasal Rhinitis Agents

(Effective 4/1/2020)
(Updated 4/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Azelastine nasal spray (Astelin®, Astepro®)
- Fluticasone propionate nasal spray (Flonase®)
- Ipratropium nasal spray (Atrovent®)

Non-Preferred Agents

- Azelastine/fluticasone nasal spray (generic for Dymista®)
- Budesonide nasal spray (generic for Rhinocort®)
- Dymista® nasal spray (azelastine/fluticasone)
- Flunisolide nasal spray (generic for Nasarel®, Nasalide®)
- Olopatadine 6% nasal spray (generic for Patanase®)
- Omnaris® nasal spray (ciclesonide)
- Qnasl®, Qnasl Childrens® nasal spray (beclomethasone)
- Ryaltris® nasal spray (olopatadine/mometasone)
- Xhance® nasal spray (fluticasone)
- Zetonna™ nasal spray (ciclesonide)

Preferred Agents with Criteria

- Mometasone furoate nasal spray (generic for Nasonex®)

Point-of-Sale (POS) Criteria for Preferred Agents with Criteria

- Beneficiary is 2-3 years of age
- If the beneficiary does not meet the age limitation, a prior authorization request is needed from the prescriber.

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Iptacopan 200 mg capsule (Fabhalta®)

(Implemented 4/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication.
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia.
- Beneficiary must be diagnosed with paroxysmal nocturnal hemoglobinuria (PNH) with absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins confirmed by high-sensitivity flow cytometry OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must be vaccinated against encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type B at least 2 weeks prior to initiation of FABHALTA, and beneficiary must be provided antibiotics if vaccines were administered less than 2 weeks before starting therapy
- Prescriber and pharmacy must be enrolled in the REMS program.
- Beneficiary currently taking eculizumab (SOLIRIS) or ravulizumab (ULTOMIRIS) must follow the required dose initiation per the package insert.
- The medication is prescribed by or in consultation with a hematologist.
- Beneficiary must be clinically symptomatic (e.g., fatigue, dyspnea, pain, thrombosis, etc.) and have abnormal labs (e.g., low hemoglobin (Hgb), high lactate dehydrogenase (LDH)).
- Beneficiary has baseline Hgb level < 10 g/dL with or without previous C5 inhibitors.
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Severe renal impairment (eGFR < 30 mL/min/1.73 m^2)
  - Severe hepatic impairment (Child-Pugh class C)
  - Active infections caused by an encapsulated bacteria (such as *Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae* type b)
  - If no vaccinations against encapsulated bacteria (such as *Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae* type b) at least 2 weeks prior to initiation of FABHALTA and no antibiotic drug prophylaxis
  - Ordered to be used concomitantly with a C5 inhibitor
  - Pregnant or breastfeeding
- Prescriber must submit the following:
  - Current chart notes
  - Documented symptoms as a baseline
  - Documentation of previous therapies
  - Current labs including complete blood count (CBC), comprehensive metabolic panel lactate dehydrogenase (LDH)
  - Recent history of blood transfusions
  - Pregnancy test results (if applicable)

Renewal Requirements

- Beneficiary is compliant on therapy (defined as 75% utilization).
- Beneficiary has an improvement in hemoglobin and/or LDH levels compared to baseline.
- Beneficiary has an improvement in overall clinical presentation (e.g., fatigue, dyspnea, reduction in transfusions).
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including CBC, CMP, and LDH

Quantity Edits

- #60/ 30 days

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Isotretinoin (Absorica®, Amnesteem®, Claravis™, Myorisan®, Zenatane™)

(Updated 1/20/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for these products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Beneficiary must be ≥ 12 years of age; **AND**
- Prescriber must be a dermatologist; **AND**
- Beneficiary must have a diagnosis of severe recalcitrant nodular acne with many inflammatory nodules measuring a diameter of 5 mm or greater; **AND**
- Beneficiary has been unresponsive to conventional therapy, including ideally 3 consecutive months using at least 2 of the following (history of each patient will be reviewed on a case-by-case basis):
  - Oral antibiotics (e.g., doxycycline, minocycline)
  - Oral contraceptives (females only)
  - Oral spironolactone (females only)
  - Topical retinoids, topical antibiotics, and/or benzoyl peroxide
  - Combination of oral antibiotics with benzoyl peroxide
- Prescriber, pharmacy, wholesaler, and beneficiary must all be registered with the iPLEDGE® Program. Pharmacy claims will not process without all registrations being active; **AND**
- Requests for ABSORICA 25 mg and 35 mg or ABSORICA LD require medical necessity over other options; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of severity of acne along with previous therapies including any OTC topical options; **AND**
  - Current labs including CBC, lipid profile, LFTs, and glucose; **AND**
  - Signed copy of iPLEDGE® Informed Consent form for both male and female beneficiaries. Female beneficiaries must also sign the Pregnancy Prevention Consent form. If the beneficiary is under 18, the parent or guardian needs to sign the form in the blank provided. Only the patient is required to initial each item; **AND**
  - Documentation that female beneficiary of reproductive potential is taking two reliable forms of birth control (one of which must be a primary form—tubal sterilization, male vasectomy, IUD, hormonal contraception) beginning one month before starting isotretinoin and for one month after stopping treatment; **AND**
  - Initial prescription requires documentation of two negative blood or urine pregnancy tests for female beneficiaries of reproductive potential as outlined by iPLEDGE®. Documentation of a negative pregnancy test must be provided; **AND**
  - Requested dose (PA is dose specific); **AND**
- Initial PA will be approved for a maximum of 165 days. One (1) renewal is possible only after at least 8 weeks following completion of the first course with a new PA request; **AND**

- Requests for diagnoses other than acne will be reviewed by DHS clinical review team on a case-by-case basis.

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported in the official Compendia; **OR**
- Prescriber is requesting more than two (2) courses of therapy; **OR**
- Beneficiary is pregnant; **OR**
- All required information is not provided; **OR**
- Beneficiary has uncontrolled hypertriglyceridemia (prescriber should submit a treatment plan for patients with high triglycerides).

Quantity Edits

- #60/30 days for max of 165 days per authorization

**Topical acne medications are not covered by Arkansas Medicaid per Social Security Act 1927.

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Istradefylline (Nourianz®)

(Updated 1/15/2020)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Must be at least 18 years of age; **AND**
- Provide current chart notes; **AND**
- Provide Liver Function Tests; **AND**
- Provide smoking status with average number of cigarettes per day; **AND**
- Should be in Parkinson's Disease stages 2 to 4 in the OFF state in the modified Hoehn and Yahr Scale; **AND**
- Must be on levodopa/carbidopa for at least one year with a stable dose at least 4 weeks prior to starting NOURIANZ; **AND**
- Must be taking at least 3 doses of levodopa per day; **AND**
- NOURIANZ will be used in combination with levodopa/carbidopa; **AND**
- Must be experiencing at least 2 hours of OFF time per day; **AND**
- If taking other PD medications, patient must be on a stable dose for at least 4 weeks prior to starting NOURIANZ (although patients can be on levodopa/carbidopa without the concomitant use of other PD medications including COMT inhibitors, MAO-B inhibitors, anticholinergics, and/or amantadine); **AND**
- Medical necessity over the increase in levodopa/carbidopa dose or changing to extended-release formulations.

Denial Criteria

- Currently taking strong CYP3A4 Inducers; **OR**
- Diagnosed with severe hepatic impairment (Child-Pugh C); **OR**
- Diagnosed with a major psychotic disorder
- < 2 hours a day of OFF time; **OR**
- Atypical parkinsonism or secondary parkinsonism variants; **OR**
- Pregnant or lactating females (Women of childbearing potential should be advised to use contraception during treatment with NOURIANZ)

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Itraconazole oral solution (Sporanox®)

(Implemented 10/11/2011)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- History of at least two claims for fluconazole (tablets or suspension) in the previous 7-30 days; **OR**
- One claim each of Nystatin Suspension and fluconazole (tablets or suspension) in the previous 7-30 days; **OR**
- NPO diagnosis within the past 365 days.

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Ivabradinetablet and solution (Corlanor®)

(Implemented 05/04/2015)
(Updated 01/17/2017)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with **ONE** of the following:
  - Adults with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either on maximally tolerated doses of beta-blockers or have a contraindication to beta-blockers
  - Pediatrics with stable, symptomatic heart failure due to dilated cardiomyopathy and are in sinus rhythm with an elevated heart rate
- Beneficiary resting heart rate goals
  - Adults - 50-60 beats per minute
  - Pediatrics - 20% reduction from baseline
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Acute decompensated heart failure
  - Clinically significant hypotension
  - Sick sinus syndrome, sinoatrial block or 3rd degree AV block, unless has pacemaker
  - Clinically significant bradycardia
  - Severe hepatic impairment
  - Pacemaker dependence (heart rate maintained exclusively by pacemaker)
  - Concomitant use of strong cytochrome P450 3A4 (CYP3A4) inhibitors
  - Pregnancy
  - If atrial fibrillation develops
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Current blood pressure on beta-blocker therapy
  - If beta blockers are contraindicated, provide documentation for reason
  - Attestation that female patients of reproductive potential are counseled on effective contraception use

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)

- Beneficiary must demonstrate a positive response with a decreased heart rate compared to baseline (preferably in target range of 50-60 bpm in adults and 20% decrease in pediatrics)
- Prescriber must submit the following:
  - Current chart notes
  - Current blood pressure
  - Attestation that female patients of reproductive potential are counseled on effective contraception use

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Kits

(Implemented 08/17/2010)

All requests for "kits" or "combo pack" products (products that consist of packaging multiple products under one NDC) require a manual review. The underlined individual active ingredients (listed next to the product) do not require a PA.

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require a manual PA

- **CENTANY AT 2% OINMENT KIT** (MUPIROCIN 2% OINTMENT – STERILE GAUZE – TAPE)
- **LIDOCAINE-PRILOCAINE 2.5%-2.5% CREAM KIT** (LIDOCAINE-PRILOCAINE 2.5%-2.5% CREAM – OCCLUSIVE DRESSINGS)
- **ROSADAN 0.75% CREAM KIT** (METRONIDAZOLE 0.75% CREAM – MOISTURIZING SKIN WASH)
- **ROSADAN 0.75% GEL KIT** (METRONIDAZOLE 0.75% GEL – MOISTURIZING SKIN WASH)
- **SYNALAR 0.025% CREAM KIT** (FLUOCINOLONE ACETONIDE 0.025% TOPICAL CREAM – EMOLLIENT CREAM)
- **SYNALAR 0.025% OINTMENT KIT** (FLUOCINOLONE ACETONIDE 0.025% TOPICAL OINTMENT – EMOLLIENT CREAM)
- **SYNAGLAR TS 0.01% KIT** (FLUOCINOLONE ACETONIDE 0.01% TOPICAL SOLUTION – HAIR & BODY CLEANSER)
- **ULTRAVATE X CREAM COMBO PACK** (HALOBETASOL PROPIONATE 0.05% TOPICAL CREAM – AMMONIUM LACTATE 10% MOISTURIZING CREAM)
- **ULTRAVATE X OINTMENT COMBO PACK** (HALOBETASOL PROPIONATE 0.05% TOPICAL OINTMENT – AMMONIUM LACTATE 10% MOISTURIZING CREAM)

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Lanadelumab-flyo (Takhzyro®)

(Implemented 4/17/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Patient must have a laboratory diagnosis of C1-INH deficient or dysfunctional HAE
- Must have ≥ 1 severe or life-threatening laryngeal attack per month or ≥ 4 moderate attacks causing extremity, facial or abdominal swelling despite treatment with medications for acute attacks
- Provider must submit a proposed treatment plan for both acute attacks and prophylaxis treatment
- Documentation of expected angioedema triggers (Trigger avoidance is crucial)
- Must NOT be on an ACEi (or other possible drug causes such as estrogens and NSAIDs)
- Follow the package inserts for specific indicated age or contraindications
- Documentation of attack frequency, comorbidities, and access to emergency care
- **IF** beneficiary has tried and had an insufficient response or contraindication to **BOTH** of the following classes of medication, provide that documentation.
  - 17α-alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
  - Antifibrinolytic agents (e.g. ε-aminocaproic acid, tranexamic acid)
- Initial PA maximum 3-month trial if approved

Denial Criteria

- History of allergic reaction for C1-INH or blood products
- Diagnosis of acquired angioedema
- < 1 severe or life-threatening laryngeal attack per month or < 4 moderate attacks per month causing extremity, facial or abdominal swelling
- Beneficiary is not diagnosed with Type I or Type II HAE (Type III would be considered separately)
- Failure to provide adequate records
- No therapeutic duplication of 2 or more agents

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Lansoprazole, Amoxicillin, and Clarithromycin combination (Prevpac®)

(Implemented 01/12/2005)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for these products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

Criterion 1:

- No history of lansoprazole, amoxicillin, and clarithromycin combination (PREVPAC) in the last 365 days; **AND**
- No history of omeprazole, amoxicillin, and clarithromycin combination (OMECLAMOX Pak) in the last 365 days; **AND**
- No concurrent proton pump inhibitor therapy within the past 30 days.

Criterion 2:

- No history of metronidazole/tetracycline/bismuth combination (PYLERA) in the last 365 days.

Additional Criteria

- Quantity limits apply

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Leniolisib 70mg tablet (Joenja®)

(Effective 7/19/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) with a documented variant in either PIK3CD or PIK3R1 **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must be a specialist with experience in APDS such as immunology, hematology/oncology, or pulmonology
- In addition to the APDS diagnosis, the beneficiary must demonstrate symptoms consistent with the diagnosis (e.g., sino-pulmonary infection, lymphoproliferation, enteropathy, organ dysfunction, etc.)
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Pregnant
  - Weighs less than 45 kg
  - Requires concomitant strong CYP3A4 inhibitors (e.g., itraconazole)
  - Requires concomitant moderate or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin)
  - Moderate to severe hepatic impairment
- Prescriber must submit ALL of the following:
  - Current chart notes with documentation of specific symptoms for this beneficiary and documentation of variant
  - Previous therapies including surgery
  - Current negative pregnancy test for females of reproductive potential
  - Current weight
  - MRI or CT imaging results documenting lesions with descriptions
  - Current labs including LFTs
  - Medical necessity over IVIG and sirolimus
  - Baseline % naïve B cell
- Initial PA for 3 months

Renewal Requirements

- Prescriber must submit ALL of the following:
  - Prescriber must submit current chart notes
  - Response to therapy
- Beneficiary has a positive response with symptoms with documented decrease in lymph node lesions and/or increase in % naïve B cells

Quantity Edits

- #62/31 days

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Letermovir tablet and vial (Prevymis®)

(Implemented 03/01/2018)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must have **ONE** of the following:
  - Needs CMV prophylaxis after hematopoietic stem cell transplant (HSCT) and are CMV-seropositive (R+)
  - Needs CMV prophylaxis after kidney transplant for those at high risk (i.e., donor CMV seropositive/beneficiary CMV seronegative [D+/R-])
- HSCT beneficiary must start on PREVYMIS between Day 0 and Day 28 post-HSCT and continue through day 100 post HSCT. Patients at risk for late CMV infection may continue through day 200 post HSCT.
- Kidney transplant beneficiary must start on PREVYMIS between Day 0 and Day 7 post-transplant and continue through Day 200 post-transplant
- Beneficiary started on cyclosporine must have dose adjustment.
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has CMV viremia prior to initiation
  - End stage renal disease (CrCl < 10 mL/min)
  - Severe hepatic impairment (Child-Pugh C)
  - Request to start after Day 28 for HSCT and after Day 7 for kidney transplant
  - Ordered concomitant pimozide or ergot alkaloids
  - Ordered concomitant pitavastatin or simvastatin and cyclosporine
- Prescriber must submit the following:
  - Current chart notes and/or discharge summary
  - Documentation of type of transplant
  - Documentation testing for viremia
  - Length of treatment requested with dose
  - If requesting IV vials, provide the medical necessity over oral therapy and treatment plan with home care
  - Current labs including kidney function and hepatic function

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Leucovorin tablet and vial

(Updated and Effective 7/15/2020)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Point-of-Sale (POS) Denial Criteria

- Beneficiary with a billed diagnosis of autistic disorder would cause a point-of-sale denial requiring manual review. Additional studies will be monitored for efficacy and safety. MicroMedex® will be monitored for support of this current off-label use.

Quantity Edits

- Tablets: #30/30 days

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Leukotriene Receptor Antagonists

(Implemented 8/11/2009)
(Updated 11/27/2017)
(Updated 4/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Montelukast tablet, chewable tablet, and granules (generic for Singulair®)

Non-Preferred Agents

- Accolate® tablet (zafirlukast)
- Singulair® tablet, chewable tablet, and granules (montelukast)
- Zafirlukast tablet (generic for Accolate®)
- Zileuton ER tablet (generic for Zyflo CR®)
- Zyflo® tablet (zileuton)

Approval Criteria for Preferred Agents

Criterion 1:

- Diagnosis of asthma in the previous 2 years; **OR**
- AR Medicaid pharmacy claim for any of the following in the previous 186 days:
  - Inhaled corticosteroid (ICS)
  - Inhaled long-acting beta2 agonist (LABA)
  - Inhaled short-acting beta2 agonist (SABA)
  - Inhaled ICS/LABA

OR

Criterion 2:

- Diagnosis of allergic rhinitis in the previous 2 years; **OR**
- AR Medicaid pharmacy claim for any of the following within the previous 60 days:
  - ≥ 1 claim for an inhaled nasal steroid
  - ≥ 1 claim for a first or second-generation antihistamine
  - ≥ 1 claim for azelastine nasal spray or ipratropium nasal spray

OR

Criterion 3:

- Diagnosis of Chronic Idiopathic Urticaria in the previous 2 years

Denial Criteria

- Failure to meet approval criteria
- Therapeutic duplication with a LTRA other than the one on the incoming claim if > 25% of the days supply of the claim in history remains
- An age edit is implemented for the montelukast 10 mg tablet of beneficiary is ≥ 15 years;
- *Maximum* age edit of 16 years on the 4 mg & 5 mg chew tablets;
- Claims for infants ≤ 23 months of age will reject at point of sale for the 4 mg and 5 mg chewable tablets;
- The age edit is implemented for the montelukast 4 mg granule for beneficiary is ≥ 6 months old < 24 months old;
- Claims for pediatric patients < 6 months of age will deny at point of sale.

Additional Criteria

- Quantity limits apply

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Levacetylleucine 1 gm granule packet (Aqneursa™)

(Implemented 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of Niemann-Pick disease type C (NPC) with variants in the NPC1 or NPC2 genes with neurological manifestations (e.g., gait problems, ataxia, cognitive deterioration, or vertical gaze palsy) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Must be prescribed by, or in consultation with, a geneticist, neurologist, or other specialist with expertise in the treatment of NPD
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Weighs < 15 kg
  - Pregnant
  - Dose requested does not match weight-based dosing found in the package insert
  - Prescribed Miplyffa™ (arimoclomol) to be used concomitantly
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried with response
  - Molecular genetic testing results confirming biallelic pathogenic variants in the NPC1 or NPC2 genes
  - Current weight and dose requested
  - Neurological symptoms for this specific patient
  - Negative pregnancy test results if applicable
  - Attestation that female beneficiary of reproductive potential has been counseled on the importance of effective contraception

Renewal Requirements

- Beneficiary remains compliant with therapy (defined as 75% utilization)
- Beneficiary demonstrates a positive response with a decrease or slowed progression in neurological symptoms compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Response to treatment with updated description of symptoms
  - Attestation that female beneficiary of reproductive potential has been counseled on the importance of continuing effective contraception and is not currently pregnant

Quantity Edits

- #120/30 days

Levodopa (Inbrija™)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851

Approval Criteria

- Will require manual review PA on a case-by-case basis
- Age ≥ 30 years old and ≤ 85 years old*
- Baseline labs including CBC, BMP and LFTs
- At baseline, beneficiary has at least 2 hours per day of “OFF” time per day excluding wakening each morning with motor fluctuations
- Carbidopa/levodopa medication did not exceed 1600 mg levodopa per day.
- Hoehn and Yahr Stage 1-3 in an “ON” state (see stages below)*
- Must be compliant on current carbidopa/levodopa therapy
- Baseline Unified Parkinson’s Disease Rating Scale (UPDRS) Part III motor score from pre-dose “OFF” state. The UPDRS part III is designed to assess the severity of the cardinal motor findings (e.g., tremor, rigidity, bradykinesia, postural instability) in patients with Parkinson's disease.
- Provide the medical necessity of adding this medication over increasing current Carbidopa/Levodopa dose

Denial Criteria

- Taking a nonselective monoamine oxidase (MAO) inhibitor
- Diagnosed with a major psychotic disorder or suicide ideation/attempt in last year
- Not recommended in patients with asthma, COPD or another chronic lung disease
- Pregnant
- ≤ 2 hours per day of “OFF” time
- Hoehn and Yahr Stage > 3 in an “ON” state

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Levoketoconazole (Recorlev®)

(Implemented 04/20/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Beneficiary must be ≥ 18 years of age; **AND**
- Beneficiary must have a diagnosis of Cushing's syndrome with hypercortisolemia and surgery is not an option or has not been curative OR a diagnosis consistent with the FDA approved indication; **AND**
- Prescriber must be an endocrinologist; **AND**
- Beneficiaries with hypokalemia or hypomagnesemia will need to delay initiation until resolved; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of surgery status; **AND**
  - Current labs including:
    - Urine free cortisol levels (normal is <150 nmol/24 hours OR 3.5-45 mcg/24 hours); **AND**
    - Liver function tests; **AND**
    - Comprehensive metabolic panel; **AND**
  - Baseline electrocardiogram; **AND**
- Beneficiary should have a trial and failure of ketoconazole and mitotane unless contraindicated or beneficiary cannot tolerate both medications

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported on the official Compendia; **OR**
- Beneficiary has cirrhosis, acute liver disease or poorly controlled chronic liver disease, recurrent symptomatic cholelithiasis, or history of drug induced liver injury due to ketoconazole; **OR**
- Beneficiaries that develop hypocortisolemia should decrease the dose or discontinue the medication; **OR**
- Beneficiary continues to have hypercortisolemia despite maximum recommended dosage of 1200 mg per day; **OR**
- Beneficiary takes other medications that cause QT prolongation or has any of the following:
  - Prolonged QTcF interval > 470 msec at baseline
  - History of torsade's de pointes
  - Ventricular tachycardia
  - Ventricular fibrillation
  - Long QT syndrome

Quantity Edits

- #248/31 days

Levothyroxine solution (Ermeza® and Thyquidity®)

(Implemented 04/01/2020)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with **ONE** of the following:
  - primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism
  - adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer
- Prescriber must submit the following:
  - Current chart notes
  - Current labs (TSH, T4)
  - Letter of medical necessity over levothyroxine tablets

Renewal Requirements

- Beneficiary must be compliant with therapy (defined as 75% utilization)
- Prescriber must submit the following:
  - Current chart notes
  - Current labs (TSH, T4)
  - Continued need over levothyroxine tablets

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Levothyroxine vial (Synthroid®)

(Implemented 04/17/2012)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with myxedema coma
- Beneficiary should be transitioned to oral therapy when able

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Lidocaine 5% ointment

(Implemented 06/29/2017)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Quantity limit to only allow one package size per NDC
- No therapeutic duplication allowed

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Lidocaine-Prilocaine 2.5%-2.5% cream (Emla®)

(Implemented 07/09/2012)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Additional Criteria

- Quantity limits apply

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Lipotropics (excluding statins)

(Implemented 01/18/2011)
(Re-review 5/10/2018)
(Updated 7/1/2018)
(Updated 1/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents without Criteria

Bile Acid Sequestrants

- Cholestyramine light powder for oral suspension (generic for Questran Light®, Prevalite®)
- Cholestyramine powder for oral suspension (generic for Questran®)
- Colestipol granules (generic for Colestid®)
- Colestipol packet (generic for Colestid®)
- Colestipol tablet (generic for Colestid®)

Cholesterol Absorption Inhibitor

- Ezetimibe tablet (generic for Zetia®)

Fibric Acids

- Fenofibrate tablet 48mg, 145mg (generic for Tricor®)
- Fenofibrate tablet 54mg, 160mg (generic for Lofibra®)
- Gemfibrozil tablet 600mg (generic for Lopid®)

Niacin

- Niacin ER tablet (generic for Niaspan ER®)

Non-Preferred Agents

Bile Acid Sequestrants

- Colesevelam powder pack (generic for Welchol®)
- Colesevelam tablet (generic for Welchol®)
- Colestid® tablet (colestipol)
- Colestid® packet (colestipol)
- Prevalite® powder (cholestyramine)
- Questran® powder (cholestyramine)
- Questran Light® powder (cholestyramine)
- Welchol® powder pack (colesevelam)
- Welchol® tablet (colesevelam)

Cholesterol Absorption Inhibitor

- Zetia® tablet (ezetimibe)

Fibric Acids

- Fenofibrate capsule 134mg, 200mg (generic for Lofibra®)
- Fenofibrate capsule 43mg, 90mg, 130mg (generic for Antara®)
- Fenofibrate capsule 50mg, 150mg (generic for Lipofen®)
- Fenofibrate capsule 67mg, 134mg, 200mg (generic for Tricor®)
- Fenofibrate tablet 40mg, 120mg (generic for Fenoglide®)
- Fenofibric acid delayed-release capsule 45mg, 135mg (generic for Trilipix®)
- Fenofibric acid tablet 35mg, 105mg (generic for Fibricor®)
- Fenoglide® tablet (fenofibrate)
- Lipofen® capsule (fenofibrate)
- Lopid® tablet (gemfibrozil)
- Tricor® tablet (fenofibrate)
- Trilipix® capsule (fenofibric acid)

Preferred Agents with Criteria

** manual review criteria
^^ POS edits

ACL Inhibitor and ACL Inhibitor/Cholesterol Absorption Inhibitor

- None

Apolipoprotein B Synthesis Inhibitor

- None

Omega-3 Fatty Acids

- Omega-3 Acid Ethyl Esters capsule (generic for Lovaza)^^

Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor

- Praluent® pen (alirocumab)**
- Repatha® syringe, autoinjector, pushtronex (evolocumab)**

PCSK9-Directed Small Interfering RNA (siRNA)

- None

Non-Preferred Agents with Criteria

** manual review criteria

ACL Inhibitor and ACL Inhibitor/Cholesterol Absorption Inhibitor

- Nexletol® tablet (bempedoic acid)**
- Nexlizet® tablet (bempedoic acid/ezetimibe)**

Apolipoprotein B Synthesis Inhibitor

- Juxtapid® capsule (lomitapide)**

Omega-3 Fatty Acids

- Icosapent Ethyl capsule (generic for Vascepa®)**
- Lovaza® capsule (omega-3 acid ethyl esters)
- ~~Vascepa® capsule (icosapent ethyl)**~~

Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Inhibitor

- None

PCSK9-Directed Small Interfering RNA (siRNA)

- Leqvio® syringe (inclisiran)**

Approval Criteria for Praluent® and Repatha®

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have one of the following diagnoses (Any off-label requests will be reviewed on a case-by-case basis.)
  - Established cardiovascular disease and at risk of myocardial infarction, stroke, or unstable angina requiring hospitalization - PRALUENT
  - Established cardiovascular disease and at risk of major adverse cardiovascular events (e.g., CV death, MI, stroke, unstable angina requiring hospitalization, coronary revascularization) – REPATHA
  - Primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH) – PRALUENT and REPATHA
  - Homozygous familial hypercholesterolemia (HoFH) – PRALUENT and REPATHA
- Beneficiary must have a trial and failure of **ALL** of the following:
  - High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40 mg) **OR** maximally tolerated statin therapy OR alternative dosing options to mitigate side effects unless a documented contraindication
  - Ezetimibe with statin therapy
- Compliance on previous lipid therapy is required unless contraindicated (defined as 90 out of 120 days). Beneficiary's Medicaid claims history will be consulted, and a pharmacy printout may be requested to ensure compliance
- Beneficiary should have an LDL-C ≥ 70mg/dL and/or non-HDL-C ≥ 100mg/dL after a compliant trial of moderate-high intensity statins and ezetimibe unless the beneficiary has a contraindication
- Prescriber must submit **ALL** of the following:
  - Current chart notes with documentation of previous treatments
  - Chart notes during trials of statins AND ezetimibe
  - Current labs including lipids as well as labs corresponding with previous trials of statins AND ezetimibe taken concomitantly
  - Diet plan for lowering cholesterol
- If beneficiary smokes, provider should submit a smoking cessation plan or documentation that the beneficiary has been counseled on smoking cessation
- Initial approval for 2 months

Renewal Requirements for Repatha® or Praluent®

- After initial approval, the beneficiary should demonstrate an improvement in the LDL-C levels
- Beneficiary must be compliant with therapy
- Renewals may be approved for 6 months with required response to therapy provided on each PA review
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Current lipid panel

Approval Criteria for Leqvio®

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), who require additional lowering of low-density lipoprotein cholesterol (LDL-C) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have a trial and failure of ALL of the following:
  - High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40 mg) **OR** maximally tolerated statin therapy **OR** alternative dosing options to mitigate side effects unless a documented contraindication
  - Ezetimibe with statin therapy
  - Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., PRALUENT or REPATHA)
- Beneficiary should have an LDL-C ≥ 70mg/dL and/or non-HDL-C ≥ 100mg/dL after a compliant trial (defined as 90 out of 120 days) of statins, ezetimibe, and PCSK9 inhibitors as defined above
- If approved, beneficiary must continue statin therapy at maximally tolerated dose
- Prescriber must submit **ALL** of the following:
  - Current chart notes with documentation of previous treatments
  - Current labs including lipids along with labs corresponding with previous trials of statin and ezetimibe used concomitantly and with the addition of a PCSK9 inhibitor
  - Treatment plan with goal LDL-C
  - Diet plan for lowering cholesterol
- If beneficiary smokes, provider should submit a smoking cessation plan or documentation that the beneficiary has been counseled on smoking cessation
- Initial approval for 3 months

Renewal Requirements for Leqvio®

- After initial approval, the beneficiary should demonstrate an improvement in the LDL-C levels
- Beneficiary must be compliant with therapy
- Renewals may be approved for 6 months with required response to therapy provided on each PA review
- Prescriber must submit ALL of the following:

- Current chart notes
- Current lipid panel

Approval Criteria for Juxtapid®

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with homozygous familial hypercholesterolemia (HoFH) and use this medication as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C)
- Beneficiary must have a trial and failure of ALL of the following:
  - High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40 mg) OR maximally tolerated statin therapy OR alternative dosing options to mitigate side effects unless a documented contraindication
  - Ezetimibe with statin therapy
  - Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., PRALUENT or REPATHA)
- Prescriber must submit ALL of the following:
  - Current chart notes with documentation of previous treatments
  - Current labs including lipids along with labs corresponding with previous trials of statin and ezetimibe used concomitantly and with the addition of a PCSK9 inhibitor
  - Treatment plan with goal LDL-C
  - Diet plan for lowering cholesterol
  - Medical necessity over all other treatments for high cholesterol

Renewal Requirements for Juxtapid®

- After initial approval, the beneficiary should demonstrate an improvement in cholesterol levels
- Beneficiary must be compliant with therapy
- Renewals may be approved for 6 months with required response to therapy provided on each PA review
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Current lipid panel

Approval Criteria for Nexletol® or Nexlizet®

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with primary hyperlipidemia with heterozygous familial hypercholesterolemia or atherosclerotic cardiovascular disease who require additional lowering of LDL-C OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.

- Beneficiary must have a trial and failure of ALL of the following:
  - High dose statin therapy (LDL reduction capability equivalent to rosuvastatin 40 mg) OR maximally tolerated statin therapy **OR** alternative dosing options to mitigate side effects unless a documented contraindication
  - Ezetimibe with statin therapy
  - Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., PRALUENT or REPATHA)
- Beneficiary should have an LDL-C ≥ 70mg/dL and/or non-HDL-C ≥ 100mg/dL after compliant trials (defined as 90 out of 120 days) of moderate-high intensity statins, ezetimibe, and PCSK9 inhibitors per current treatment guidelines unless the beneficiary has a contraindication
- Beneficiary must be prescribed concomitant statin therapy unless contraindicated or patient demonstrated statin intolerance
- Prescriber must submit ALL of the following:
  - Current chart notes with documentation of previous treatments
  - Current labs including lipids along with labs corresponding with previous trials of statin and ezetimibe used concomitantly and with the addition of a PCSK9 inhibitor and uric acid levels for patients with a gout diagnosis
  - Treatment plan with goal LDL-C
  - Diet plan for lowering cholesterol
  - Medical necessity over the use of medication outlined in current treatment guidelines
- If beneficiary smokes, provider should submit a smoking cessation plan or documentation that the beneficiary has been counseled on smoking cessation
- Initial approval for 2 months

Renewal Requirements for Nexletol® or Nexlizet®

- After initial approval, the beneficiary should demonstrate an improvement in the LDL-C levels
- Beneficiary must be compliant with therapy
- Renewals may be approved for 6 months with required response to therapy provided on each PA review
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Current lipid panel

Approval Criteria for Omega-3 Acid Ethyl Esters (generic for Lovaza®)

Approval Criteria for POS Edit:

- Diagnosis in Medicaid medical history in previous 3 years of hypertriglyceridemia; **AND**
- Triglyceride level ≥ 500mg/dL in the last 180 days; **AND**
- Beneficiary's Medicaid pharmacy drug history indicates at least three (3) claims of fibric acid derivatives in the last 365 days; **AND**
- Beneficiary's Medicaid pharmacy drug history indicates at least one (1) paid claim for one of the following in the past 14-60 days preferably containing a seven (7) day overlap with a fibric acid derivative:
  - Maximally tolerated statin dose
  - Ezetimibe

Manual review PA will be on a case-by-case basis if the above requirements are not found in the Medicaid system for POS approval. Prescribers must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

Approval Criteria for Icosapent Ethyl (generic for Vascepa®)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must meet one of the following:
  - Use as an adjunct to maximally-tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride levels AND both of the following:
    - Laboratory documentation of fasting triglycerides ≥150mg/dL and LDL-C ≤ 100 mg/dL
    - Must be diagnosed with either established cardiovascular disease or diabetes mellitus and 2 or more additional risk factors for CVD
  - Use as an adjunct to diet to reduce TG with severe (≥ 500 mg/dL) hypertriglyceridemia.
- Beneficiary must be compliant on a maximally tolerated statin therapy for at least 4 weeks
- Provider must submit ALL of the following:
  - Current chart notes with documentation of previous treatments
  - Current labs including lipids along with labs
  - Treatment plan with goal LDL-C and triglycerides
  - Diet plan for lowering triglycerides
  - Medical necessity over omega-3 acid ethyl esters and fibric acid agents

Renewal Requirements for Icosapent Ethyl (generic for Vascepa®)

- After initial approval, the beneficiary should demonstrate an improvement in the triglyceride levels
- Beneficiary must be compliant with therapy
- Renewals may be approved for 6 months with required response to therapy provided on each PA review
- Prescriber must submit ALL of the following:
  - Current chart notes
  - Current lipid panel

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Lithium ER or SA

(Implemented 04/08/2014)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- ≥ 90 days of Lithium ER or Lithium SA therapy in the past 120 days

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Lofexidine (Lucemyra™)

(*Implemented 7/18/2018)*

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary is an adult ≥ 18 years;
- Beneficiary is physically dependent on opioid drug(s) and currently has acute withdrawal symptoms due to abrupt opioid discontinuation;
- Beneficiary is not currently receiving any opioid medications;
- The prescribed dose will not exceed 16 tablets (2.88 mg) per day, or 4 tablets (0.72 mg) in a single dose, or 14 days of treatment with LUCEMYRA;
- Beneficiary is not hospitalized during this treatment;
- Prescriber must submit chart notes and treatment plan;

Denial Criteria

- Beneficiary does not meet approval criteria;
- Beneficiary is hospitalized at time of request;
- Request is for greater than 96 tablets
- Request is for greater than 14 days of treatment in previous 365 days;

Quantity Limits

- One 14-day treatment allowed once per 365 days;
- The quantity allowed for a one-time treatment will not exceed 96 tablets;
- One claim allowed per 365 days;
- One claim will pay for one bottle of 96 tablets or one bottle of 36 tablets

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Lotilaner 0.25% drops (Xdemvy™)

(Implemented 1/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary has been diagnosed with *Demodex* blepharitis verified by presence of collarettes through a slit lamp exam **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Xdemvy™ must be prescribed by or in consultation with an optometrist or ophthalmologist
- Prescriber must submit **ALL** the following:
  - Documentation of results seen with slit lamp examination
  - Other therapies tried
  - Medical necessity over topical tea tree oil/shampoo and oral ivermectin

Renewal Requirements

- Beneficiary had a previous positive response with a reduction in collarettes and mites.
- Maximum of 2 treatments per year

Quantity Edits

- 1 bottle per 6 weeks

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Maralixibat (Livmarli®)

(Implemented 4/20/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication; **AND**
- Beneficiary is prescribed no more than the maximum dose or treatment duration for their weight and diagnosis based on the manufacturer's package insert or support from the official Compendia; **AND**
- Beneficiary must have a confirmed diagnosis of **ONE** (1) of the following:
  - Alagille syndrome with a baseline presence of cholestatic pruritis
  - Progressive Familial Intrahepatic Cholestasis with a baseline presence of cholestatic pruritis
  - Diagnosis consistent with any new FDA indication
- Beneficiary has elevated serum bile acid concentration; **AND**
- Beneficiary has documented failure of ursodeoxycholic acid (URSODIOL) **AND** a bile acid sequestrant unless there is a documented contraindication; **AND**
- Beneficiary should continue ursodeoxycholic acid concomitantly; **AND**
- Beneficiary should not have hepatic decompensation
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including serum bile acid level, LFTs, and fat-soluble vitamins (A, D, E, and INR); **AND**
  - Current weight for dose determination; **AND**
- Initial approval for 3 months

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with decrease in pruritis or decrease in serum bile acid after trial with maximum dose of 380 mcg/kg per day
- Provider should provide the following:
  - Current chart notes
  - Current labs including serum bile acid level, LFTs, and fat-soluble vitamins (A, D, E, and INR);
  - Current weight for dose determination

Quantity Edits

- 9.5 mg/ml = 3 bottles (90 ml)/30 days
- 19 mg/ml = 2 bottles (60 ml)/30 days
- 10 mg, 15 mg, & 20 mg tablet = #62/31 days
- 30 mg tablet = #31/31 days

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Maribavir (Livtencity®)

(Implemented 4/20/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 12 years of age and weigh at least 35 kg; **AND**
- Beneficiary must have received either a hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT) with diagnosed CMV that is refractory to treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet **OR** a diagnosis consistent with the FDA approved indication; **AND**
- Beneficiary must not exceed the following dosages:
  - 800 mg per day
  - If co-administered with carbamazepine: 1600 mg per day
  - If co-administered with phenytoin or phenobarbital: 2400 mg per day
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Labs confirming active CMV infection with CMV DNA level and CBC; **AND**
  - Negative pregnancy test if of reproductive potential; **AND**
  - Documentation of previous therapies; **AND**
  - Current weight; **AND**
- Initial PA request approved for maximum of 2 months

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported on the official Compendia; **OR**
- Beneficiary is pregnant; **OR**
- Beneficiary's treatment plan includes concomitant use with valganciclovir or ganciclovir; **OR**
- Beneficiary has end state renal disease or severe hepatic impairment; **OR**
- Prescriber ordered as prophylaxis therapy; **OR**
- Beneficiary has been diagnosed with central nervous system CMV disease including CMS retinitis; **OR**
- Prescriber orders for dose outside of recommendation by the manufacturer

Quantity Edits

- #124/31 days

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Mavacamtan (Camzyos™)

(Implemented 7/20/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be at least 18 years of age; **AND**
- Beneficiary must have a diagnosis of NYHA Class II-III obstructive hypertrophic cardiomyopathy **OR** a diagnosis consistent with any updated FDA indications; **AND**
- Prescribers, patients, and pharmacies must be enrolled in the Camzyos™ REMS program due to risk of heart failure due to systolic dysfunction; **AND**
- Beneficiary must have tried and failed beta blockers and calcium channel blockers unless contraindicated; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Previous treatment; **AND**
  - Confirmation for absence of pregnancy and attestation that females of reproductive potential will use effective contraception; **AND**
  - Baseline LVEF, Valsalva LVOT peak gradient, and mixed peak oxygen consumption

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported on the official Compendia; **OR**
- Beneficiary has a baseline LVEF < 55% or Valsalva LVOT peak gradient < 50 mmHg; **OR**
- Beneficiary requires moderate to strong CYP2C19 inhibitors or inducers, **OR** strong CYP3A4 inhibitors, **OR** moderate to strong CYP3A4 inducers; **OR**
- Beneficiary is pregnant

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Mavorixafor capsule (Xolremdi™)

(Implemented 10/16/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis) that has genotype-confirmed variant of CXC chemokine receptor 4 (CXCR4) with low number of circulating mature neutrophils and lymphocytes **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have an absolute neutrophil count (ANC) ≤ 400 cells/µL at baseline
- Prescribed by or in consultation with an immunologist, hematologist or dermatologist
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Pregnant
  - Breastfeeding
  - Severe renal impairment (CrCl < 30 mL/min)
  - Moderate to severe hepatic impairment
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies
  - Current labs including CBC with differential, liver function tests, and basic metabolic panel
  - Current weight
  - Dose requested
  - Pregnancy test for female patient of reproductive potential
  - Attestation that the female patient of reproductive potential has been counseled on the use of an effective method of contraception during treatment for 3 weeks after the final dose.

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a clinical benefit based on any of the following (compared to baseline):
  - Reduced frequency, duration or severity of infections
  - Fewer warts
  - Improved labs (e.g., absolute neutrophil count, white blood cell count, and absolute lymphocyte count)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of clinical response to treatment

- Current labs including CBC with differential, liver function tests, and basic metabolic panel

Quantity Edits

- #120/ 30 days

Top of the document

Mecasermin vial (Increlex®)

(Implemented 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with **ONE** of the following:
  - Primary IGF-1 deficiency with **ALL** of the following:
    - Height >3 standard deviations (SD) below the mean; and
    - Basal IGF-1 >3 SD below the mean; and
    - Normal or elevated growth hormone (GH)
  - Growth hormone gene deletion and have developed neutralizing antibodies to growth hormone
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Diagnosed with secondary IGF-1 deficiency related to GH deficiency, malnutrition, hypothyroidism, or chronic steroid therapy
  - Has evidence of malignant neoplasm
  - Has closed epiphyses
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Baseline growth velocity charts
  - Current weight to confirm requested dose
  - Current bone age with documentation of epiphyses status
  - Documentation of diagnosis with any of the following:
    - Mutation in GH receptor; OR
    - Mutation in the post-GHR signaling pathway; OR
    - IGF-1 gene defects (i.e., Laron Syndrome)

Renewal Requirements

- Beneficiary has been compliant with therapy (defined as 75% utilization)
- Beneficiary has a positive response to treatment with improvement in growth velocity compared to baseline
- Beneficiary must continue to have open epiphyses for renewal
- Prescriber must submit the following:
  - Current chart notes
  - Current calculated growth velocity
  - Documentation of open epiphyses

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Medication Assisted Treatment Medications

(Implemented 04/21/2009)
(Updated September 7, 2018)
(Updated July 1, 2019)
(Updated 1/1/2020)
(Updated 10/1/2021)
(Updated 1/1/2023)
(Updated 5/22/2023)
(Updated 9/1/2023)
(Updated 7/1/2024)

Preferred Opioid Dependence Agents with NO Criteria

- Buprenorphine sublingual tablet
- Naltrexone 50mg tablet
- Suboxone® Film (BRAND ONLY)
- Zubsolv SL tablet

As of 1/1/2020 the preferred oral agents for MAT therapy will no longer require a PA

Effective 1/1/2025, the maximum daily allowed dose will increase to the equivalent of 32 mg of buprenorphine. At that time, a therapeutic duplication edit will be implemented for oral opioid use disorder (OUD) agents to prevent overlapping claims for multiple oral dosage forms. There will not be a therapeutic duplication edit place between the oral and injectable products.

Preferred Injectable Medication Assisted Treatment (MAT) Agents

- Brixadi® SQ syringe (buprenorphine extended release)
- Sublocade® SQ injection (buprenorphine extended release)
- Vivitrol® IM suspension (naltrexone for extended release)

Preferred Injectable MAT Agents may be billed at point-of-sale in a pharmacy setting or through the patient's medical benefits. No PA is required at the pharmacy.

Preferred Opiate Overdose Agents/Rescue Medications with NO Criteria

- Kloxxado 8 mg nasal spray
- Naloxone 0.4 mg/mL vial
- Naloxone 2 mg/2 mL syringe
- Naloxone 4 mg nasal spray
- Narcan 4 mg nasal spray
- Rextovy 4 mg nasal spray
- Zimhi 5 mg/0.5 mL syringe

Preferred Alcohol Dependence Agents with NO Criteria

- Acamprosate DR 333mg tablets
- Disulfiram 250mg and 500mg tablets
- Naltrexone 50mg tablets

Non-Preferred Opioid Dependence Agents

- Buprenorphine/naloxone SL tablets (generic for Suboxone tablets)
- Buprenorphine/naloxone sublingual film (generic for Suboxone films)

Non-Preferred Injectable MAT Agents

- None

Non-Preferred Opiate Overdose Agents/Rescue Medications

- Lifems naloxone 2mg/2mL kit
- Lucemyra 0.18mg tablets
- Nalmefene 2mg/2mL vial
- Naloxone 0.4mg/mL carpuject
- Opvee nasal spray

Additional Criteria

- Quantity limits apply

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Medroxyprogesterone (Depo-Provera®)

(Implemented 02/12/2013)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- No Therapeutic Duplication with any other injectable Depo-Provera®

DESCRIPTION
MEDROXYPROGESTERONE ACETATE 104 MG/0.65 ML SYRINGE
MEDROXYPROGESTERONE ACETATE 150 MG/ML SYRINGE
MEDROXYPROGESTERONE ACETATE 150 MG/ML VIAL
MEDROXYPROGESTERONE ACETATE 400 MG/ML VIAL

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Megestrol (Megace® and Megace ES®)

(Implemented 10/18/2006)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- History of HIV/AIDS in the past two years; **OR**
- History of a paid claim for an antiviral: HIV agent in the past 60 days; **OR**
- History of malignancy in the past two years

Additional Criteria

- Quantity limits apply

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Meprobamate tablet (Equanil®)

(Implemented 07/09/2012)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Additional Criteria

- Quantity limits apply

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Meropenem-Vaborbactam injection (Vabomere®)

(Implemented 03/01/2018)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drug that requires a manual review for prior authorization

- Vabomere® Injection

Additional Criteria

- Age limits apply
- Quantity limits apply

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Methotrexate injection (Otrexup® and Reditrex®)

(Implemented 07/08/2014)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for these products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with **ONE** of the following:
  - Rheumatoid arthritis (RA)
  - Polyarticular juvenile idiopathic arthritis (pJIA)
  - Psoriasis
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Prescribed for treatment of neoplastic disease
  - RA and pJIA patients that have not trialed and failed full dose non-steroidal anti-inflammatory agents (unless documented contraindication)
  - Dosing is not supported by the package insert or official Compendia for the specific patient indication
  - Pregnant
- Prescriber must submit the following:
  - Current chart notes with documentation of diagnosis
  - Previous therapies tried with timeframe and response
  - Confirmation of negative pregnant status for female patient of reproductive potential
  - Letter of medical necessity for the use over oral methotrexate and methotrexate vials which are both available without prior authorization

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a significant improvement in the treated diagnosis
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Continued medical necessity over oral methotrexate or methotrexate vials

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Methotrexate sodium (Trexall®)

(Implemented 8/17/2010)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with **ONE** of the following:
  - Acute lymphoblastic leukemia (ALL)
  - Mycosis fungoides (cutaneious T-cell lymphoma)
  - Relapsed or refractory non-Hodgkin lymphomas
  - Rheumatoid arthritis (RA)
  - Polyarticular juvenile idiopathic arthritis (pJIA)
  - Psoriasis
- Beneficiary should not be approved if pregnant
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried with timeframe and response
  - Current labs to monitor myelosuppression, renal toxicity, and liver toxicity
  - Confirmation of negative pregnant status for female patient of reproductive potential
  - Letter of medical necessity for the use over generic oral methotrexate which is available without a PA

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a significant improvement in the treated diagnosis
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Continued medical necessity over oral generic methotrexate

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Methoxsalen capsule (Oxsoralen-Ultra®)

(Implemented 09/23/2014)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with severe, recalcitrant, disabling psoriasis
- Beneficiary must be getting concomitant long wave ultraviolet radiation
- Must be prescribed by, or in consultation with, a dermatologist knowledgeable in treatment with photochemotherapy
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Has a disease that is associated with photosensitivity (e.g., lupus, xeroderma pigmentosum, albinism)
  - Has history of melanoma
  - Has invasive squamous cell carcinoma
  - Has aphakia
  - Has not had an ophthalmologic examination prior to starting therapy then yearly thereafter
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried with timeline and response

Renewal Requirements

- Beneficiary is compliant with therapy (defined as 75% utilization)
- Beneficiary has a positive response with improvement in psoriasis without intolerable side effects
- Prescriber must submit the following:
  - Current chart notes

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Methscopolamine (Pamine®, Pamine Forte®, Pamine FQ®)

(Implemented 06/19/2008)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- History of peptic ulcer disease in Medicaid medical history in previous 6 months; **AND**
- CPT code for H.Pylori in procedure history in the past 6 months; **AND**
- At least 112 days of PPI therapy in the last 120 days.

Denial Criteria

- History of glaucoma

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Metoclopramide spray (Gimoti™)

(Implemented 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with recurrent diabetic gastroparesis
- Beneficiary should not be approved or continue this therapy with any of the following:
  - <18 years of age
  - Moderate or severe hepatic impairment (Child-Pugh B or C)
  - Moderate or severe renal impairment (CrCl < 60 mL/minute)
  - Requires concomitant strong CYP2D6 inhibitors
  - Prescribed a treatment duration >12 weeks
  - History of tardive dyskinesia
  - Has seizures
  - Caution in gastrointestinal hemorrhage, mechanical obstruction or perforation
  - Initial therapy for gastroparesis in patients ≥65 years of age
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Letter of medical necessity for the use over metoclopramide tablets or metoclopramide oral solution. Prescriber must provide a patient-specific clinically significant reason this dosage form is required.

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Metreleptin 11.3mg vial (Myalept®)

(Implemented 09/23/2014)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with congenital or acquired generalized lipodystrophy and experiencing complications of leptin deficiency
- Beneficiary must be prescribed this medication as an adjunct to diet as replacement therapy
- Prescriber and pharmacy must be enrolled in the MYALEPT REMS program
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Diagnosed with partial lipodystrophy
  - Prescribed for the treatment of liver disease (i.e., nonalcoholic steatohepatitis)
  - Diagnosed with HIV-related lipodystrophy
  - Diagnosed with metabolic disease (i.e., diabetes and hypertriglyceridemia) without concurrent evidence of congenital or acquired generalized lipodystrophy
  - Diagnosed with general obesity not associated with congenital leptin deficiency
  - At risk of pancreatitis
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including fasting leptin concentration, baseline HbA1c, fasting glucose and fasting triglycerides

Renewal Requirements

- Beneficiary is compliant with therapy (defined as 75% utilization)
- Beneficiary has a positive response with improvement in serum leptin, HbA1c, and triglycerides
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to treatment

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Metronidazole 375 mg capsule (Flagyl®)

(Implemented 08/17/2010)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Diagnosis of NPO (Appendix A) in the previous year; **OR**
- < 7 years of age

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Metronidazole 500mg/5mL suspension (Likmez™)

(Implemented 1/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with trichomoniasis, amebiasis, or anaerobic bacterial infection with **ONE** of the following specific bacteria:
  - Intra-abdominal infections, including peritonitis, intra-abdominal abscess, and liver abscess, caused by *Bacteroides* species including the *B. fragilis* group (*B. fragilis, B. ovatus, B. thetaiotaomicron, B. vulgatus*), *Parabacteroides distasonis, Clostridium* species, *Eubacterium* species, *Peptococcus* species, and *Peptostreptococcus* species.
  - Skin and skin structure infections caused by *Bacteroides* species including the *B. fragilis* group, *Clostridium* species, *Peptococcus* species, *Peptostreptococcus* species, and *Fusobacterium* species.
  - Gynecologic infections, including endometritis, endomyometritis, tubo-ovarian abscess, and postsurgical vaginal cuff infection, caused by *Bacteroides* species including the *B. fragilis* group, *Clostridium* species, *Peptococcus* species, *Peptostreptococcus* species, and *Fusobacterium* species.
  - Bacterial septicemia caused by *Bacteroides* species including the *B. fragilis* group and *Clostridium* species.
  - Bone and joint infections, (as adjunctive therapy), caused by *Bacteroides* species including the *B. fragilis* group.
  - Central nervous system (CNS) infections, including meningitis and brain abscess, caused by *Bacteroides* species including the *B. fragilis* group.
  - Lower respiratory tract infections, including pneumonia, empyema, and lung abscess, caused by *Bacteroides* species including the *B. fragilis* group.
  - Endocarditis caused by *Bacteroides* species including the *B. fragilis* group.
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Report indicating diagnosis/bacteria requiring treatment
  - Culture and sensitivity if available
  - Medical necessity over other antibiotics available without a PA including metronidazole tablets
  - Dose requested

Renewal Requirements

- Continuation requires a report that documents continued bacteria positivity

Quantity Edits

- No set maximum quantity since based on dose required

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Metronidazole-Tetracycline-Bismuth (Pylera®)

(Implemented 01/12/2005)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

Criterion 1:

- No history of lansoprazole, amoxicillin, and clarithromycin combination (PREVPAC) in the last 365 days; **AND**
- No history of omeprazole, amoxicillin, and clarithromycin combination (OMECLAMOX-Pak) in the last 365 days; **AND**

Criterion 2:

- No history of metronidazole, tetracycline, and bismuth combination (PYLERA) in the last 365 days.

Denial Criteria

Criterion 1:

- History of lansoprazole, amoxicillin, and clarithromycin combination (PREVPAC) in the last 365 days; **OR**
- History of omeprazole, amoxicillin, and clarithromycin combination (OMECLAMOX-Pak) in the last 365days; **AND**

Criterion 2:

- History of metronidazole, tetracycline, and bismuth combination (PYLERA) in the last 365 days

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Mifepristone 300 mg tablet (Korlym®)

(Implemented 07/23/2012)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with hyperglycemia secondary to hypercortisolism due to endogenous Cushing's syndrome and has type 2 diabetes mellitus or glucose intolerance
- Beneficiary must have failed surgery intended to correct the cause of endogenous Cushing's syndrome or not be a candidate for surgery that is expected to correct the cause of endogenous Cushing's syndrome
- Must be prescribed by, or in consultation with, an endocrinologist
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Pregnant
  - Requires concomitant drugs metabolized by CYP3A (e.g., simvastatin, cyclosporine, tacrolimus)
  - Requires systemic corticosteroids for lifesaving purposes (e.g., immunosuppression after organ transplantation)
  - History of unexplained vaginal bleeding or endometrial hyperplasia with atypia or endometrial carcinoma
  - Suspected adrenal insufficiency (KORLYM can be restarted at a lower dose after resolution of adrenal insufficiency)
  - Prescribed more than 600 mg per day when renally impaired or has mild to moderate hepatic impairment
  - Has severe hepatic impairment
  - Has hypokalemia (must be corrected prior to initiating KORLYM)
- Prescriber must submit the following:
  - Current chart notes with patient specific symptoms of Cushing's syndrome
  - Pregnancy test results for female patients of reproductive potential
  - Current labs including baseline HbA1c, fasting glucose, renal function, hepatic function, and baseline cortisol and ACTH levels
  - Attestation that female patients of reproductive potential are using a non-hormonal method of contraception or have undergone surgical sterilization
  - Current weight (maximum dose is 1200 mg per day but should not exceed 20 mg/kg per day)

Renewal Requirements

- Beneficiary is compliant with therapy (defined as 75% utilization)
- Beneficiary has demonstrated a positive response to treatment without intolerable side effects

- Prescriber must submit the following:
  - Current chart notes with documentation of response to therapy
  - Current labs to support response to therapy including HbA1c, fasting glucose, renal function, hepatic function, cortisol and ACTH levels
  - Current weight for dose verification

Quantity Edits

- #120/30 days

Top of the document

Migalastat (Galafold®)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Galafold®

Approval Criteria

- Beneficiary is an adult ≥ 18 years of age
- Provider must submit documentation that beneficiary has diagnosis of Fabry disease with renal manifestations, **AND** has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data, **AND** the amenable variant must be a disease-causing variant
- Beneficiary is on a low protein diet
- Provider must submit beneficiary's urine albumin, urinary creatinine, serum creatinine, glomerular filtration rate (GFR), serum BUN, serum electrolytes, plasma globotriaosylsphingosine (lyso-Gb3) for the last 12 months
- Beneficiary must have tried Enzyme Replacement Therapy and provider must submit Medication Administration Records (MARs) and response to therapy for the last 12 months
- Provider must submit patient specific measurable treatment goals for outcomes with GALAFOLD and include the treatment plan if the measurable treatment goals are not met and GALAFOLD is discontinued
- Initial approval can be for 6 months

Denial Criteria

- Beneficiary does not have Fabry disease with an amenable galactosidase alpha gene (GLA) variant
- The GLA variant is not a disease-causing variant
- Beneficiary did not show positive response to therapy
- Request for doses exceeding 1 capsule every other day

Quantity Edits

- Limited to 1 capsule every 2 days (Dose is 1 capsule every other day)
- Quantity limited to 14 capsules for a 28-day supply

Top of the document

Miglustat 65mg capsule (Opfolda™)

(Implemented 1/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be an adult diagnosed with late-onset Pompe disease (LOPD) based on documentation of one of the following:
  - Deficiency of GAA enzyme
  - GAA genotyping
- Beneficiary must have tried enzyme replacement therapy (ERT) for at least 24 months without improvement (e.g., improved FVC or 6MWT) with one of the following:
  - Lumizyme (alglucosidase alfa) intravenous infusion; **OR**
  - Nexviazyme (avalglucosidase alfa-ngpt) intravenous infusion
- Must be prescribed by or in consultation with a geneticist, neurologist, or provider that specializes in the treatment of lysosomal storage disorders
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Pregnant
  - Not prescribed concomitant Pombiliti infusions (medical billing will be verified)
  - End stage renal disease (moderate-severe impairment requires dose decrease)
  - < 40 kg
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Generic testing to confirm LOPD
  - Attestation that both female subjects of childbearing potential and male subjects are using contraception
  - Baseline pulmonary function tests (specifically FVC %predicted) and labs for renal function
  - Baseline 6 minute walk test (6MWT)
- Initial PA for 6 months

Renewal Requirements

- Beneficiary must continue to receive Pombiliti infusions every 2 weeks and receiving therapy compliantly
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Attestation that both female subjects of childbearing potential and male subjects continue to use contraception
  - Updated PFTs and renal function labs
  - Updated 6MWT

Quantity Edits

- # 8 capsules/ 28 days

Top of the document

Miglustat capsule (Zavesca®)

(Implemented 01/13/2015)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with **ONE** of the following:
  - Mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g. due to allergy, hypersensitivity, or poor venous access).
  - Niemann-Pick Disease to use concomitantly with MIPLYFFA (arimoclomol citrate) - {off-label use of this medication}
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Severe renal impairment (creatinine clearance <30 mL/min/1.73 m^2) ; mild-moderate renal impairment requires dosage adjustment
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried including enzyme replacement therapy for Gaucher disease patients
  - For Gaucher disease—Baseline liver and spleen volume, platelet count, and hemoglobin (used for determining response to treatment)
  - For Niemann-Pick Disease—patient specific neurological symptoms and molecular genetic testing results confirming biallelic pathogenic variants in the NPC1 or NPC2 genes
  - Letter of medical necessity for the use of this medication over enzyme replacement therapy for Gaucher disease and over the use of Aqneursa™ (levacetylleucine) for Niemann-Pick disease

Renewal Requirements

- Beneficiary is compliant with therapy (defined as 75% utilization)
- Beneficiary has demonstrated a positive response to treatment without intolerable side effects
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
    - Gaucher disease—current liver and spleen volume, platelet count, and hemoglobin
    - Niemann-Pick disease—updated description of symptoms

Quantity Edits

- #90/30 days

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Migraine Treatment (Acute) - Other

(*Implemented 10/21/2020)*
(Updated 7/20/2022)
(Updated 1/1/2023)
(Updated 1/18/2023)
(Updated 1/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agent with Criteria

- Nurtec ODT® (rimegepant)

Non-Preferred Agents

- Diclofenac potassium powder pack (generic for Cambia®)
- Dihydroergotamine injection (generic for D.H.E.45)
- Dihydroergotamine nasal spray (generic for Migranal®)
- Elyxyb® solution (celecoxib)
- Ergomar® SL tablet (dihydroergotamine)
- Migranal® spray (dihydroergotamine)
- Reyvow® tablet (lasmiditan)
- Trudhesa® nasal spray (dihydroergotamine)
- Ubrelvy® tablet (urogepant)
- Zavzpret® Nasal Spray (zavegepant)

Approval Criteria

Any new medications for acute migraine treatment released will follow this same criterion and follow documentation in the manufacturer's label. Preferred drug list status will apply.

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of acute migraines with or without auras as defined by the International Classification of Headache Disorders 3rd edition (ICHD-3)
- Beneficiary must have a failure of at least **TWO** (2) preferred 5HT1B/1D receptor agonists (triptans) using **TWO** (2) different chemical agents (not just different dosage forms) at maximally tolerated doses unless beneficiary has one of the following contraindications:
    - Ischemic coronary artery disease; **OR**
    - Arrhythmias; **OR**
    - History of stroke or transient ischemic attack (TIA); **OR**
    - Peripheral vascular disease; **OR**
    - Ischemic bowel disease; **OR**
    - Uncontrolled hypertension

- Beneficiary should not be approved or continue the medication if one of the following is met:
  - Requires continued use of a strong CYP3A4 inhibitor (i.e., ketoconazole, itraconazole, clarithromycin, etc.) – UBRELVY and NURTEC ODT
  - Requires continued use of a strong CYP3A4 inducer (i.e., rifampin) – UBRELVY and NURTEC ODT
  - Requires continued use of P-gp substrate (i.e., digoxin) – REYVOW
  - End stage renal disease (CrCl < 15mL/min) – UBRELVY, NURTEC ODT, and ELYXYB
  - Severe hepatic impairment (Child-Pugh Class C) – REYVOW, NURTEC ODT, and ELYXYB
  - NSAID allergy or recent coronary artery bypass graft (CABG) surgery – ELYXYB
  - If beneficiary prescribed UBRELVY 100 mg and has severe hepatic impairment (ChildPugh Class C) or severe renal impairment (CrCl 15-29 mL/min)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of migraine frequency and severity/duration
  - List of all therapies trialed with timeframes
  - Attestation that medication overuse headaches have been ruled out

Renewal Requirements

- Beneficiary demonstrates a positive response with a decrease in the severity/duration of migraines; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of current migraine frequency and severity/duration.

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Migraine Treatment (Acute) -Triptans

(Implemented 07/01/2010)
(Updated 1/1/2020)
(Updated 7/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Naratriptan tablet (generic for Amerge)
- Rizatriptan 10mg MLT (generic for Maxalt MLT)
- Rizatriptan 10mg tablet (generic for Maxalt)
- Rizatriptan 5mg MLT (generic for Maxalt MLT)
- Rizatriptan 5mg tablet (generic for Maxalt)
- Sumatriptan succinate tablet (generic for Imitrex)
- Zolmitriptan tablet (generic for Zomig)
- Zolmitriptan ODT (generic for Zomig ZMT)

Preferred Agents with Criteria

- Sumatriptan 4mg/0.5ml kit refill (generic for Imitrex)
- Sumatriptan 6mg/0.5ml kit refill (generic for Imitrex)
- Sumatriptan 6mg/0.5ml vial (generic for Imitrex)
- Sumatriptan 20mg nasal spray (generic for Imitrex)
- Sumatriptan 5mg nasal spray (generic for Imitrex)

Non-Preferred Agents

- Almotriptan malate tablet (generic for Axert)
- Eletriptan HBr tablet (generic for Relpax)
- Frova tablet (frovatriptan)
- Frovatriptan succinate tablet (generic for Frova)
- Imitrex kit (sumatriptan)
- Imitrex tablet (sumatriptan)
- Maxalt MLT (rizatriptan MLT)
- Maxalt tablet (rizatriptan)
- Relpax tablet (eletriptan)
- Sumatriptan 4mg/0.5ml syringe
- Sumatriptan 6mg/0.5ml syringe
- Sumatriptan succinate/naproxen sodium tablet (generic for Treximet)
- Symbravo tablet (meloxicam/rizatriptan)
- Tosymra nasal spray (sumatriptan)
- Zembrace Symtouch pen (sumatriptan)
- Zolmitriptan 2.5 mg and 5 mg nasal spray (generic for Zomig)
- Zomig tablet (zolmitriptan)

Approval Criteria for Preferred Agents with Criteria

- Preferred Injection (sumatriptan injection 4mg or 6mg)
- Any serotonin 5-HT 1 receptor agonist within past 365 days
- Preferred nasal spray (sumatriptan nasal spray 5mg or 20mg) must meet one (1) of the following criteria:
  - Trial and failure of 2 different chemical entities for 5-HT 1 receptor agonists in the last 12 months with either of the following:
    - 1 preferred oral tablet **AND** 1 preferred oral disintegrating tablet (ODT) from 2 different chemical entities; **OR**
    - 2 preferred oral disintegrating tablets (ODT) from 2 different chemical entities

OR

- 5-HT 1 receptor agonist nasal spray in history within past 365 days with history for look back starting 7/1/2024

Denial Criteria for All Agents

- Therapeutic duplication of any serotonin 5-HT 1 receptor agonist

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Migraine Treatment (Prophylactic Agents)

(Implemented 10/1/2019)
(Updated 7/20/2022)
(Updated 1/1/2023)
(Updated 1/18/2023)
(Updated 1/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Aimovig® autoinjector (erenumab-aooe)
- Emgality® 120 mg pen and syringe (galcanezumab)
- Nurtec ODT® (rimegepant)
- Qulipta® tablet (atogepant)

Non-Preferred Agents

- Ajovy® injection 225mg syringe (fremanezumab-vfrm)
- Emgality® injection 100 mg pen and syringe (galcanezumab)

Approval Criteria for Preferred Agents with Criteria

Any new medications for migraine prevention released will follow this same criterion and follow documentation in the manufacturer's label. Preferred drug list status will apply.

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia.
- Beneficiary must have a diagnosis of either:
  - Chronic migraines with or without auras as defined by the International Classification of Headache Disorders 3rd edition (ICHD-3) with ≥ 15 headache days per month with ≥ 8 migraine days per month ; **OR**
  - Episodic migraine or episodic cluster headache; **OR**
  - Diagnosis consistent with FDA indication
- Beneficiary requesting an oral CGRP agent (including preferred medications) must have a documented failure of a **6-month** trial (defined as 186 days of therapy in the past 270 days) with at least **ONE** injectable CGRP agent or a contraindication to the use
- Beneficiary should not be approved or continue the medication if one of the following is met:
  - Continuation should not be approved if there is no reduction from baseline in monthly migraine days or migraine severity after 3 months
  - Diagnosed with medication overuse headache caused by opiate overuse or other headache medication overuse as identified by the prescriber
  - Requires continued use of a strong CYP3A4 inhibitor (i.e., ketoconazole, itraconazole, clarithromycin, etc.) – NURTEC ODT
  - Requires continued use of a strong CYP3A inducer (i.e., rifampin) – NURTEC ODT
  - End stage renal disease (CrCl < 15 mL/min) – NURTEC ODT
  - Severe hepatic impairment (Child-Pugh Class C) – NURTEC ODT and QULIPTA
- Prescriber must submit ALL of the following:
  - Current chart notes

- Documentation of migraine frequency and severity/duration
- List of all therapies trialed with timeframes
- Attestation that medication overuse headaches have been ruled out
- Medical necessity over other preventative classes (i.e.,anticonvulsants, antidepressants, and beta blockers)

Renewal Requirements

- Beneficiary must have a reduction in monthly migraine days and migraine severity after 3rd month of treatment while remaining compliant on therapy
- Prescriber must submit the following:
  - Chart notes since previous PA approval
  - Documentation of current migraine frequency and severity
  - Beneficiary has decreased claims of acute migraine treatment

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Misoprostol (Cytotec®)

(Implemented 01/09/2008)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

Criterion 1:

- Female; **AND**
- Long Term Care; **OR**
- Current birth control drug claim (within the past 30 days); **OR**
- Current injectable birth control drug claim; **OR**
- Medical history of tubal ligation; **OR**
- Medical history of hysterectomy; **OR**
- Medical history of menopause; **OR**
- Hormone replacement therapy in the past 45 days; **OR**
- Age > 55; **AND**
- NSAID claim in past 30 days

Criterion 2:

- Male; **AND**
- NSAID claim in the past 30 days

Denial Criteria

- Medical history of current pregnancy

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Mitapivat (Pyrukynd®)

(Implemented 04/20/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 18 years of age; **AND**
- Beneficiary must have a confirmed diagnosis of pyruvate kinase (PK) deficiency with hemolytic anemia **OR** a diagnosis consistent with FDA approved indication or Compendia support; **AND**
- Beneficiary's baseline hemoglobin should be ≤ 10 g/dL; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including baseline hemoglobin, LFTs; **AND**
  - Dose requested (initial dose should be 5 mg twice daily); **AND**
  - Test results for variants of the PKLR gene; **AND**
  - Previous treatment including transfusion frequency and RBC units required for baseline; **AND**
  - Medical necessity over other treatment options; **AND**
  - Attestation that prescriber has counseled the patient on compliance importance and the requirement to taper if discontinuing

Denial Criteria

- Beneficiary does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Prescriber is requesting a dose > 50 mg twice daily; **OR**
- Beneficiary has moderate or severe hepatic impairment; **OR**
- Beneficiary requires either a strong CYP3A inhibitor or strong CYP3A inducer and a dose modification may be needed for use with a moderate CYP3A inhibitor or moderate CYP3A inducer; **OR**
- Beneficiary has 2 non-missense variants; **OR**
- Beneficiary has seen no benefit by 24 weeks of therapy based on hemoglobin level or transfusion frequency

Quantity Edits

- #62 per month of each strength

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Mupirocin cream

(Implemented 02/16/2016)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Drugs that require manual review for prior authorization

- Mupirocin 2% Cream

Drugs that do not require a prior authorization

- Mupirocin 2% Ointment

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Mycophenolate suspension (Cellcept®)

(Implemented 10/11/2011)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Diagnosis of Organ Transplant in Medicaid history in the last 3 years
- < 7 years old; **OR**
- NPO (Appendix A) within the last 365 days

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Mycophenolate mofetil 200 mg/mL suspension (Myhibbin™)

(Implemented 7/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary has had an allogeneic kidney transplant, heart transplant or liver transplant **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary should not be approved with any of the following:
  - Doesn't meet the minimum age and dose per the package insert
  - Medical necessity over generic mycophenolate was not established
  - ≥ 7 years of age and no reason why patient could not use a solid oral dosage form
- Prescriber must submit the following:
  - Current chart notes with medical reason for immunosuppressant
  - Current labs to monitor kidney function and watch for neutropenia
  - Medical necessity of Myhibbin™ over generic Cellcept® suspension and solid oral formulations

Renewal Requirements

- Beneficiary must remain compliant (defined as 75% utilization)
- Prescriber must submit the following:
  - Current chart notes
  - Continued need for suspension dosage form over solid oral form
  - Current labs to monitor kidney function and watch for neutropenia

Quantity Edits

- 3 bottles per 35 days

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Narcolepsy Agents

(Implemented 05/27/2009)
(Re-review on 5/10/2018) (Effective 7/1/18)
(Updated 7/1/2021)
(Updated 10/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for CIV Stimulants may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents that require manual review for prior authorization

- Armodafinil tablet (generic for Nuvigil®)
- Xyrem® solution (sodium oxybate) **(BRAND ONLY)**

Non-Preferred Agents

- Lumryz ER® suspension (sodium oxybate) – when rebate eligible
- Modafinil tablet (generic for Provigil®)
- Nuvigil® (armodafinil)
- Provigil® tablet (modafinil)
- Sodium oxybate solution (generic for Xyrem®)
- Sunosi® tablet (solriamfetol)
- Wakix® tablet (pitolisant)
- Xywav® solution (calcium, magnesium, potassium, and sodium oxybates)

Approval Criteria

All requests for non-FDA approved diagnoses or for new indications without developed criteria will be reviewed on a case-by-case basis.

NARCOLEPSY

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with excessive sleepiness associated with narcolepsy. Diagnosis of narcolepsy is based on International Classification of Sleep Disorders (ICSD-3) or Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria. Requests for any other diagnosis will be reviewed on a case-by-case basis.
- Beneficiary profile will be reviewed for medications or diagnoses that may be attributing to excessive daytime sleepiness besides narcolepsy
- Prescriber should submit the following for initial request for narcolepsy:
  - Most recent polysomnogram (PSG) results

  - Most recent multiple sleep latency test (MSLT) from morning after PSG with the following:
    - Mean sleep latency of less than 8 minutes per nap
    - Documented sleep onset rapid eye movement (SOREM) periods in more than 2 naps (one MSLT SOREM may be replaced by SOREM during PSG the night preceding MSLT)
  - Current chart notes
  - Baseline Epworth Sleepiness Scale (ESS)
- Requests for non-preferred medications require a documented trial and failure of CII and CIV stimulants in the last year with documentation of the medical necessity over the preferred medications.

OBSTRUCTIVE SLEEP APNEA (OSA)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with excessive sleepiness associated with obstructive sleep apnea (OSA)
- Beneficiary profile will be reviewed for medications or diagnoses that may be attributing to excessive daytime sleepiness besides OSA
- Prescriber should submit the following for initial request for obstructive sleep apnea (OSA):
  - Most recent polysomnogram (PSG) results
  - Current chart notes
  - Documentation of plan for monitoring compliance of positive airway treatment
  - CPAP or BiPAP usage report for documentation of compliance for at least 1 month
- Requests for non-preferred medications require a documented trial and failure of CII and CIV stimulants in the last year with documentation of the medical necessity over the preferred medications.
- PA renewal requires CPAP or BiPAP compliance

SHIFT WORK DISORDER (SWD)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with excessive sleepiness associated with shift work disorder (SWD)
- Beneficiary profile will be reviewed for medications or diagnoses that may be attributing to excessive daytime sleepiness besides SWD
- Prescriber must submit the following for initial request for shift work disorder (SWD):
  - Most recent polysomnogram (PSG) results with sleep study performed during patient's normal sleep time
  - Most recent multiple sleep latency test (MSLT) performed during patient's normal worktime
    - Mean sleep latency of less than 8 minutes per nap
    - Documented sleep onset rapid eye movement (SOREM) periods in more than 2 naps (one MSLT SOREM may be replaced by SOREM during PSG the night preceding MSLT)

- Current chart notes
- Baseline Epworth Sleepiness Scale (ESS)
- Current work schedule

NARCOLEPSY WITH CATAPLEXY

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with narcolepsy with cataplexy
- Beneficiary ages ≥ 7 years and < 19 years must have a trial of a CII stimulant in the last year
- Beneficiary ≥ 19 years must have both of the following unless contraindicated:
  - Trial and failure of CII stimulant in the last year
  - Trial and failure of a preferred CIV stimulant in the last year
- Prescriber should submit the following for initial request:
  - Most recent polysomnogram (PSG) results
  - Most recent multiple sleep latency test (MSLT) from morning after PSG with the following:
    - Mean sleep latency of less than 8 minutes per nap
    - Documented sleep onset rapid eye movement (SOREM) periods in more than 2 naps (one MSLT SOREM may be replaced by SOREM during PSG the night preceding MSLT)
  - Current labs including LFTs
  - Current chart notes
  - Baseline Epworth Sleepiness Scale (ESS) Score for excessive daytime sleepiness associated with narcolepsy
  - Baseline description of cataplexy events for beneficiaries with cataplexy diagnosis;
- Requests for non-preferred medications for beneficiary ≥ 19 years require a documented trial and failure of CII and CIV stimulants in the last year with documentation of the medical necessity over the preferred medications.
- Requests for non-preferred medications for beneficiary ≥ 7 years and < 19 years require a documented trial and failure of CII in the last year with documentation of the medical necessity over the preferred medications.

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Nedosiran sodium 80 mg vial, 128 mg, 160 mg syringe (Rivfloza®)

(Implemented 4/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with primary hyperoxaluria type 1 (PH1) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- PH1 must be confirmed by **ONE** of the following:
  - Molecular genetic testing confirming a mutation in the alanine-glyoxylate aminotransferase (AGXT) gene
  - Liver biopsy results demonstrating reduced alanine-glyoxylate aminotransferase (AGXT) activity
- Beneficiary must have relatively preserved kidney function (≥ 30 mL/min/1.73 m^2)
- Must be prescribed by or in consultation with a urologist or nephrologist
- Beneficiary has tried high dose pyridoxine and did not obtain an adequate response (defined as had < 30% reduction in urinary or plasma oxalate concentration)
- Beneficiary should not be approved or continue this therapy with any of the following:
  - eGFR < 30 mL/min/1.73 m^2
  - Prescribed concomitant lumasiran (OXLUMO)
  - Does not have genetic testing confirming a mutation in the AGXT gene or liver biopsy confirming reduced AGXT activity
  - Dose is not consistent with weight-based dosing in the package insert
  - Moderate or severe hepatic impairment
  - Diagnosed with any other primary hyperoxaluria type besides PH1
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Current labs including eGFR, urinary or plasma oxalate levels
  - Genetic testing results confirming a mutation in the AGXT gene or liver biopsy results
  - Current weight and dose requested

Renewal Requirements

- Beneficiary must have reduced urinary or plasma oxalate levels
- Beneficiary continues to have stable kidney function (continues to meet approval criteria)
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including eGFR, urinary or plasma oxalate levels
  - Current weight and dose requested

Quantity Edits

- 80 mg (0.5 mL) single-dose vial—2 vials per month (for patients 9-11 years of age weighing less than 50 kg)
- 128 mg (0.8 mL) single-dose pre-filled syringe – 1 syringe per month

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Neomycin 0.5%/Fluocinolone 0.025% cream (Neo-Synalar®)

(Implemented 07/22/2015)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must have a diagnosis of corticosteroid-responsive dermatoses with secondary infection
- Prescriber must submit the following:
  - Current chart notes
  - Letter of medical necessity for the use of NEO-SYNALAR over other treatment options available without prior authorization

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Neuropathic Pain Agents

(Implemented 06/05/2008)
(Updated 03/07/2019)
(Updated 1/1/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Duloxetine (generic for Cymbalta®)
- Gabapentin capsule and tablet (generic for Neurontin®)
- Pregabalin (generic for Lyrica®)

Non-Preferred Agents

- Cymbalta® (duloxetine)
- Drizalma™ sprinkle (duloxetine)
- Gabapentin 250mg/5ml solution (generic for Neurontin®)*
- Gabapentin ER tablet (generic for Gralise®)
- Gabarone™ tablet (gabapentin)
- Gralise® tablet (gabapentin ER)
- Horizant® tablet (gabapentin ER)
- Lidoderm® patch (lidocaine)
- Lyrica® (pregabalin)
- Lyrica CR® (pregabalin)
- Lyrica® solution (pregabalin)
- Neurontin® capsule, tablet, solution (gabapentin)
- Pregabalin solution (generic for Lyrica® solution)
- Pregabalin ER (generic for Lyrica CR®)
- Savella® (milnacipran)
- Ztlido® patch (lidocaine)

*Follows NPO rules (either <7 years of age OR NPO within the past 365 days)

Non-Preferred Agents with Criteria

- Lidocaine patch (generic for Lidoderm®)

Approval Criteria for generic Lidoderm® patch:

- Submitted diagnosis post-herpetic neuralgia (ICD-10 codes: B0222 POSTHERPETIC TRIGEMINAL NEURALGIA and B0223 POSTHERPETIC POLYNEUROPATHY) within the past 12 months; **OR**
- Paid claim in history identifying appropriate antiviral medication (Table 4) for post- herpetic neuralgia within the past 30 days

Table 4 – Antivirals

- Acyclovir 200mg
- Acyclovir 400mg
- Acyclovir 800mg
- Famciclovir 125mg
- Famciclovir 250mg
- Famciclovir 500mg
- Valacyclovir 500mg caplet
- Valacyclovir 1g caplet

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Nifurtimox tablet (Lampit®)

(Effective 9/21/2020)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be a pediatric patient less than 18 years of age diagnosed with Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi* **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Diagnosed with other treatment subgroups outside for the FDA approved indication
  - Dose or duration of therapy that exceeds FDA approved dose and duration
- Prescriber must submit the following:
  - Current chart notes
  - Prescriber must submit current weight. Weight-based dose will be calculated and monthly quantity entered at the time the PA is approved
- Length of PA shall not exceed 60 days

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Nimodipine solution (Nymalize®)

(Implemented 1210/2013)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with subarachnoid hemorrhage (SAH) and this medication must be ordered to help with improvement of neurological outcome by reducing the incidence and severity of ischemic deficits
- Prescriber must submit the following:
  - Current chart notes
  - Baseline blood pressure
  - Letter of medical necessity over preferred dihydropyridine agents and nimodipine oral capsules

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Nintedanib (Ofev®)

(Updated 1/15/2020)
(Updated 10/16/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Prescribed by or in consultation with a pulmonologist
- Beneficiary must be diagnosed with idiopathic pulmonary fibrosis, chronic fibrosing interstitial lung disease with progressive phenotype, **OR** systemic sclerosis-associated interstitial lung disease. Confirmation will require the following depending on diagnosis:
  - **Idiopathic pulmonary fibrosis (IPF)**
    - Confirmed by either a lung biopsy or high-resolution computed tomography (CT) scan of the lungs with presence of the usual interstitial pneumonia (UIP) pattern with documentation of some of the following:
      - Basal and peripheral dominance
      - Honeycombing (usually subpleural)
      - Reticular opacities or ground-glass opacities
      - Traction bronchiectasis
      - Airspace enlargement with fibrosis
    - Baseline Pulmonary Function Tests (PFTs)
      - Forced vital capacity (FVC) is ≥ 50% predicted; **AND**
      - Carbon monoxide diffusing capacity (DLCO) corrected for hemoglobin is 30-79% of predicted
    - Other known causes of interstitial lung disease (e.g., environmental exposures, connective tissue disease, drug toxicity) have been ruled out
  - **Chronic fibrosing interstitial lung diseases with progressive phenotype (also called progressive pulmonary fibrosis)** with a high-resolution CT scan indicating pulmonary fibrosis is affecting ≥ 10% of the lungs with at least **TWO** of the following criteria with at least **ONE** of the examples listed with the criteria in the last 24 months:
    - Worsening respiratory symptoms (e.g., increased dyspnea on exertion)
    - Radiological evidence of disease progression with at least **ONE** of the following examples:
      - Increased extent or severity of traction bronchiectasis and bronchiolectasis
      - New ground-glass opacity with traction bronchiectasis
      - New fine reticulation
      - Increased extent or increased coarseness of reticular abnormality
      - New or increased honeycombing
      - Increased lobar volume loss

- PFTs indicate disease progression with at least **ONE** of the following examples:
  - FVC decline ≥ 10% predicted; **OR**
  - FVC decline ≥ 5% and < 10% predicted with worsening symptoms or imaging; **OR**
  - DLCO decline (corrected for Hb) ≥ 10% predicted
- **Systemic sclerosis-associated interstitial lung disease (SSC-ILD)** requires a diagnosis of systemic sclerosis (SSC) based on rheumatology guidelines and interstitial lung disease with the following:
  - High-resolution CT scan indicates pulmonary fibrosis is affecting ≥ 10% of the lungs
  - Baseline PFTs
    - Forced vital capacity (FVC) is ≥ 40% predicted; **AND**
    - Carbon monoxide diffusing capacity (DLCO) corrected for hemoglobin is 30-89% of predicted

- Beneficiary should not be approved or continue the medication if one of the following is met:
  - Likely to receive a lung transplant or has had a lung transplant
  - Has relevant airways obstruction (i.e., pre-bronchodilator FEV1/FVC < 0.7)
  - Pregnant or breastfeeding
  - Currently smoking
  - Moderate or severe hepatic impairment (Child Pugh B or C). Patients with mild hepatic impairment (Child Pugh A) can be treated with a reduced dose of OFEV.
  - Has gastrointestinal perforation
  - Severe renal impairment (CrCl < 30 mL/min) or end-stage renal disease
  - Caution in beneficiaries with known risk of bleeding (benefit outweighing the risk should be provided)
- Prescriber must submit the following:
  - Current chart notes and documentation to support the diagnosis (e.g., CT scan results and/or biopsy results)
  - Dose requested (PA is entered for specific dose
  - Current labs including liver function test
  - Baseline pulmonary function tests (PFTs)
  - Baseline 6-minute walk test (6MWT
  - Letter of medical necessity over immunosuppressant for SSC-ILD patients (i.e., mycophenolate)
  - Documentation verifying the smoking status with **ONE** of the following:
    - exhaled carbon monoxide level (eCO) < 6 ppm; **OR**
    - carboxyhemoglobin (COHb) levels of < 3%; **OR**
    - urine continine concentration < 200 mg/mL

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must remain a non-smoker
- Beneficiary must demonstrate a positive response with improved, stable or slowed progression based on radiographic results, pulmonary function tests, and/or clinical presentation
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including LFTs
  - Documentation of response to therapy with any of the following:

- Current pulmonary function tests
- Current 6MWT
- Current CT scan results of lungs

Quantity Edits

- 100 mg--#60/30 days
- 150 mg--#60/30 days

Top of the document

Nitisinone capsule/suspension (Orfadin®)

(Implemented 09/23/2014)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with hereditary tyrosinemia type 1 (HT-1) and must take this medication in combination with dietary restrictions of tyrosine and phenylalanine.
- Prescriber must submit the following:
  - Current chart notes
  - Attestation that patient follows dietary restrictions of tyrosine and phenylalanine
  - Current labs including CBC, platelets, and serum tyrosine (goal plasma tyrosine levels below 500 micromol/L)

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Nitrofurantoin suspension (Furadantin®)

(Implemented 10/11/2011)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- < 7 years of age; **OR**
- NPO (Appendix A) within the past 365 days.

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Nitroglycerin 0.4% rectal ointment (Rectiv®)

(Implemented 07/09/2012)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with moderate to severe pain associated with chronic anal fissure
- Treatment prescribed longer than 3 weeks will not be approved
- Prescriber must submit the following:
  - Current chart notes
  - Letter of medical necessity over other topical anesthetics available without prior authorization (e.g., lidocaine ointment, lidocaine-prilocaine cream)

Quantity Edits

- #1 tube every 60 days

Top of the document

Obeticholic acid tablet (Ocaliva®)

(Implemented 01/17/2017)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with primary biliary cholangitis (PBC) confirmed by **TWO** of the following:
  - An alkaline phosphatase (ALP) level of at least 1.67 times (1.67X) the upper limit of normal
  - Presence of antimitochondrial antibodies (AMA) at a titer of 1:40 or higher
  - Histologic evidence of PBC (nonsuppurative destructive cholangitis and destruction of interlobular bile ducts)
- Must be prescribed by or in consultation with a hepatologist or gastroenterologist
- Beneficiary must have had an inadequate response to ursodeoxycholic acid (UDCA) without improvement in LFTs and documented PBC related symptoms after a 1-year trial or the beneficiary must demonstrate intolerance to UDCA (e.g., Ursodiol)
- Beneficiary with an inadequate response to UDCA alone must take OCALIVA concomitantly with UDCA unless intolerant to UDCA
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
  - Pregnant
  - Complete biliary obstruction
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Documentation of previous therapies tried with response
  - Baseline description of muscle pain or myopathy (evaluate periodically for new onset or worsening muscle pain, myopathy, or rhabdomyolysis)
  - Labs including liver function tests with baseline alkaline phosphatase
  - Current treatment plan
  - Medical necessity over UDCA taken as monotherapy

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to OCALIVA with an improvement in symptoms and corresponding labs while experiencing no intolerable side effects

- Beneficiary must remain on ursodeoxycholic acid (UDCA) concomitantly unless there are tolerability issues
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy with summary of current symptoms
  - Current labs including liver function tests with alkaline phosphatase
  - Description of muscle pain or myopathy

Quantity Edits

- #30/30 days

Top of the document

Omadacycline (Nuzyra®)

(Implemented 7/17/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary is > 18 years old;
- Beneficiary has a diagnosis of: Community-Acquired Bacterial Pneumonia (CABP) **OR** Acute Bacterial Skin and Skin Structure Infections (ABSSSI)
- Prescriber should provide culture and susceptibility report if available
- Prescriber must provide explanation of medical necessity for use of this antibiotic over a different agent that does not require prior authorization
- Prescriber must submit documentation of loading dose of IV infusion or loading dose of oral tablets beneficiary received

Denial Criteria

- No diagnosis of CABP or ABSSSI with an organism listed in the approval criteria;
- Age < 18 years old;
- Tetracycline allergy
- Susceptibility report shows organism is resistant
- Female beneficiary is in 2nd or 3rd trimester of pregnancy or breastfeeding
- Known or suspected healthcare associated infection
- Request is for greater than 14 days of therapy

Quantity Limits

- Quantity limit for either tablets or vials for length of therapy (7 to 14 days) will be entered at the time of the PA approval
- Length of therapy will not exceed 14 days

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Octreotide (Mycapssa®)

(Implemented 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary is diagnosed with acromegaly and has responded to and tolerated treatment with octreotide or lanreotide
- Beneficiary has elevated insulin-like growth factor-1 (IGF-1) levels for age and/or gender
- Must be prescribed by, or in consultation with, an endocrinologist or oncologist
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has not tried either octreotide or lanreotide injections
  - Has end stage renal disease (must start at 20 mg daily)
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Baseline IGF-1 level
  - Documentation that beneficiary has had an inadequate response to surgery or is not a candidate for surgery
  - Letter of medical necessity with clinically significant reason the beneficiary cannot continue the injectable octreotide/lanreotide

Renewal Requirements

- Beneficiary has been compliant with therapy (defined as 75% utilization)
- Beneficiary has a positive response to treatment similar to the injection somatostatin product with decrease or normalized IGF-1 level
- Prescriber must submit the following:
  - Current chart notes
  - Current IGF-1 level

Quantity Edits

- #120/30 days

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Octreotide Acetate (Sandostatin® LAR Depot)

(Implemented 04/10/2015)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
  - Beneficiary must be diagnosed with one of the following:
    - Acromegaly with an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy, is not an option.
    - Severe diarrhea and flushing episodes associated with metastatic carcinoid tumors
    - Profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas)
  - Prescribed by or in consultation with an endocrinologist or oncologist
  - Beneficiary should not be approved or continue this therapy with any of the following:
    - Develops complications of cholelithiasis
    - Has not tried regular Sandostatin injection to ensure tolerability
  - Prescriber must submit the following:
    - Current chart notes with documentation of diagnosis
    - Previous therapies tried with response
    - If no surgery or radiation, provide rationale for requesting in acromegaly patients
    - Baseline labs--Monitor the following at baseline and throughout treatment
      - Acromegaly: Growth Hormone, IGF-1 (somatomedin C)
      - Carcinoid: 5-HIAA (urinary 5-hydroxyindole acetic acid), plasma serotonin, plasma Substance P
      - VIPoma: VIP (plasma vasoactive intestinal peptide) baseline and periodic total and/or free T4 measurements should be performed during chronic therapy
      - Additional monitoring—blood glucose, TSH, total and/or free T4, vitamin B12, zinc

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to treatment
- Prescriber must submit the following:
  - Current chart notes
  - Provide current labs as listed below
    - Acromegaly: Growth Hormone, IGF-1 (somatomedin C)

- Carcinoid: 5-HIAA (urinary 5-hydroxyindole acetic acid), plasma serotonin, plasma Substance P
- VIPoma: VIP (plasma vasoactive intestinal peptide) baseline and periodic total and/or free T4 measurements should be performed during chronic therapy
- Additional monitoring—blood glucose, TSH, total and/or free T4, vitamin B12, zinc

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Odevixibat (Bylvay®)

(Implemented 10/20/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 3 months of age; **AND**
- Beneficiary must have a confirmed diagnosis of progressive familial intrahepatic cholestasis (PFIC) with a baseline presence of pruritus OR a diagnosis consistent with FDA indication; **AND**
- Beneficiary has elevated serum bile acid concentration; **AND**
- Beneficiary has documented failure of ursodeoxycholic acid (URSODIOL) **AND** cholestyramine unless there is a documented contraindication; **AND**
- Beneficiary should continue ursodeoxycholic acid concomitantly; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including serum bile acids, serum levels of vitamins A, D, E, and INR (for vitamin K) and LFTs; **AND**
  - Genetic testing results with PFIC type and presence or absence of the ABCB11 variant
- Initial approval for 3 months

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported on the official Compendia; **OR**
- Beneficiary has PFIC type 2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3); **OR**
- Beneficiary has decompensated liver disease; **OR**
- Beneficiary should discontinue BYLVAY if continued pruritis or has no decrease in serum bile acid after trial with maximum dose of 120 mcg/kg per day; **OR**
- Beneficiary is not concurrently ordered ursodeoxycholic acid

Quantity Edits

- 200 mcg pellet - #62 per 31 days
- 600 mcg pellet - #31 per 31 days
- 400 mcg capsule - #155 per 31 days
- 1200 mcg capsule - #155 per 31 days

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Olezarsen 80 mg/0.8 ml injection (Tryngolza™)

(Effective 4/16/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with familial chylomicronemia syndrome (FCS) confirmed by molecular genetic test with fasting triglycerides level ≥ 880 mg/dL and multifactorial (polygenic) chylomicronemia has been ruled out
- Prescribed by, or in consultation with, a cardiologist, endocrinologist, or specialist experienced in treating severe hypertriglyceridemia
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Not on a low-fat diet of ≤ 20 gm of fat per day
  - Currently smoker
- Prescriber must submit the following:
  - Current chart notes with genetic testing to confirm diagnosis
  - Previous medications tried for lowering triglycerides
  - Current fasting labs including lipid panel
  - Documentation of symptoms associated with FCS (e.g., fatigue, pancreatitis/ abdominal pain, eruptive xanthomas, lipemia retinalis, hepatosplenomegaly)
  - Attestation that beneficiary is on a low-fat diet with ≤ 20 gm of fat per day
- Initial PA will be for 3 months, renewal PAs may be up to 6 months

Renewal Requirements

- Beneficiary is compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with decrease in fasting triglycerides and decrease in symptoms documented at baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current fasting labs including lipid panel
  - Current documentation of symptoms
  - Attestation that the beneficiary remains on low-fat diet with ≤ 20 gm of fat per day

Quantity Edits

- 1 injection per 30 days

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Omaveloxolone 50 mg capsule (Skyclarys™)

(Effective 10/18/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with Friedreich's ataxia confirmed by detection of a mutation of the FXN gene **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must exhibit clinical symptoms consistent with Friedreich's ataxia (e.g., muscle weakness, decline in coordination, frequent falling)
- Skyclarys™ is prescribed by a neurologist
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Severe hepatic impairment (Child-Pugh C); dosage adjustment for moderate hepatic impairment (Child-Pugh B)
  - Require treatment with a strong or moderate CYP3A4 inducer
  - Require treatment with a strong or moderate CYP3A4 inhibitor (may use concomitantly with a dose adjustment)
  - Consider discontinuation with signs and symptoms of fluid overload and/or heart failure
  - B-type Natriuretic Peptide (BNP) >200 pg/mL
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Current labs including ALT, AST, bilirubin, B-type Natriuretic Peptide (BNP), and lipid parameters prior to initiating therapy (ALT, AST, bilirubin monthly for the first 3 months)
  - Specific symptoms associated with Friedreich's ataxia for this beneficiary as a baseline with a description concerning bulbar function, upper limb coordination, lower limb coordination, and upright stability
  - Genetic test results confirming the diagnosis

Renewal Requirements

- Prescriber must submit the following:
  - Current chart notes with documentation of current clinical presentation
  - Current labs (monitor every 3 months) including ALT, AST, and bilirubin
- Beneficiary must demonstrate a reduction in rate of disease progression or stabilization in clinical presentation compared to baseline
- Beneficiary must continue to meet approval criteria

Quantity Edits

- #90/30 days

Top of the document

Omeprazole, Amoxicillin, and Clarithromycin(Omeclamox-Pak™)

(Implemented 05/21/2012)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for these products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

Criterion 1:

- No history of lansoprazole, amoxicillin, and clarithromycin combination (PREVPAC) in the last 365 days; **AND**
- No history of omeprazole, amoxicillin, and clarithromycin combination (OMECLAMOX-PAK) in the last 365 days; **AND**
- No concurrent proton pump inhibitor therapy within the past 30 days.

Criterion 2:

- No history of metronidazole/tetracycline/bismuth combination (PYLERA) in the last 365 days.

Denial Criteria

Criterion 1:

- History of lansoprazole, amoxicillin, and clarithromycin combination (PREVPAC) in the last 365 days; **OR**
- Current proton pump inhibitor therapy within the past 30 days.

Criterion 2:

- No history of omeprazole, amoxicillin, and clarithromycin combination (OMECLAMOX-PAK) in the last 365 days; **AND**
- No concurrent proton pump inhibitor therapy within the past 30 days.

Criterion 3:

- No history of metronidazole/tetracycline/bismuth combination (PYLERA) in the last 365 days.

Additional Criteria

- Quantity limits apply

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Oncology, Oral (Arimidex®, Femara®, Gomekli™, Koselugo®, Rezurock®, Turalio®)

(Implemented 4/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests may be faxed to the state pharmacy unit at 1-800-424-5851.

Information concerning oral Oncology Medications (not limited to just the medications listed above) may be found at these links:

Oncology Drug Management Policy
Prior Authorization Criteria for Select Oncology Medications
Oncology Prior Authorization Form

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Ophthalmics - Allergic Conjunctivitis Agents

(Implemented 01/12/2012)
(Updated and added to PDL 7/1/2020)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Azelastine HCl 0.05% eye drops (generic for Optivar®)
- Cromolyn sodium 4% eye drops (generic for Opticrom®)
- Ketotifen fumarate 0.025% eye drops (generic for Alaway® or Zaditor®)
- Olopatadine HCl 0.1% eye drops (generic for Patanol®)
- Olopatadine HCl 0.2% eye drops (generic for Pataday®)

Non-Preferred Agents

- Alaway® 0.025% eye drops (ketotifen fumarate)
- Alrex® 0.2% eye drops (loteprednol)
- Bepotastine besilate 1.5% eye drops (generic for Bepreve®)
- Bepreve® 1.5% eye drops (bepotastine besilate)
- Epinastine HCl 0.05% eye drops (generic for Elestat®)
- Loteprednol etabonate 0.2% eye drops (generic for Alrex®)
- Pataday® 0.7% eye drops (olopatadine)
- Zerviate® 0.24% eye drops (cetirizine)
- Zaditor® 0.025% eye drops (ketotifen fumarate)

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Ophthalmics - Antibiotic Drops

(Implemented 08/21/2009)
(Updated 5/10/17, Effective 7/1/17)
(Updated 7/1/2020)
(Updated 4/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.
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Preferred Agents

- Bacitracin/polymyxin B ophthalmic ointment (generic for Polycin®)
- Ciloxan® (ciprofloxacin) 0.3% ophthalmic ointment
- Ciprofloxacin 0.3% ophthalmic solution drops (generic for Ciloxan®)
- Erythromycin 0.5% ophthalmic ointment
- Gentamicin 0.3% ophthalmic solution drops
- Moxifloxacin 0.5% ophthalmic solution drops (generic for Vigamox®)
- Polymyxin B/trimethoprim ophthalmic solution drops (generic for Polytrim®)
- Tobramycin 0.3% ophthalmic solution drops (generic for Tobrex®)

Non-Preferred Agents

- Azasite® (azithromycin) 1% ophthalmic solution drops
- Bacitracin ophthalmic ointment 500 units/gm
- Besivance® (besifloxacin) 0.6% ophthalmic suspension drops
- Gatifloxacin 0.5% ophthalmic solution drops (generic for Zymaxid®)
- Moxifloxacin 0.5% ophthalmic solution drops (generic for Moxeza®)
- Natacyn® (natamycin) 5% ophthalmic suspension drops **- May be approved upon request after receiving documentation/attestation of fungal infection of the eye**
- Neomycin/polymyxin B/bacitracin ophthalmic ointment
- Neomycin/polymyxin B/gramicidin ophthalmic solution drops
- Ocuflox® (ofloxacin) 0.3% ophthalmic solution
- Ofloxacin 0.3% ophthalmic solution drops (generic for Ocuflox®)
- Polycin® (bacitracin/polymyxin B) ointment
- Sulfacetamide 10% ointment, ophthalmic solution drops
- Tobrex® (tobramycin) 0.3% ointment
- Vigamox® (moxifloxacin) 0.5% ophthalmic solution drops
- Zymaxid® (gatifloxacin) 0.5% ophthalmic solution drops

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Ophthalmics - Antibiotic-Steroid Combination Drops

(Implemented 10/11/2011)
(Updated 5/10/17, Effective 7/1/17)
(Updated 7/1/2020)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Neomycin sulfate/polymyxin B/dexamethasone eye ointment (generic for Maxitrol®)
- Neomycin sulfate/polymyxin B/dexamethasone 0.1% eye suspension drops (generic for Maxitrol®)
- Sulfacetamide sodium 10%/prednisolone sodium phosphate 0.23% eye solution drops
- Tobradex® eye ointment (tobramycin 0.3%/dexamethasone 0.1%)
- Tobramycin 0.3%/dexamethasone 0.1% eye suspension drops (generic for Tobradex®)

Non-Preferred Agents

- Maxitrol® eye ointment (neomycin/polymyxin B/dexamethasone)
- Maxitrol® eye susp drops (neomycin/polymyxin B/dexamethasone)
- Neomycin sulfate/polymyxin B sulfates/bacitracin zinc/ hydrocortisone eye ointment (generic for Cortisporin®)
- Neomycin 3.5 mg/polymyxin B sulfates 10K/hydrocortisone 1% eye suspension drops (generic for Cortisporin®)
- Tobradex® ST eye susp drops (tobramycin 0.3%/dexamethasone 0.05%)
- Zylet® eye susp drops (loteprednol 0.5%/tobramycin 0.3%)

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Ophthalmics - Anti-inflammatory Drops

(Implemented 01/12/2010)
(Updated and added to PDL 7/1/2020)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Bromfenac 0.09% eye drops (generic for Bromday®)
- Dexamethasone sodium phosphate 0.1% eye drops (generic for Decadron®)
- Diclofenac 0.1% eye drops (generic for Voltaren®)
- Fluorometholone 0.1% eye suspension drops (generic for FML Liquifilm®)
- Flurbiprofen 0.03% eye drops (generic for Ocufen®)
- FML Forte® 0.25% eye susp drops (fluorometholone)
- Ketorolac 0.5% eye drops (generic for Acular®)
- Prednisolone acetate 1% susp eye drops (generic for Pred Forte®)
- Prednisolone sodium 1% eye drops (generic for AK-Pred®)

Non-Preferred Agents

- Acular® 0.5%, Acular LS® 0.4% eye drops (ketorolac)
- Acuvail® 0.45% eye drops (ketorolac)
- Bromfenac 0.07% eye drops (generic for Prolensa®)
- Bromfenac 0.075% eye drops (generic for BromSite®)
- Bromsite® 0.075% eye drops (bromfenac)
- Difluprednate 0.05% eye drops (generic for Durezol®)
- Durezol® 0.05% eye drops (difluprednate)
- Flarex® 0.1% eye susp drops (fluorometholone)
- FML Liquifilm® 0.1% eye susp drops (fluorometholone)
- Ilevro® 0.3% eye susp drops (nepafenac)
- Inveltys® 1% eye susp drops (loteprednol)
- Ketorolac 0.4% eye drops (generic for Acular LS®)
- Lotemax® 0.5% eye drops/12ps (loteprednol)
- Lotemax® 0.5% eye gel drops (loteprednol)
- Lotemax® 0.5% eye ointment (loteprednol)
- Lotemax SM® 0.38% eye gel drops (loteprednol)
- Loteprednol etabonate 0.5% eye drop/12ps (generic for Lotemax®)
- Loteprednol etabonate 0.5% eye gel drops (generic for Lotemax®)
- Maxidex 0.1% eye susp drops (dexamethasone)

- Nevanac® 0.1% eye susp drops (nepafenac)
- Pred Forte® 1% eye susp drops (prednisolone)
- Pred Mild® 0.12% eye susp drops (prednisolone)
- Prolensa® 0.07% eye drops (bromfenac)

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Ophthalmics, Dry Eye Agents

(Effective 1/18/2011)
(Updated 4/1/2020)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Cyclosporine 0.05% emulsion, single dose vials (Restasis®)

Non-Preferred Agents

- Cyclosporine 0.05% emulsion, multidose vial (Restasis®)
- Cyclosporine Emulsion (Verkazia®)
- Cyclosporine 0.09% solution (Cequa®)
- Cyclosporine 0.1% solution (Vevye®)
- Lifitegrast 5% solution (Xiidra®)
- Perfluorohexyloctane drops (Miebo®)
- Tryptyr® solution (acoltremon)
- Varenicline nasal spray (Tyrvaya®)

Approval Criteria for Preferred Agents with Criteria

- Diagnosis of one of the following diagnoses associated with dry eye in the past two years:
  - Keratoconjunctivitis sicca, non-Sjogren's syndrome
  - Keratoconjunctivitis sicca, Sjogren's syndrome
  - Keratoconjunctivitis, exposure
  - Tear film insufficiency, unspecified (Dry eye syndrome)
  - Xerosis

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Opicapone (Ongentys®)

(Implemented 1/20/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 18 years of age; **AND**
- Beneficiary must have a diagnosis of Parkinson's Disease for at least 3 years and experiencing "off" episodes while compliant on levodopa/carbidopa **OR** a diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Current labs including LFTs and renal function; **AND**
- Beneficiary should be in Parkinson's Disease stages 2 to 4 in the OFF state in the modified Hoehn and Yahr Scale; **AND**
- Beneficiary must be on levodopa/carbidopa for at least one year with a stable dose at least 4 weeks prior to starting ONGENTYS; **AND**
- Beneficiary must be taking at least 3 doses of levodopa per day; **AND**
- Beneficiary must take ONGENTYS in combination with levodopa/carbidopa; **AND**
- Beneficiary must be experiencing at least 2 hours of OFF time per day excluding in the morning prior to first dose of the day; **AND**
- If taking other PD medications along with levodopa/carbidopa, beneficiary must be on a stable dose for at least 4 weeks prior to starting ONGENTYS (e.g., COMT inhibitors, MAO-B inhibitors, anticholinergics, and/or amantadine); **AND**
- Prescriber must provide the medical necessity over the increase in levodopa/carbidopa dose, changing to extended-release formulations, and changing to Stalevo/entacapone + levodopa/carbidopa.

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported in the official Compendia; **OR**
- Beneficiary is diagnosed with severe hepatic impairment (Child-Pugh C); OR • Beneficiary is diagnosed with end stage renal disease; **OR**
- Beneficiary has a history of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms; **OR**
- Beneficiary takes concomitant non-selective monoamine oxidase (MAO) inhibitors; **OR**
- Beneficiary is diagnosed with a major psychotic disorder in the last year (i.e., major depressive disorder, bipolar, psychosis, generalized anxiety disorder); O**R**
- Beneficiary has < 2 hours a day of OFF time; **OR**
- Beneficiary has a diagnosis of atypical parkinsonism or secondary parkinsonism variants; **OR**
- Beneficiary is pregnant or breastfeeding.

Quantity Edits

- 30 per 30 days

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Opioids, Long Acting

(Implemented 08/01/2008)
(Updated 08/18/2016)
(Updated 4/1/2019)
(Updated 4/1/2020)
(Updated 1/1/2024)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Butrans® patch (buprenorphine) - **BRAND ONLY**
- Morphine sulfate long-acting tablet (generic for MS Contin®)
- Tramadol ER tablet (generic for Ultram ER®)

Non-Preferred Agents with Criteria

- Belbuca® film (buprenorphine)
- Buprenorphine patch (generic for Butrans®)
- Fentanyl patch (generic for Duragesic®)
- Hydrocodone ER capsule (generic for Zohydro ER®)
- Hydrocodone ER tablet (generic for Hysingla ER®)
- Hydromorphone HCl extended-release tablet (generic for Exalgo ER®)
- Methadone HCl tablet (generic for Dolophine®)
- Methadone solution
- Methadone Intensol™ concentrate (generic for Methadose®)
- Morphine sulfate extended-release capsule (generic for Avinza®, Kadian®)
- Oxycodone extended-release tablet (generic for Oxycontin®)
- Oxycontin® tablet (oxycodone)
- Oxymorphone HCl extended-release tablet (generic for Opana ER®)
- Tramadol ER capsule (generic for Conzip®)
- Tramadol ER tablet (generic for Ryzolt®)

Non-Preferred Agents without Criteria

- Conzip® capsule (tramadol ER)
- Hysingla ER® tablet (hydrocodone ER)
- Methadose® oral concentrate (methadone)
- MS Contin® tablet (morphine sulfate)

Approval Criteria for Preferred Agents with Criteria

- Medical necessity of using a long-acting opiate for chronic, non-cancer pain over short-acting opioids or other medications used for pain
- Claim for long-acting opiate within the previous 60 days (continuation criteria)

Approval Criteria for Non-Preferred Agents with Criteria

- Belbuca, Fentanyl patch, Hydrocodone ER, Hydromorphone ER, Morphine sulfate ER capsule, Oxycodone ER, Oxymorphone ER, Tramadol ER (generic for Conzip®/Ryzolt®)
  - Diagnosis of cancer with malignancies in the last 365 days; **OR**
  - Currently in LTC; **OR**
  - For fentanyl patches only, NPO (Appendix A) in the last 365 days.
- Methadone
  - Diagnosis of cancer with malignancies in the last 365 days
- Methadone oral solution for Neonatal Abstinence Syndrome
  - Beneficiary is ≤ 90 days of age; **AND**
  - Quantity of methadone oral solution dispensed is not more than 10 mL; **AND**
  - Accumulated methadone oral solution quantity between incoming claim and any other claims within the previous 30 days do not equal more than 10 ml total; **OR**
    - The prescriber provides medical necessity, quantity requested, dose, and taper plan schedule via prior authorization request.

Overdose Denial Criteria

- An incoming claim for any opioid pain medication will trigger a search of the beneficiary's Medicaid medical diagnoses history for diagnosis of poisoning or overdose the previous 12 months.
- If a diagnosis for poisoning (overdose) for opioids, narcotics, barbiturates, benzodiazepines, or "unspecified drug or substance" is found in the Medicaid medical history in the previous 12 months, an incoming claim for an opioid pain medication or an incoming claim for a benzodiazepine medication will deny at point of sale.
- Exception
  - Beneficiaries with a cancer diagnosis in the past 12 months will be exempt from the diagnosis check for poisoning (overdose).

Denial Criteria

- Paid claim for Suboxone or Subutex in the past 90 days
- Therapeutic duplication of long-acting opiates
- No medical necessity of long-acting opiate
- Opioid claims exceed the current MME limits

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Opioids, Short-Acting

(Implemented 11/12/2008)
(Updated 05/10/2017, Effective 7/1/2017)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Accumulation quantity limit will allow up to a maximum of 93 units of any solid oral short acting opioid paid by Medicaid per the previous 31 calendar days. ***Additional information listed under Exemptions***
- No drug claim in the past 90 days for SUBUTEX; **OR**
- No drug claim in the past 90 days for SUBOXONE; **AND**
- Therapeutic duplication between short-acting opioids with less than 25% of the days' supply remaining on the previous claim; **OR**
- Therapeutic duplication between a short-acting opioid and tramadol IR (ULTRAM) with less than 25% of the days' supply remaining on the previous claim; **OR**
- Therapeutic duplication between a short-acting opioid and tramadol/acetaminophen (ULTRACET) with less than 25% of the days' supply remaining on the previous claim
- Therapeutic duplication between a short-acting opioid and tramadol ODT (RYBIX) with less than 25% of the days' supply remaining on the previous claim

Additional information listed under Exemptions

Denial Criteria

- Therapeutic duplication between two short-acting opioids with more than 25% of the days' supply remaining on previous claim
- Therapeutic duplication between a short-acting opioid and tramadol (UTRAM and ULTRACET) with more than 25% of the days' supply remaining on previous claim
- Therapeutic duplication between a short-acting opioid and tramadol ODT (RYBIX) with more than 25% of the days' supply remaining on previous claim
- Drug claim in history for SUBUTEX
- Drug claim in history for SUBOXONE
- Solid oral dosage forms for short-acting opioids will reject for children less than 6 years of age.
- Greater than 93 units of any solid oral short acting opioid paid by Medicaid per the previous 31 calendar days.
- An incoming claim for any opioid pain medication will trigger a search of the beneficiary's Medicaid medical diagnoses history for diagnosis of poisoning or overdose the previous 12 months.

- If a diagnosis for poisoning (overdose) for opioids, narcotics, barbiturates, benzodiazepines, or "unspecified drug or substance" is found in the Medicaid medical history in the previous 12 months, an incoming claim for an opioid pain medication or an incoming claim for a benzodiazepine medication will deny at point of sale.
  Additional information listed under Exemptions

Exemptions

- Patients who have a diagnosis of malignant cancer in the past 12months:
  - Are exempt from the therapeutic duplication requirement.
  - Are exempt from the diagnosis check for a poisoning (overdose) of opioids, narcotics, barbiturates, benzodiazepines, or unspecified drug or substance.
  - Accumulation quantity limit will allow up to a maximum of 124 units of any solid oral short acting opioid paid by Medicaid per the previous 31 calendar days.

Preferred Status only for strengths noted

(Quantity edits, MME edits, accumulation edits, and refill too soon edits apply)

- Acetaminophen/codeine 120 mg-12 mg/5 ml oral solution 473 ml bottle
- Acetaminophen/codeine 300-15 mg, 300-30 mg, 300-60 mg tablet
- Codeine 15 mg, 30 mg, 60 mg tablet
- Hydrocodone/acetaminophen 7.5-325 mg/15 ml oral solution
- Hydrocodone/acetaminophen 5/325 mg, 7.5/325 mg, 10/325 mg tablet (generic for Norco®)
- Hydrocodone/ibuprofen 7.5/200 mg tablet (generic for Vicoprofen®)
- Hydromorphone 2 mg, 4 mg, 8 mg tablet (generic for Dilaudid®)
- Meperidine 50 mg/5 ml oral solution (generic for Demerol®)
- Meperidine 50 mg tablet (generic for Demerol®)
- Morphine concentrated 100 mg/5 ml oral solution
- Morphine IR 15 mg, 30 mg tablet (generic for MSIR®)
- Morphine 10 mg/5 ml, 20 mg/5 ml oral solution
- Oxycodone 5 mg/5 ml oral solution (generic for Roxicodone®)
- Oxycodone 5 mg, 10 mg, 15 mg, 20 mg, 30 mg tablet (generic for Roxicodone®)
- Oxycodone/acetaminophen 5-325 mg/5 ml solution (generic for Roxicet®)
- Oxycodone/acetaminophen 5 mg-325 mg, 7.5 mg-325mg, 10mg-325 mg tablet (generic for Percocet®)
- Tramadol 50 mg tablet (generic for Ultram®)
- Tramadol/acetaminophen 37.5 mg-325 mg tablet (generic for Ultracet®)

Non-Preferred Status for all strengths unless otherwise noted

- Acetaminophen/codeine 120 mg-12 mg/5 ml and 300 mg-30 mg/12.5 ml oral solution (unit dose cups)
- Butalbital/caffeine/APAP w/codeine 50 mg-40 mg-325 mg-30 mg and 50 mg-40 mg-300 mg-30 mg capsule (generic for Fioricet® with Codeine)
- Butalbital/caffeine/ASA w/codeine 50 mg-40 mg-325mg-30 mg capsule (generic for Fiorinal® with Codeine)

- Butorphanol 10 mg/ml nasal spray (generic for Stadol® NS)
- Dilaudid® tablet and oral solution (hydromorphone)
- Fioricet® with Codeine 50 mg-40 mg-300 mg-30 mg capsule (butalbital/caffeine/APAP with codeine)
- Hydrocodone/APAP 10 mg-325 mg/15 ml oral solution (generic for Zamicet®
- Hydrocodone/APAP 7.5-325 mg/15 ml, 2.5-108 mg/5 ml, 5-217 mg/10 ml oral solution (unit dose cups)
- Hydrocodone/acetaminophen 5-300 mg,7.5-300 mg, 10-300 mg, 2.5-325 mg tablet
- Hydrocodone/ibuprofen tablet 10 mg-200 mg, 5 mg-200 mg tablet (generic for Ibudone® and Reprexain™)
- Hydromorphone 1 mg/1 ml oral solution (generic for Dilaudid®)
- Levorphanol 2 mg tablet
- Oxycodone 5 mg/5 ml solution unit dose cups
- Oxycodone 5 mg capsule (generic for OxyIR®)
- Oxycodone concentrated 20 mg/ml oral solution (generic for Roxicodone Intensol®)
- Oxycodone/APAP 2.5 mg-325 mg tablet (generic for Percocet®)
- Oxymorphone tablet (generic for Opana®)
- Pentazocine/naloxone tablet (generic for Talwin NX®)
- Percocet® tablet (oxycodone/APAP)
- Prolate® 5/300 mg, 7.5/300 mg, 10/300 mg, 10 mg-300 mg/5 ml (oxycodone/APAP)
- Roxicodone® tablet (oxycodone)
- RoxyBond™ 5 mg, 10 mg, 15 mg, 30 mg tablet (oxycodone)
- Tramadol 25 mg, 75 mg, 100 mg tablet
- Tramadol 5 mg/ml oral solution (generic for Qdolo®)

Additional Criteria

- Quantity limits apply
- Age restrictions apply

Tramadol IR Age Edit

- ≥ 17 years of age

Tramadol/APAP Age Edit

- ≥ 16 years of age

Oral Asthma Medications (Terbutaline 2.5 mg, 5 mg tablet, and vial)

(Implemented 01/17/2017)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Terbutaline 2.5 mg tablet
- Terbutaline 5 mg tablet
- Terbutaline vial

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Osilodrostat (Isturisa®)

(Implemented 7/15/2020)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication; **AND**
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia; **AND**
- Diagnosis of Cushing's syndrome and pituitary surgery **AND/OR** pituitary radiation are not options or have not been curative **OR** diagnosis consistent with FDA indication; **AND**
- Prescriber must be an endocrinologist; **AND**
- Beneficiary should have a trial and failure of ketoconazole and mitotane unless contraindicated or beneficiary cannot tolerate both medications; **AND**
- Current labs should indicate the beneficiary does not have hypokalemia or Hypomagnesemia; **AND**
- Beneficiaries with risk factors for QT prolongation should have more frequent ECG monitoring; AND
- Beneficiary must not be showing symptoms of adrenal insufficiency; AND
- Prescriber must provide the following:
  - Current chart notes with documentation of surgery status; **AND**
  - Current labs including:
    - Urine free cortisol levels (normal is < 150 nmol/24 hours OR 3.5-45mcg/24 hours); **AND**
    - Liver function tests; **AND**
    - Comprehensive metabolic panel; **AND**
  - Baseline electrocardiogram; **AND**
  - Assessment for Adrenalectomy

Quantity Edits

- Due to titration and variety of doses, do not recommend quantity edits on 1 mg and 5 mg
- 10 mg tablets - #180/30 days

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Osteoporosis Drugs

(Implemented 08/17/2010)
(Updated 10/1/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Alendronate sodium 5mg daily dose (generic for Fosamax®)
- Alendronate sodium 10mg daily dose (generic for Fosamax®)
- Alendronate sodium 35mg weekly dose (generic for Fosamax®)
- Alendronate sodium 40mg weekly dose (generic for Fosamax®)
- Alendronate sodium 70mg weekly dose (generic for Fosamax®)

Non-Preferred Agents with Criteria

- Prolia® injection (denosumab) **– BRAND ONLY**
- Evista® tablet (raloxifene)

Non-Preferred Agents without Criteria

- Actonel® tablet (risedronate)
- Atelvia® tablet (risedronate DR)
- Binosto® effervescent tablet (alendronate)
- Boniva® tablet (ibandronate)
- Boniva® injection (Ibandronate)
- Calcitonin-Salmon (Miacalcin® and Fortical®)
- Conexxence® (denosumab-bnht)*
- Evenity® injection (romosozumab-aqqg)
- Fosamax® Plus D tablet
- Fosamax® oral solution (alendronate)
- Forteo® injection (teriparatide)
- Jubbonti® injection (denosumab-bbdz)*
- Stoboclo® injection (denosumab-bmwo)*
- Teriparatide injection (generic for Forteo®)
- Tymlos® injection (abaloparatide)

*Signifies a biosimilar

Approval Criteria for Non-Preferred with Criteria - Prolia®

Prolia® will continue to be covered through a manual review PA on a case-by-case basis for the initial dose. POS PA continuation approval criteria for Prolia® will apply as follows:

- One Prolia® claim is found in Medicaid drug history in the previous 12 months.
- In addition, a therapeutic duplication edit will reject an incoming Prolia® claim if an Xgeva® (denosumab) claim is found in the medical claims history in previous 6 months.

- A quantity edit for Prolia® of one injection per 175 days will be implemented.

Approval Criteria for Non-Preferred with Criteria - Evista®

- Diagnosis of post-menopause in the previous 2 years; **AND**
  - Diagnosis of carcinoma in situ of breast in the previous 2 years; **OR**
  - Diagnosis of atypical hyperplasia of breast in the previous 2 years; **OR**
  - Diagnosis of Family History of Malignant Neoplasm of Breast in previous 2 years; **OR**
- Diagnosis of post-menopause in the previous 2 years; **AND**
- Diagnosis of osteoporosis in the previous 2 years; **AND**
  - Diagnosis of esophageal strictures in the previous 2 years; **OR**
  - Diagnosis of esophageal achalasia in the previous 2 years

Continuation Criteria for Evista®

- At least 4 or more claims for raloxifene in the past 186 days

Additional Criteria

- Forteo® quantity limits apply

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Oteseconazole 150 mg capsule (Vivjoa™)

(Implemented 01/18/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary is an adult, female with a history of recurrent vulvovaginal candidiasis (RVVC) defined as ≥ 4 episodes of vulvovaginal candidiasis in as 12 month period **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Beneficiary must have permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy, or post-menopausal)
- Beneficiary should not be approved with any of the following:
  - Severe renal impairment (eGFR 15-29 mL/min) or ESRD (eGFR < 15mL/min)
  - Moderate to severe hepatic impairment (Child-Pugh B or C)
- For diabetic beneficiaries with HbA1c > 9%, prescriber must provide efforts taken to achieve better glycemic control
- Beneficiary must have continued vulvovaginal candidiasis despite a minimum of fluconazole 150mg once weekly for 6 months
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - History of symptomatic vulvovaginal candidiasis with previous treatment
  - Vaginal discharge culture or microscopy report
  - Current HbA1c
  - Documentation verifying that the current infection is recurrent and not a non-clearance of a previous infection
  - Medical necessity over fluconazole
  - Note which therapy will be initiated
    - VIVJOA only; **OR**
    - Fluconazole/VIVJOA
- PA will be approved for a maximum of 12 weeks

Renewal Requirements

- Reviewed on a case-by-case basis
- Prescriber should submit the following:
  - Current chart notes with confirmation of RVVC despite previous treatment
  - Diabetic beneficiaries must maintain glycemic control with HbA1c < 9%
  - Rationale for a subsequent treatment when the package insert does not support beyond one 12 week course

Quantity Edits

- #18 for full course over 12 weeks

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Otic Preparations

(Implemented 09/21/2009)
(Updated 01/18/2011)
(Updated 10/01/2016)
(Updated 10/1/2019)
(Updated 4/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Acetic acid 2% otic solution
- Acetic acid/HC otic solution
- Ciprodex® otic suspension (ciprofloxacin and dexamethasone) **BRAND NAME**
- Ciprofloxacin/dexamethasone suspension (generic for Ciprodex®)
- Neomycin/polymyxin/HC otic solution/suspension (generic for Cortisporin®)
- Ofloxacin otic drops (generic for Floxin®)

Non-Preferred Agents

- Cipro HC® otic suspension (ciprofloxacin/hydrocortisone)
- Cortisporin-TC® otic suspension (neomycin/colist/hydrocortisone/thonzonium)
- Ciprofloxacin otic solution (generic for Cetraxal®)
- Ciprofloxacin/fluocinolone solution (generic for Otovel®)
- Otovel® 0.3%-0.025% solution (ciprofloxacin/fluocinolone)

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Overactive Bladder Agents

(Implemented 07/14/2009)
(Updated 4/1/2020)
(Update 1/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Fesoterodine fumarate ER tablet (generic for Toviaz®)
- Myrbetriq ER® tablet (mirabegron extended release) **BRAND NAME ONLY**
- Oxybutynin chloride syrup, 5mg tablet (generic for Ditropan®)
- Oxybutynin chloride ER tablet (generic for Ditropan XL® Tablet)
- Solifenacin succinate tablet (generic for Vesicare®)

Non-Preferred Agents

- Darifenacin hydrobromide ER tablet (generic for Enablex®)
- Detrol® tablet (tolterodine tartrate)
- Detrol LA® capsule (tolterodine tartrate ER)
- Flavoxate HCl tablet (generic for Urispas®)
- Gemtesa® tablet (vibegron)
- Mirabegron ER tablet (generic for Myrbetriq®)
- Myrbetriq ER® granules (mirabegron)
- Oxybutynin 2.5mg tablet
- Oxytrol® patch (oxybutynin)
- Tolterodine tartrate tablet (generic for Detrol®)
- Tolterodine tartrate ER capsule (generic for Detrol LA®)
- Toviaz® tablet (fesoterodine fumarate)
- Trospium chloride ER capsule (generic for Sanctura XR®)
- Trospium chloride immediate-release tablet (generic for Sanctura®)
- Vesicare® tablet (solifenacin succinate)
- Vesicare LS® suspension (solifenacin succinate)

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Oxymetazoline topical cream (Rhofade®)

(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with moderate to severe, persistent facial erythema associated with rosacea
- Must be prescribed by, or in consultation with, a dermatologist
- Prescriber must submit the following:
  - Current chart notes
  - Baseline clinician erythema assessment (CEA) 5-point scale (must indicate moderate to severe)
  - Letter of medical necessity over other products available without prior authorization that treat rosacea

Renewal Requirements

- Beneficiary must demonstrate at least a 2-grade reduction in erythema compared to baseline used the clinician erythema assessment (CEA) 5-point scale
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy with description of erythema with CEA score

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Pain Medications, Injectable

(Implemented 04/12/2011)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Injectable agents

- Buprenorphine Injectable
- Butorphanol Injectable
- Hydromorphone Injectable
- Levorphanol Injectable
- Meperidine Injectable
- Morphine Injectable
- Nalbuphine Injectable
- Pentazocine Injectable

Approval Criteria

- No drug claim in the past 90 days for SUBUTEX; **OR**
- No drug claim in the past 90 days for SUBOXONE; **AND**
- Therapeutic duplication between short-acting opioids with less than 25% of the days' supply remaining on the previous claim; **OR**
- Therapeutic duplication between a short-acting opioid and tramadol IR (ULTRAM) with less than 25% of the days' supply remaining on the previous claim; **OR**
- Therapeutic duplication between a short-acting opioid and tramadol/acetaminophen (ULTRACET) with less than 25% of the days' supply remaining on the previous claim; **OR**
- Therapeutic duplication between a short-acting opioid and tramadol ODT (RYBIX) with less than 25% of the days' supply remaining on the previous claim

Denial Criteria

- Therapeutic duplication between two short-acting opioids with more than 25% of the days' supply remaining on previous claim; **OR**
- Therapeutic duplication between a short-acting opioid and tramadol (UTRAM and ULTRACET) with more than 25% of the days' supply remaining on previous claim; **OR**
- Therapeutic duplication between a short-acting opioid and tramadol ODT (RYBIX) with more than 25% of the days' supply remaining on previous claim; **OR**
- Drug claim in history for SUBUTEX; **OR**
- Drug claim in history for SUBOXONE

Exemptions

- Patients who have a diagnosis of malignant cancer in the past 12 months are exempt.

Additional Criteria

- Quantity limits apply

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Peanut allergen powder-dnfp (Palforzia®)

(Implemented 1/19/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 1 year of age and ≤ 17 years of age to initiate treatment; **AND**
- Beneficiary must have a confirmed diagnosis of a peanut allergy; **AND**
- Prescriber must be an Allergy and Immunology specialist; **AND**
- Prescriber, clinic, pharmacy, and beneficiary must be enrolled in the Risk Evaluation and
- Mitigation Strategy (REMS) program and remain compliant with program requirements; **AND**
- Prescriber must attest that the beneficiary has been counseled to continue a peanut-avoiding diet as this medication is for accidental exposure to peanuts; **AND**
- Beneficiary must continue to have injectable epinephrine on hand with a pharmacy claim within the last year; **AND**
- Prescriber must require Initial Dose Escalation and first dose of each up-dosing stage to occur in the office to monitor for anaphylaxis for at least 60 minutes and provide a plan on how to manage potential anaphylaxis reactions while in the office; **AND**
- Prescriber should provide the following:
  - Current chart notes; **AND**
  - Documentation of a systemic reaction to peanuts **AND** at least one of the following:
    - Positive serum immunoglobulin E (IgE) to peanuts within the past 12 months; **OR**
  - Skin prick test (SPT) to peanut with a mean wheal diameter of ≥ 8mm compared to control; **OR**
  - Documented reaction to peanut upon supervised oral food challenge at a dose of ≤ 100 mg peanut protein (≤ 200 mg peanut flour).
- PA will be approved for 2 months at a time with correct dosages per the taper. Compliance, response to therapy, and tolerance will be reviewed on renewal request.

Denial Criteria

- Beneficiary does not meet the FDA approved indication **OR** have a diagnosis supported in the official Compendia; **OR**
- Beneficiary has uncontrolled asthma, markedly compromised lung function, severe mast cell disorder or cardiovascular disease (decreased ability to survive anaphylaxis); **OR**
  - Uncontrolled asthma is defined per the 2007 NHLBI, and involves: asthma symptoms throughout the day, nighttime awakenings often (7x/week), poor lung function (FEV1 < 60% predicted; FEV1/FVC reduced > 5%), extreme limitation on normal activity, and the need to use a short-acting beta agonist (rescue inhaler) several times a day.
- Beneficiary has suspected eosinophilic esophagitis and/or other eosinophilic gastrointestinal disease; **OR**
- Beneficiary cannot tolerate doses up to and including the 3 mg dose during Initial Dose Escalation; **OR**
- Beneficiary had a severe or life-threatening anaphylaxis within the previous 60 days

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Palopegteriparatide 168 mcg, 294 mcg, 420 mcg injection (Yorvipath®)

(Implemented 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with hypoparathyroidism
- Must be prescribed by, or consultation with, an endocrinologist, nephrologist or other specialist knowledgeable in treating hypoparathyroidism
- Beneficiary must not have adequate control of hypocalcemia with calcium and vitamin D supplements prior to approval
- Beneficiary must have a baseline albumin-corrected serum calcium of at least 7.8 mg/dL while using calcium and active vitamin D treatment
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - At increased risk of osteosarcoma
  - Open epiphyses. YORVIPATH is not approved in pediatric patients
  - Metabolic bone diseases other than hypoparathyroidism, including Paget's disease of bone.
  - Unexplained elevations of alkaline phosphatase.
  - Bone metastases or a history of skeletal malignancies.
  - History of external beam or implant radiation therapy involving the skeleton.
  - Hereditary disorders predisposed to osteosarcoma
  - Has acute post-surgical hypoparathyroidism
  - Requested dose exceeds 30 mcg per day or dose requested requires more than 1 injection
  - Prescribed concomitant teriparatide (FORTEO)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Dose requested
  - Current labs including calcium, vitamin D, magnesium
  - Treatment plan that includes monitoring calcium levels 7-10 days after first dose and after any dose change of YORVIPATH, active vitamin D, or calcium supplements. For maintenance, labs should be checked at a minimum every 4-6 weeks or when patient experiences symptoms of hypocalcemia or hypercalcemia

Renewal Requirements

- Beneficiary must remain compliant with therapy including calcium and vitamin D supplements if prescribed concomitantly (compliance defined as 75% utilization)

- Beneficiary has a positive response with albumin-corrected serum calcium within normal limits
- If labs are not within desired range and beneficiary takes a 30 mcg daily dose along with calcium and vitamin D supplements, provide medical necessity for continuing the medication.
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including calcium, vitamin D, magnesium

Quantity Edits

- #2 pens/28 days

Top of the document

Palovarotene 1mg, 1.5mg, 2.5mg, 5mg, 10mg capsule (Sohonos™)

(Implemented 1/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication (As of 1/3/2024, minimum age is 8 years for females and 10 years for males.)
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia.
- Beneficiary must be diagnosed with fibrodysplasia ossificans progressive (FOP) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescribed by or in consultation with a specialist knowledgeable in FOP
- Growing pediatric patients should have baseline assessment of skeletal maturity via hand/wrist and knee x-rays, standard growth curves and pubertal staging. Continued monitoring is recommended every 6-12 months until skeletal maturity. Palovarotene can cause premature epiphyseal closure and risk vs. benefit may need to be determined.
- Female beneficiaries of reproductive potential should have highly effective contraception.
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Pregnancy
  - Moderate to severe hepatic impairment or severe renal impairment
  - Vertebral fractures (consider the benefit vs. risk)
  - Require strong CYP3A inhibitors (e.g., ritonavir, ketoconazole) and moderate or strong CYP3A inducers (e.g., carbamazepine, phenytoin)
  - Requires tetracycline derivatives
  - Requires high dose Vitamin A
- Prescriber must submit **ALL** of the following:
  - Current chart notes with previous therapies tried.
  - Description of this beneficiary's symptoms and disease progression (volume of heterotopic ossification if available as a baseline)
  - Negative pregnancy test within 1 week of initiating therapy
  - Baseline assessment of bone maturity
  - Dose requested (PA is specific to NDC)

Renewal Requirements

- Beneficiary continues to meet approval criteria.
- Provider has considered the benefit versus risk on epiphyseal closure.
- Prescriber must submit the following:
  - Current chart notes
  - Negative pregnancy test results

- Skeletal maturity test results at least once a year
- Dose requested (PA is specific to NDC)

Quantity Edits

- Nothing specific as multiple doses must be available depending on need of patient.

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Pancreatic Enzymes

(Implemented 10/01/2016)
(Updated 1/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Creon
- Zenpep

Non-Preferred Agents

- Pancreaze
- Pertzye
- Viokace

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Papaverine 30 mg/ml

(Implemented 08/10/2007)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Denial Criteria

- Submitted diagnosis for erectile dysfunction
- Submitted diagnosis for Impotence

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Pasireotide diaspartate ampule (Signifor®)

(Implemented 09/18/2013)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with Cushing's disease and pituitary surgery is not an option or has not been curative
- Must be prescribed by, or in consultation with, an endocrinologist
- Beneficiary should be monitored and therapy adjusted with the following:
  - Consider interrupting therapy if beneficiary develops hypocortisolism
  - Consider discontinuing if beneficiary develops uncontrolled hyperglycemia
  - If cholelithiasis is suspected, discontinue therapy
  - Consider altering other therapy if bradycardia or QT prolongation develops
  - Moderate hepatic impairment (Child-Pugh B) requires dose adjustment
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has severe hepatic impairment (Child-Pugh C)
- Prescriber must submit the following:
  - Current chart notes with patient specific symptoms of Cushing's syndrome
  - Baseline labs--Monitor the following at baseline and throughout treatment
    - Urinary free cortisol (UFC) level
    - Fasting plasma glucose, hemoglobin A1c, liver tests, serum potassium and magnesium level
    - Pituitary function (TSH/free T4, GH/IGF-1)
  - Baseline ECG

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must have a positive response from therapy with decrease in urine free cortisol (UFC) compared to baseline after 6 months of therapy
- Prescriber must submit the following:
  - Current chart notes with updated patient specific symptoms of Cushing's syndrome
  - Current labs
    - Urinary free cortisol (UFC) level
    - Fasting plasma glucose, hemoglobin A1c, liver tests, serum potassium and magnesium level
    - Pituitary function (TSH/free T4, GH/IGF-1)

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Patiromer powder (Veltassa®)

(Implemented 04/26/2016)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with hyperkalemia
- Beneficiary has either discontinued or decreased the dose on medications known to cause hyperkalemia to the lowest effective dose [e.g., aldosterone antagonists, nonsteroidal anti-inflammatory drugs (NSAIDs)]
- Beneficiary must be prescribed a low potassium diet
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders
  - Prescribed as an emergency treatment
  - Dose requested exceeds 25.2 gm per day
- Prescriber must submit the following:
  - Current chart notes
  - Previous treatments tried
  - Current potassium and magnesium levels
  - Letter of medical necessity over other products available for lowering potassium that do not require prior authorization (e.g., sodium polystyrene, potassium-depleting diuretics)

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must have a positive response to therapy with a decrease in potassium levels
- Prescriber must submit the following:
  - Current chart notes
  - Current potassium and magnesium

Top of the document

Pegcetacoplan (Empaveli™)

(Implemented 7/21/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 18 years of age; **AND**
- Beneficiary must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) **OR** a diagnosis consistent with FDA indications; **AND**
- Beneficiary must be vaccinated against encapsulated bacteria, including *Streptococcus pneumoniae* and *Neisseria meningitidis* types A, C, W, Y, and B at least 2 weeks prior to initiation of EMPAVELI, and beneficiary must be provided antibiotics if vaccines were administered less than 2 weeks before starting therapy; **AND**
- Prescriber, pharmacy, and beneficiary must be enrolled in the REMS program; **AND**
- Beneficiary currently taking eculizumab (Soliris®) or ravulizumab (Ultomiris®) must follow the required dose initiation per the package insert; **AND**
- Beneficiaries taking eculizumab (Soliris®) or ravulizumab (Ultomiris®) must have been stable for at least 3 months; **AND**
- Female beneficiaries of reproductive potential should use contraception and have a negative pregnancy test prior to starting therapy; **AND**
- Beneficiary's baseline hemoglobin level is
  - Current chart notes; **AND**
  - Documentation of previous therapies; **AND**
  - Current labs including CBC and LDH; **AND**
  - Pregnancy test results (if applicable)

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported on the official Compendia; **OR**
- Beneficiary has not been vaccinated according to package insert/REMS requirements; **OR**
- Beneficiary has an unresolved serious infection caused by encapsulated bacteria; **OR** including *Streptococcus pneumoniae* and *Neisseria meningitidis*
- Beneficiary is pregnant or breastfeeding

Quantity Edits

- 10 vials/ 30 days

Top of the document

Pegvaliase-pqpz (Palynziq®)

(Implemented 7/18/2018)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary is an adult ≥18 years of age;
- Beneficiary has phenylketonuria and has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L while adherent to a strict Phenylalanie (Phe)-limited diet;
- Prescriber must submit beneficiary's blood phenylalanine concentration with PA request;
- Beneficiary is adherent to a Phe-restricted diet that restricts phenylalanine protein;
- Prescriber must submit chart notes to substantiate that beneficiary was a non-responder to KUVAN while adherent to the Phe-restricted diet;
- If female beneficiary is child-bearing age, she must be willing to use 2 acceptable methods of contraception while receiving PALYNZIQ;
    - Females who have been in menopause for at least 2 years, have had a tubal ligation at least 1 year prior to first dose of PALYNZIQ, or have had a total hysterectomy do not need to use any other forms of contraception while receiving PALYNZIQ.
    - Males post vasectomy 2 years with no known pregnancies for at least 2 years do not need to use any other forms of birth control while receiving PALYNZIQ.
- Prescriber must administer the initial dose of PALYNZIQ and closely observe the beneficiary for at least 60 minutes following the injection;
- Prescriber must ensure beneficiary is capable of recognizing signs and symptoms of anaphylaxis and can administer the autoinjector of epinephrine;
- Prescriber must prescribe and ensure beneficiary filled the Medicaid preferred autoinjector of epinephrine;
- If approved, due to the recommended dosing schedule, the initial PA will be approved for 5 weeks at 2.5 mg once weekly for 4 weeks, and 2.5 mg twice weekly for 1 week, for a total of six 2.5 mg syringes; quantity will be entered at the time of the PA approval;

Denial Criteria

- HIV positive;
- Beneficiary is pregnant;
- Beneficiary is < 18 years of age;
- Beneficiary has a history of substance abuse in the past 12 months or current alcohol or drug abuse; • Beneficiary was not adherent to a strict Phe-restricted diet;
- Beneficiary did not have adequate trial of Kuvan;
- Beneficiary was not adherent to prescribed dose of PALYNZIQ;
- Beneficiary did not show at least a 20% reduction in blood phenylalanine concentration from pretreatment baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily

Quantity Edits

- Quantity limit for the required strength to be entered at the time of each PA approval

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Pegvisomant injection (Somavert®)

(Implemented 04/17/2012)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with elevated serum insulin-like growth factor-1 (IGF-1) due to acromegaly with an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy, is not an option.
- Prescribed by or in consultation with an endocrinologist or oncologist
- Beneficiary's dose should not be based on growth hormone concentrations or sign/symptoms. The dose should be titrated to normalize serum IGF-1 concentration.
- Prescriber must submit the following:
  - Current chart notes with documentation of diagnosis
  - Previous therapies tried with response
  - If no surgery or radiation, provide rationale for requesting in acromegaly patients
  - Baseline labs--Monitor the following at baseline and throughout treatment
    - IGF-1
    - Baseline liver function tests

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must have a positive response to therapy with a decrease in serum IGF-1
- Prescriber must submit the following:
  - Current chart notes
  - Updated labs including IGF-1 and liver function tests

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Penicillamine/Cystine Depleting Agents

(Implemented 09/18/2013)
(Updated 9/7/18)]
(Updated 7/1/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents

- Cuprimine® capsule (penicillamine) - **BRAND NAME ONLY**
- Depen® tablet (penicillamine) - **BRAND NAME ONLY**
- Potassium citrate tablet (generic for Urocit-K®)
- Thiola® tablet (tiopronin) - **BRAND NAME ONLY**
- Thiola® EC tablet (tiopronin) - **BRAND NAME ONLY**

Non-Preferred Agents

- Penicillamine capsule (generic for Cuprimine®)
- Penicillamine tablet (generic for Depen®)
- Tiopronin tablet (generic for Thiola®)
- Tiopronin DR tablet (generic for Thiola® EC)
- Urocit-K® ER tablet (potassium citrate)

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Phenoxybenzamine capsule (Dibenzyline®)

(Implemented 05/04/2015)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be experiencing hypertension and sweating due to pheochromocytoma
- Prescriber must submit the following:
  - Current chart notes with patient specific symptoms
  - Current blood pressure and heart rate
  - Treatment plan (DIBENZYLINE is not intended for long-term use)
  - Medical necessity over other treatment options including surgery to remove pheochromocytoma

Top of the document

Phosphate Removing Agents

(Implemented 07/08/2014)
(Re-review 5/10/18)
(Effective 7/1/18)
(Updated 7/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Calcium acetate capsule
- Calcium acetate tablet
- Sevelamer carbonate tablet (generic for Renvela®)

.

Non-Preferred Agents

- Auryxia® tablet (ferric citrate)
- Ferric citrate (generic for Auryxia®)
- Fosrenol® chewable tablet(lanthanum carbonate)
- Lanthanum carbonate chewable tablet (generic for Fosrenol®)
- Phoslyra® 667 mg/5 ml oral solution (calcium acetate)
- Renvela® powder pack (sevelamer carbonate)
- Renvela® tablet (sevelamer carbonate)
- Sevelamer HCl tablet (generic for Renagel®)
- Velphoro® chewable tablet (sucroferric oxyhydroxide)
- Xphozah® tablet (tenapanor)

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Pilocarpine (Vuity®)

(Implemented 01/19/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥18 years of age; **AND**
- Beneficiary must have a diagnosis of presbyopia **OR** a diagnosis consistent with FDA approved indication; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Medical necessity over other treatment options for presbyopia

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported on the official Compendia; **OR**
- Beneficiary has a history of glaucoma or ocular hypertension; **OR**
- Beneficiary has a history of cataract surgery, phakic intraocular lens surgery, corneal inlay surgery, radial keratotomy, or any intraocular surgery

Quantity Edits

- 1 bottle per 22 days

Top of the document

Pirfenidone tablet, capsule (Esbriet®)

(Updated 1/15/2020)
(Updated 10/16/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Prescribed by or in consultation with a pulmonologist
- Beneficiary must be diagnosed with idiopathic pulmonary fibrosis (IPF). Confirmation will require the following:
  - Confirmed by either a lung biopsy or high-resolution computed tomography (CT) scan of the lungs with presence of the usual interstitial pneumonia (UIP) pattern with documentation some of the following:
    - Basal and peripheral dominance
    - Honeycombing (usually subpleural)
    - Reticular opacities or ground-glass opacities
    - Traction bronchiectasis
    - Airspace enlargement with fibrosis
  - Baseline Pulmonary Function Tests (PFTs)
    - Forced vital capacity (FVC) is ≥ 50% predicted; **AND**
    - Carbon monoxide diffusing capacity (DLCO) is ≥ 30% predicted
  - Other known causes of interstitial lung disease (e.g., environmental exposures, connective tissue disease, drug toxicity) have been ruled out
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Likely to receive a lung transplant or has had a lung transplant
  - Has relevant airways obstruction (i.e., pre-bronchodilator FEV1/FVC < 0.8)
  - Currently smoking
  - Severe hepatic impairment (Child Pugh C). Patients with mild to moderate hepatic impairment (Child Pugh A or B) should use ESBRIET with caution and consider dose modification or discontinuation if needed.
  - End-stage renal disease requiring dialysis. For patients with mild to severe renal impairment, monitor for adverse events and modify dose or discontinue as needed.
  - Develops Severe Cutaneous Adverse Reactions (SCAR)
- Prescriber must submit the following:
  - Current chart notes and documentation to support the diagnosis (e.g., CT scan results and/or biopsy results)
  - Strength of medication and dosage form requested (PA is entered for specific dose)
  - Current labs including liver function tests
  - Baseline pulmonary function tests (PFTs)
  - Baseline 6-minute walk test (6MWT)
  - Documentation verifying the smoking status with **ONE** of the following:

- exhaled carbon monoxide level (eCO) < 6 ppm; **OR**
- carboxyhemoglobin (COHb) levels < 3%; **OR**
- urine continine concentration < 200 mg/mL

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must remain a non-smoker
- Beneficiary must demonstrate a positive response with improved, stable or slowed progression based on radiographic results, pulmonary function tests, and/or clinical presentation
- Prescriber must submit the following
  - Current chart notes
  - Current labs including LFTs
  - Documentation of response to therapy with any of the following:
    - Current pulmonary function tests
    - Current 6MWT
    - Current CT scan results of lung

Quantity Edits

- 267 mg tablet or capsule #270/30 days
- 801 mg tablet #90/30 days

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Pituitary Suppressive Agents

(Implemented 7/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

NOTE: All medications with a prostate cancer indication will be available as a medical bill option only. The medications available as medical bill for prostate cancer include:

- Camcevi® 42 mg (leuprolide)
- Eligard® 7.5 mg, 22.5 mg - 3 month, 30 mg - 4 month, and 45 mg - 6 month (leuprolide)
- Lupron® 1 mg (leuprolide)
- Lupron Depot® 7.5 mg, 22.5 mg - 3 month, 30 mg - 4 month, 45 mg - 6 month, and Lupron® 2 week kit (leuprolide)
- Trelstar® 3.75 mg, 11.25 mg, 22.5 mg (triptorelin)

Endometriosis or Uterine Leiomyoma

Preferred Agents

- Lupaneta® 3.75 mg for monthly administration up to 6 months (leuprolide injection and norethindrone tablets)
- Lupron Depot® 3.75 mg and 11.25 mg - 3 month (leuprolide)

Non-Preferred Agents

- None

Point-of-Sale (POS) Approval Criteria

- Billed diagnosis of endometriosis or uterine leiomyoma (fibroids); **AND**
  o < 12 billed claims of 3.75 mg leuprolide injection (which would include Lupaneta®) in the previous 3 year Medicaid history; **OR**
  o < 4 billed claims of 11.25 mg leuprolide injection (which would include Lupaneta®) in the previous 3 year Medicaid history; **AND**
- No Therapeutic Duplication with other leuprolide products

Denial Criteria

- Diagnosis of infertility in Medicaid history (3 year look back)
- Thrombophlebitis
- Thromboembolic disorders
- Cerebral apoplexy in Medicaid history
- Carcinoma of the breast in Medicaid history

Breast Cancer or Ovarian Cancer

Preferred Agents

- Lupron-Depot® 3.75 mg, 7.5 mg, and 11.25 mg – 3 month (leuprolide)

Non-Preferred Agents

- None

Point-of-Sale (POS) Approval Criteria (Breast Cancer or Ovarian Cancer)

- Billed diagnosis in Medicaid history of breast cancer or ovarian cancer in the last 2 years
- No Therapeutic Duplication with other leuprolide products

Central Precocious Puberty – Manual Review

Preferred Agents

- Fensolvi® 45 mg (leuprolide)
- Lupron Depot-Ped® 7.5 mg, 11.25 mg, 15 mg, 11.25 mg - 3 month kit, 30 mg - 3 month kit, and the 45 mg - 6 month kit (leuprolide)
- Synarel® spray (nafarelin)

Non-Preferred Agents

- Triptodur® (triptorelin) 22.5mg - 6 month (triptorelin)

Approval Criteria

Requests for Lupron Depot-Ped®, Synarel® nasal spray, Fensolvi®, Triptodur® or other gonadotropin-releasing hormone (GnRH) agonist drugs, for treating CPP, will require manual review prior authorization on a case-by-case basis.

- Beneficiary is diagnosed with Central Precocious Puberty (CPP)
- Beneficiary must demonstrate full activation of the hypothalamus-pituitary-gonadal (HPG) axis before 8 years of age in females and before 9 years of age in males
- Females shall be less than 8 years of age and males shall be less than 9 years of age when initiating treatment with a GnRH agonists for treatment of CPP
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - When the goal is for the treatment of premature adrenarche (PA) associated with normal rate of growth and no evidence of clitoromegaly, penile growth or testicular enlargement
  - When the goal is for the treatment of premature menarche in the young girl with vaginal bleeding but no or little breast development and no evidence of endocrinopathy on the basis of pelvic ultrasonography or concentrations of LH, FSH and estradiol
  - There is no activation of the HPG axis, and FSH, LH and estradiol or testosterone concentrations are at prepubertal levels.
  - When the goal is for the treatment of premature thelarche (PT) in the very young females (e.g., age < 2 years) without additional indicators for CPP
  - If the only signs of sexual development are pubic and/or axillary hair and/or axillary odor
  - When the child's predicted adult height is within the normal range
  - When pubertal suppression is being used for increasing linear growth
  - When initial age for female ≥ 11 years and male ≥ 12 years
- Prescriber must submit the following:
  - Current chart notes
  - Letter of medical necessity
  - Documentation of growth rate acceleration above normal growth rate for age

- All testing and documentation used to determine CPP (e.g., notes on Tanner stage of development, progressive female breast development confirmed by palpation before 8 years of age, progressive penis and testicular enlargement, etc.)
- Bone age determination and predicted adult height
- Baseline labs tests for luteinizing hormone (LH), and either estradiol or testosterone, and follicle stimulating hormone (FSH) (e.g., LH of > 0.3 IU/L is the most reliable screening test for CPP on a random blood sample. If LH is < 0.3 and CPP is suspected, a stimulation test with a gonadotrophin-releasing hormone (GnRH) analog may be necessary.)
- TSH test for hypothyroidism if the growth velocity is slow instead of rapid (to exclude hypothyroidism as the cause of CPP)
- If requesting a non-preferred medication, provide the medical necessity over the preferred option(s)

Renewal Requirements

- Female < 11 years of age or male < 12 years of age for continuation of GnRH therapy previously initiated for treatment of CPP
- Prescriber to provide data that child shows positive response to the drug therapy (e.g., slowing of the growth velocity to < 7cm/year, shrinkage or softening of the glandular breast tissue or the testes, or documentation of suppression of the HPG axis).

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Platelet Aggregation Inhibitors

(Reviewed 5/10/2018)
(Effective 7/1/2018)
(Updated 7/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Aspirin/dipyridamole (generic for Aggrenox®)
- Brilinta® tablet (ticagrelor) – **BRAND NAME ONLY**
- Clopidogrel (generic for Plavix®)
- Dipyridamole
- Prasugrel (generic for Effient®)

Non-Preferred Agents

- Effient®
- Plavix®
- Ticagrelor (generic for Brilinta®)

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Podofilox 0.5% topical solution and gel (Condylox®)

(Implemented 01/09/2008)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for these products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

Podofilox 0.5% Topical Solution (CONDYLOX)

- ≥ 18 years of age; **AND**
- No therapeutic duplication with Podofilox 0.5% gel; **AND**
- Diagnosis of Condyloma Acuminata (commonly known as external genital or perianal warts) within the past two months

Podofilox 0.5% Topical Gel (CONDYLOX) **Plan Prefers Brand**

- ≥ 18 years of age; **AND**
- No therapeutic duplication with Podofilox 0.5% solution; **AND**
- Diagnosis of of Condyloma Acuminata (commonly known as external genital or perianal warts) within the past two months

Denial Criteria

- Absence of approval criteria
- < 18 years of age
- Therapeutic duplication of gel/solution

Additional Criteria

- Quantity limits apply

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Posaconazole suspension (Noxafil®)

(Implemented 01/09/2008)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

Criterion 1:

Diagnosis code in Medicaid history for at least one of the following in the past 365 days:

- ≥ 13 years of age; **AND**
- HIV/AIDS; **OR**
- Organ transplant procedure; **OR**
- Graft vs. host disease; **OR**
- Neutropenia

Criterion 2:

The following drug claims in Medicaid history in the past 365 days:

- ≥ 13 years of age; **AND**
- HIV/AIDS pharmacotherapy drug claims in history; **OR**
- Anti-rejection/Immunosuppression medication

Criterion 3:

- ≥ 13 years of age; **AND**
- At least one paid claim for Fluconazole in the past 30 days; **AND**
- At least one paid claim for Itraconazole in the past 30 days.

Criterion 4:

- ≥ 13 years of age; **AND**
- History of paid claim for requested drug (NOXAFIL) in the past 180 days.

Denial Criteria

- < 13 years of age
- Absence of approval criteria
- History of a paid drug claim for the any of the following in the last 30 days:
  - Ergot alkaloids
  - Pimozide
  - Quinidine

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Posaconazole 100 mg tablet and 300 mg vial (Noxafil®)

(Implemented 07/08/2014)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Noxafil DR® 100 mg tablet
- Noxafil® 300 mg vial

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Potassium chloride 20 mEq packet (Klor-con®)

(Updated 04/14/2017)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with hypokalemia and dietary management with potassium-rich foods or diuretic dose reduction is insufficient.
- Prescriber must submit the following:
    - Current chart notes
    - Letter of medical necessity for the powder packets over other potassium supplement products available without prior authorization (e.g., capsules, tablets)

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Potassium chloride oral liquid and effervescent tablet

(Implemented 01/17/2017)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- < 7 years of age; **OR**
- NPO (Appendix A) within the past 365 days.

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Prednisolone

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that do not require prior authorization

- Prednisolone sodium phosphate 15mg/5ml (generic for Orapred® solution)
- Methylprednisolone dose pack
- Methylprednisolone tablet
- Prednisone dose pack
- Prednisone tablet

Drugs that require manual review for prior authorization

- Flo-Pred 16.7 (15) mg/5 ml suspension – *Implemented 07/08/2011*
- Millipred 5 mg Dose Pack – *Implemented 01/18/2011*
- Millipred 5 mg tablet – *Implemented 01/18/2011*
- Millipred 10 mg/5 ml solution – *Implemented 04/21/2009*
- Orapred ODT tablet – *Implemented 08/17/2010*
- Veripred 20 mg/5 ml solution – *Implemented 04/21/2009*

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Prednisone DR tablet (Rayos®)

(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary is diagnosed with a disease or condition that is typically treated with corticosteroids
- Prescriber must submit the following:
  - Current chart notes with diagnosis needing steroids
  - Letter of medical necessity for RAYOS over the numerous oral corticosteroids available without prior authorization (e.g., prednisone, dexamethasone)

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Pretomanid tablets

(Updated 4/1/2020)

The Arkansas Department of Health reviews all TB therapy – if you have not contacted the ADH please do so.

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Diagnosed with pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB); **AND**
- Age ≥ 18 years; **AND**
- Taking Sirturo® (bedaquiline) and Zyvox® (linezolid) concomitantly unless otherwise contraindicated; **AND**
- Provide baseline ECG if also taking other medications that prolong QT interval; **AND**
- Request must have been reviewed and submitted by the Arkansas Departmentof Health's TB Control Program. If a prescriber outside of the Department of Health requests this medication, the TB control program must be notified.

Denial Criteria

- Does not meet FDA approved diagnosis; **OR**
- Clinically significant ventricular arrhythmia or QTcF interval > 500ms; **OR**
- Coadministration of moderate or strong CYP3A4 inducers

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Primaquine tablets

Quantity Limit

- Primaquine - #14 tablets per claim

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Propafenone SR (Rythmol SR®)

(Implemented 04/08/2014)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- >/= 90 days of Propafenone SR therapy in the past 120 days

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Proton Pump Inhibitors

(Implemented 08/17/2010)
(Reviewed 5/8/2019)
(Effective 7/1/2019)
(Updated 7/1/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- Omeprazole capsule (generic for Prilosec® (Rx only))
- Pantoprazole sodium tablet (generic for Protonix®)

Non-Preferred Agents

- Aciphex® tablet (rabeprazole)
- Dexilant® capsule (dexlansoprazole)
- Dexlansoprazole (generic for Dexilant®)
- Esomeprazole magnesium capsule (generic for Nexium®)
- Esomeprazole magnesium packet (generic for Nexium® Packet)
- Esomeprazole magnesium/naproxen tablet (generic for Vimovo®)
- Konvomep® suspension (omeprazole/sodium bicarbonate)
- Lansoprazole capsule (generic for Prevacid®)
- Lansoprazole ODT (generic for Prevacid® solutab)
- Omeprazole/sodium bicarbonate (generic for Zegerid®)
- Prevacid® (lansoprazole)
- Prevacid® Solutab (lansoprazole)
- Prilosec® Suspension (omeprazole)
- Protonix® tablet (pantoprazole)
- Rabeprazole sodium (generic for Aciphex®)
- Vimovo® (esomeprazole magnesium/naproxen)
- Zegerid® capsule/packet (omeprazole/sodium bicarbonate)

Non-Preferred Agents with Criteria

- Nexium® packets for suspension (esomeprazole) - **BRAND NAME ONLY**
- Protonix® suspension (pantoprazole) - **BRAND NAME ONLY**

Approval Criteria for Preferred Agents with Criteria

- Approve up to 93 days of proton pump inhibitor therapy per year for all beneficiaries age 24 months or older
- Approve treatment beyond 93 days for beneficiaries 24 months or older who have a diagnosis in history for Zollinger-Ellison Syndrome, Barrett's esophagus, esophageal varices, or an endoscopy (Appendix I) in the past 24 months
- Approve treatment beyond 93 days for beneficiaries 24 months or older who have a diagnosis in history for Cystic Fibrosis, pancreatic insufficiency, or pancreatic disease in the past 24 months

Approval Criteria for Non-Preferred Agents with Criteria

- Nexium® packet
  - Beneficiary ≤ 4 years of age
- Protonix® suspension
  - Beneficiary < 7 years of age; **OR**
  - History of NPO (Appendix A) within the past 365 days

Denial Criteria

- Nexium packet
  - Beneficiary Age > 4
- Protonix suspension
  - No documented history of NPO (Appendix A) within past 365 days
  - Beneficiary age ≥ 7
- All Proton Pump Inhibitors
  - 93 days of PPI therapy in the past 365 days for beneficiaries 24 months or older, unless there is a diagnosis in history for Zollinger- Ellison Syndrome, Barrett's esophagus, Cystic Fibrosis, pancreatic insufficiency, pancreatic disease, or an endoscopy (Appendix I) in the past 24 months

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Pulmonary Arterial Hypertension (PAH) Agents

(Implemented 04/01/2017)
(Updated 10/16/2019)
(Updated 1/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred PAH Agents without Criteria

- Remodulin® vial (treprostinil) - **BRAND ONLY**
- Veletri® vial (epoprostenol) - **BRAND ONLY**

Preferred PAH Agents with Criteria

- Ambrisentan (generic for Letairis®)
- Sildenafil tablet (generic for Revatio®) see sildenafil
- Sildenafil vial
- Tadalafil tablet (generic for Adcirca®, Alyq®) see tadalafil
- Tracleer® tablet (bosentan) – **BRAND ONLY**

Non-Preferred PAH Agents

- Adcirca® tablet (tadalafil)
- Adempas® tablet (riociguat)
- Bosentan tablet (generic for Tracleer®)
- Bosentan tablet for suspension (generic for Tracleer®)
- Epoprostenol vial (generic for Veletri®)
- Epoprostenol vial (generic for Flolan®)
- Flolan® vial (epoprostenol)
- Letairis® tablet (ambrisentan)
- Liqrev® suspension (sildenafil)
- Opsumit® tablet (macitentan)
- Opsynvi® tablet (macitentan/tadalafil)
- Orenitram® tablet (treprostinil)
- Revatio® suspension (sildenafil)
- Revatio® tablet (sildenafil)
- Sildenafil suspension (generic for Revatio®)
- Tadliq® suspension (tadalafil)
- Tracleer® tablet for suspension (bosentan)
- Treprostinil vial (generic for Orenitram®)
- Tyvaso® vial and Tyvaso DPI® (treprostinil)
- Uptravi® injection and tablet (selexipag)
- Ventavis® (iloprost)
- Winrevair® vial (sotatercept-csrk) see Winrevair
- Yutrepia™ capsule (treprostinil)

Denial Criteria

- **THERAPEUTIC DUPLICATION (TD) edit** for the preferred drugs to not allow therapeutic duplication within same drug class type (ERA, PDE5, and Prostacyclin) or same pathway (endothelin, NO/cGMP, and prostacyclin).

PDL STATUS	DRUG	DRUG CLASS	PATHWAY
PREFERRED	LETAIRIS (ambrisentan) Tablet	ENDOTHELIN RECEPTOR TYPE A (ERA)	endothelin pathway
PREFERRED	TRACLEER (bosentan) Tablet	ENDOTHELIN RECEPTOR TYPE A (ERA)	endothelin pathway
PREFERRED	REVATIO (sildenafil) Tablet	phosphodiesterase type 5 (PDE-5is)	NO/cGMP pathway
PREFERRED	ADCIRCA (tadalafil) Tablet	phosphodiesterase type 5 (PDE-5is)	NO/cGMP pathway

- LETAIRIS (ambrisentan), TRACLEER (bosentan), ADCIRCA (tadalafil), OR generic sildenafil (aka REVATIO): Deny claim for diagnosis of current pregnancy in Medicaid medical history.
- LETAIRIS: Deny incoming LETAIRIS claim if diagnosis of idiopathic pulmonary fibrosis (ICD- 10 code J84.112) is in Medicaid medical history in previous 2 years.
- TRACLEER: Deny incoming TRACLEER claim if beneficiary has a drug claim for glyburide in Medicaid drug history in previous 45 days, and vice-versa (deny incoming claim for glyburide if beneficiary has drug claim for TRACLEER in Medicaid drug history in previous 45 days.)
- ADCIRCA: Deny incoming ADCIRCA claim if beneficiary has a drug claim for ADEMPAS (riociguat) in Medicaid drug history in previous 45 days.

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Pyridostigmine (Mestinon® Timespan)

(Implemented 04/08/2014)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- ≥ 90 days of Pyridostigmine ER therapy in the past 120 days

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Pyrimethamine tablet (Daraprim®)

(Implemented 02/16/2016)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with toxoplasmosis
- Beneficiary must be prescribed a sulfonamide antibiotic to be taken concomitantly with pyrimethamine
- Dose and treatment duration must be supported by the manufacturer's package insert or MicroMedex®
- Prescriber must submit the following:
  - Current chart notes
  - Test results confirming toxoplasmosis

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Quinine sulfate (Qualaquin®)

(Implemented 06/27/2007)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Submitted diagnosis of uncomplicated plasmodium falciparum malaria in the previous 6 months; **AND**
- Concurrent therapy with seven days of Tetracycline; **OR**
- Concurrent therapy with seven days Doxycycline; **OR**
- Concurrent therapy with seven days Clindamycin.

Denial Criteria

- Absence of approval criteria

Additional Criteria

- Quantity limits apply

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Ranolazine (Ranexa®)

(Implemented 10/18/2006)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Diagnosis of hepatic impairment in the last 12 months

Additional Criteria

- Quantity limits apply

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Respiratory Syncytial Virus (RSV) Medications

(Implemented 01/01/1999)

(Updated 10/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Arkansas Medicaid will follow ACIP/CDC recommendations for RSV prophylaxis.

- **SYNAGIS (palivizumab)**
  - SYNAGIS will continue to require prior authorization (PA). Fax the PA request to 800-424-7976.
    - Documentation needed for PA review:
      - Medical necessity of SYNAGIS over BEYFORTUS
      - Discharge summary and current chart notes
      - Completed form Arkansas Medicaid Synagis Prior Authorization Request Form Year 2024-25 Forms & Documents - Arkansas (primetherapeutics.com)
    - Requests for SYNAGIS will continue to use AAP guidelines from 2014 in addition to medical necessity over BEYFORTUS.
    - If SYNAGIS is approved, PA renewals will require prescriber attestation that WebIZ has been checked prior to PA submission, and documentation that the patient has not gotten BEYFORTUS since the last SYNAGIS dose.
    - If < 5 SYNAGIS doses have been given, the patient can be changed to BEYFORTUS.
- **BEYFORTUS (nirsevimab)**
  - BEYFORTUS is available through the Vaccines for Children (VFC) program, and no prior authorization is required.
  - ACIP recommends 1 dose of nirsevimab for all infants aged < 8 months born during or entering their first RSV season (50mg for infants weighing < 5kg [< 11 lb] and 100 mg for infants weighing ≥ 5kg [≥ 11 lb]). Providers should bill with procedure code 90380 or 90381.
  - ACIP recommends 1 dose of nirsevimab (200 mg, administered as two 100 mg injections given at the same time at different injection sites) for infants and children aged 8-19 months who are increased risk for severe RSV disease and entering their second RSV season. Providers should bill with procedure code 90380 U1 or 90381 U1.
  - The recommendations for nirsevimab apply to infants and children recommended to receive palivizumab by AAP.
  - If BEYFORTUS has been given, the patient cannot be given SYNAGIS.

Arkansas Medicaid RSV Prevention Coverage for Adults:

- **ABRYSVO**
  - ABRYSVO is a vaccine indicated for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age. Also, ABRYSVO is indicated for active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

    - For beneficiaries who are also VFC eligible, the provider will bill 90678 with VFC modifiers.
    - For adults, the provider will bill 90678 and use 90471/90472 for administration.
- **AREXVY**
    - AREXVY is a vaccine indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in:
        - Individuals 60 years of age and older; the provider will bill 90679 and 90471-90472 for administration.
- **MRESVIA**
    - MRESVIA is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) cause by respiratory syncytial virus (RSV) in individuals 60 years of age and older.
        - For ages 60+ requires manual pricing, majority of providers will submit clinical and invoice when they initially bill. If it denies for (error code 6000-manual pricing), they will then submit documentation required per explanation of benefits.
        - Providers will bill 90471 for administration.

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Resmetirom 60 mg, 80 mg, 100 mg tablet (Rezdiffra™)

(Implemented 7/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Must be prescribed by on in consultation with a gastroenterologist or hepatologist
- Beneficiary must be diagnosed with metabolic-associated steatohepatitis (MASH) [formerly known as noncirrhotic nonalcoholic steatohepatitis (NASH)] with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Fibrosis staging documentation requires the following:
  - Liver biopsy results; **OR**
  - Fibrosis score results from **TWO** (2) testing modalities with at least ONE (1) blood-based non-invasive test (NITs) **AND** at least **ONE** (1) imaging test from the lists below:
    - NITs
      - Fibrosis-4 index (FIB-4)
      - AST to platelet ratio index (APRI)
      - NAFLD fibrosis score (NFS)
      - Enhanced liver fibrosis (ELF) or simplified ELF index
      - FibroSure®
    - Imaging tests
      - Vibration-controlled transient elastography (VCTE) (e.g., FibroSCAN®)
      - Two-dimensional shear weave elastography
      - Point shear wave elastography
      - Magnetic Resonance Elastography (MRE)
- Beneficiary must use this medication in conjunction with appropriate diet and exercise
- Prescriber must rule out any other cause for fibrosis (e.g., alcohol, hepatitis C)
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Fibrosis score is not consistent with F2 or F3 fibrosis
  - Concomitant use with a strong CYP2C8 inhibitor is requested (e.g., gemfibrozil)
  - Concomitant use with a moderate CYP2C8 inhibitor (e.g., clopidogrel) requires dosage modification for REZDIFFRA
  - Severe renal impairment

- Prescriber must submit the following:
  - Current chart notes
  - Fibrosis staging documentation as listed above
  - Attestation that the patient has been counseled on an appropriate diet and exercise
  - Current labs including comprehensive metabolic panel
  - Documentation of alcohol intake history
  - Current weight for dose verification
    - < 100 kg, the recommended dosage is 80 mg orally once daily.
    - ≥ 100 kg, the recommended dosage is 100 mg orally once daily.

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- To continue the medication after 12 months of therapy, the beneficiary should demonstrate a positive response to the medication as defined by:
  - Resolution of MASH/NASH without worsening of fibrosis; **OR**
  - No worsening of MASH/NASH **AND** improvement in fibrosis by ≥ 1 stage
- Beneficiary must continue to refrain from excessive alcohol use
- Prescriber must submit the following:
  - Current chart notes
  - Current weight
  - Current labs
  - Attestation that patient continues with diet and exercise plan
  - Current fibrosis staging documentation requires the following:
    - Liver biopsy results; **OR**
    - Fibrosis score results from **TWO** (2) testing modalities with at least **ONE** (1) blood-based non-invasive test (NITs) **AND** at least **ONE** (1) imaging test from the lists below:
      - NITs
        - Fibrosis-4 index (FIB-4)
        - AST to platelet ratio index (APRI)
        - NAFLD fibrosis score (NFS)
        - Enhanced liver fibrosis (ELF) or simplified ELF index
        - FibroSure®
      - Imaging results
        - Vibration-controlled transient elastography (VCTE) (e.g., FibroSCAN®)
        - Two-dimensional shear weave elastography
        - Point shear wave elastography
        - Magnetic Resonance Elastography (MRE)

Quantity Edits

- Each strength #31/31 days

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Rifamycin (Aemcolo®)

(Implemented 10/20/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 18 years of age; **AND**
- Beneficiary must be diagnosed with travelers' diarrhea caused by non-invasive strains of Escherichia coli **OR** a diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation of previous treatment; **AND**
  - Medical necessity over other antibiotics available without a PA

Denial Criteria

- Beneficiary does not meet approval criteria **OR** have a diagnosis supported on the official Compendia; **OR**
- Prescriber ordered a dosage or therapy duration outside of FDA indication or support on the official Compendia; **OR**
- Beneficiary has a fever and/or bloody stools

Quantity Edit

- #12/23 days

Top of the document

Rifaximin 550 mg tablet (Xifaxan®)

(Implemented 09/28/2010)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Diagnosis of Hepatic Encephalopathy in the previous 2 years.

Additional Criteria

- Quantity limits apply

Top of the document

Risdiplam tablet/solution (Evrysdi®)

(Implemented 10/21/2020)
(Updated 10/16/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with spinal muscular atrophy (SMA) by genetic testing with the following:
  - Documentation of SMN1 gene deletion or mutation; **AND**
  - Documentation of ≤ 4 copies of SMN2 gene whether a pre-symptomatic infant or symptomatic patient (SMA Type 1, 2, or 3)
- Prescribed by or in consultation with a neurologist experienced in treating SMA
- Beneficiary should not be approved or continue the medication if meet one of the following
  - Dosage requested is not consistent with the beneficiary's age and weight
  - Pregnant
  - Requires a Multidrug and Toxin Extrude (MATE1) substrate such as metformin, cimetidine or acyclovir. If concomitant use cannot be avoided, monitor for drug-related toxicities and consider dosage reduction of the co-administered drug
  - Beneficiary had previous administration of gene therapy (i.e., Zolgensma® [onasemnogene abeparvovec-xioi]) either in a clinical study or as part of medical care
  - Provider requests concomitant treatment with a SMN2-targeting antisense oligonucleotide (i.e., Spinraza® [nusinersen])
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies tried
  - Documentation of symptoms and age of onset if not pre-symptomatic
  - Current weight to verify dose requested
  - Genetic testing results
  - Documentation of pulmonary status (e.g., tracheostomy, hours on ventilation, etc.)
  - Negative pregnancy test for a female beneficiary of childbearing potential prior to beginning EVRYSDI therapy and/or has documentation of contraception use
  - Attestation that a female beneficiary of childbearing potential has been counseled about contraception
  - Attestation that a male beneficiary has been counseled about potential infertility with EVRYSDI therapy
  - Documentation that the beneficiary is receiving physical therapy
  - Baseline motor ability assessment results of one of the following:
    - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOPINTEND); **OR**
    - Motor Function Measure Score (MFM-32); **OR**

- Revised Upper Limb Module (RULM); **OR**
- Hammersmith Infant Neurological Examination Module 2 (HINE-2); **OR**
- Hammersmith Functional Motor Scale Expanded (HFMSE); **OR**
- Bayley Scales of Infant and Toddler Development, Third Addition (BSID-III or Bayley-III)

Renewal Requirements

- Beneficiary must be compliant with therapy (defined as 75% utilization)
- A symptomatic beneficiary must demonstrate a positive response in SMA associated signs and symptoms by either an improvement or no significant decline in motor function score compared to baseline assessment by using the same measuring scale as the baseline score **OR** demonstrating improvement or no significant decline in pulmonary function
- A beneficiary starting treatment prior to onset of symptoms must demonstrate a new motor milestone or maintained muscle function compared to pretreatment baseline with better outcomes than would be expected without treatment.
- Beneficiary has not received Zolgensma® since began Evrysdi® and beneficiary has not been ordered Spinraza® to be given concomitantly
- Prescriber must submit the following:
  - Current chart notes
  - Current weight
  - Female beneficiaries of childbearing potential must have a negative pregnancy test prior to PA renewal **OR** has documentation of contraception usage
  - Documentation of continued physical therapy
  - Documentation of response to therapy using the same measuring scale as the baseline

Quantity Edits

- Based on max dose of 5 mg per day, #3 bottles (240 mL total) per 31 days
- #30 tablets per 30 days

Top of the document

Roflumilast tablet (Daliresp®)

(Updated 1/1/2020)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with severe chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis and a history of exacerbations despite compliance with GOLD guidelines recommended maintenance therapy (i.e., LAMA/LABA or LAMA/LABA/ICS)
- Beneficiary must remain on standard maintenance therapy and use this medication as add-on therapy
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Moderate to severe liver impairment (Child-Pugh B or C)
  - Prescribed for relief of acute bronchospasm
  - Require concomitant strong CYP3A4 inducers (e.g., rifampicin, phenobarbital, carbamazepine, phenytoin)
  - FEV1 > 50% predicted
  - Current smoker that refused to start a cessation plan
- Prescriber must submit the following:
  - Current chart notes with previous and current therapies
  - Current pulmonary function tests as baseline
  - History of exacerbations
  - Documentation of smoking history
  - If currently smoking, provide smoking cessation plan

Renewal Requirements

- Beneficiary is compliant with therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to therapy as indicated by at least **ONE** (1) of the following:
  - Decrease in quantity and/or severity of exacerbations; **OR**
  - Improvement in lung function/FEV1 over baseline; **OR**
  - Improvement in COPD-related symptoms and/or quality of life
- Beneficiary must remain a non-smoker
- Prescriber must submit the following:
  - Current chart notes
  - Current PFTs
  - Attestation that the beneficiary continues to refrain from smoking

Top of the document

Roflumilast cream (Zoryve®)

(Updated 10/19/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851

Approval Criteria

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating plaque psoriasis
- Beneficiary has a documented diagnosis of moderate to severe plaque psoriasis
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must trial ≥ 6 months of topical drug therapy with either corticosteroids, calcipotriene, calcitriol, tazarotene, or a combination
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried with duration and response
  - Current BSA
  - Current Investigator's Global Assessment (IGA) score
  - Current Worst Itch-Numeric Rating Score (WI-NRS)
  - Medical necessity over all other topical treatment options

Quantity Edits

- 1 tube (60 gm)/30 days

Top of the document

Roflumilast foam (Zoryve®)

(Implemented 4/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with seborrheic dermatitis OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Based on the Investigator Global Assessment (IGA), the beneficiary must have moderate to severe seborrheic dermatitis which would be an IGA score of 3-4 with current standard of care treatment (i.e., topical antifungals, topical corticosteroids, topical calcineurin inhibitors)
- Beneficiaries with scalp seborrheic dermatitis must have tried and failed a 30-day trial for all of the following within the last 6 months:
  - Over-the-counter (OTC) antifungal shampoo (e.g., selenium sulfide, zinc pyrithione)
  - Prescription antifungal shampoo (e.g., ketoconazole)
  - High-potency topical corticosteroids
- Beneficiaries with non-scalp seborrheic dermatitis (body and face) must have tried and failed a 30-day trial for all of the following within the last 6 months:
  - Topical antifungal (e.g., ketoconazole, ciclopirox)
  - Low-potency topical corticosteroids for face and medium-potency topical corticosteroids for body
  - Topical calcineurin inhibitor (e.g., tacrolimus)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried with duration and response
  - Current BSA impacted
  - Current Investigator's Global Assessment (IGA) score (between 0-4)
  - Current Worst Itch-Numeric Rating Score (WI-NRS) (between 0-10)
  - Medical necessity over all other topical treatment options
- Initial approval will be for 2 months

Renewal Requirements

- For continuation, the beneficiary must demonstrate clinical improvement with decreased IGA score and WI-NRS. IGA score must show a 2-grade improvement compared to baseline.
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy
  - Medical necessity for continuation of therapy

Quantity Edits

- 60 gm (1 container) per 30 days

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Rosacea Treatment

(Implemented 06/19/2006)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Drug

- Brimonidine 0.33% gel (generic for Mirvaso®)
- Finacea® 15% gel (azelaic acid)
- Metrogel® 1% topical (metronidazole)
- Mirvaso® 0.33% gel (brimonidine)
- Noritate® 1% cream (metronidazole)

Approval Criteria

- Diagnosis of rosacea in Medicaid history in previous 2 years
- 2 paid claims for generic metronidazole 0.75% cream, gel, or lotion in the previous 27-60 days

Denial Criteria

- History of acne vulgaris in the last 60 days

Drugs that do not require a PA

- Metronidazole 0.75% topical cream (generic for MetroCream® 0.75%)
- Metronidazole 0.75% topical gel (generic for Metrogel® 0.75%)
- Metronidazole 0.75% topical lotion (generic for MetroLotion® 0.75%)

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Ruxolitinib (Opzelura®)

(Implemented 7/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria for Nonsegmental Vitiligo

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with nonsegmental vitiligo
- Beneficiary must meet the following:
  - Body surface area (BSA) involvement must be ≤10%
  - Trial and failure of the following within the last 6 months with 12 weeks trial each
    - Medium to superpotent topical corticosteroid used continuously or intermittently
    - Topical calcineurin inhibitor (i.e., pimecrolimus or tacrolimus)
  - Treatment area includes face, neck, eyelids, or hands
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Baseline description of vitiligo with location
  - BSA of vitiligo
  - Letter of medical necessity over other treatment options
- Beneficiaries that do not meet the above criteria will require prior authorization review on a case-by-case basis
- Initial approval will be 24 weeks

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must have documented at least a 50% improvement (Clinical trial measured 75% and 90%)
- Prescriber must submit the following:
  - Current chart notes
  - Current BSA
  - Current description of vitiligo

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Salicylic acid gel (Salicate™)

(Implemented 10/16/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with excessive keratin in hyperkeratotic skin disorders (e.g., verrucae and the various ichthyoses, keratosis palmaris and plantaris, keratosis pilaris, pityriasis rubra pilaris, and psoriasis)
- At a minimum, beneficiary must have trial and failure of salicylic acid products over the counter
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Description of beneficiary's skin disorder as a baseline
  - Letter of medical necessity of this product over other treatment options available including products available over the counter

Renewal Requirements

- Beneficiary must demonstrate an improvement of excessive keratin compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy

Quantity Edits

- 1 bottle every 30 days

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Sapropterin dihydrochloride (Kuvan® and Javygtor™)

(Implemented 04/12/2011)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with tetrahydrobiopterin-(BH4-) responsive Phenylketonuria (PKU) with elevated blood phenylalanine (Phe) levels
- Must be prescribed by, or in consultation with, an endocrinologist, geneticist, or other specialist knowledgeable in treating PKU
- Beneficiary must use a Phe-restricted diet
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Dose requested is not supported for beneficiary's weight
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Current blood phenylalanine (Phe) level drawn within 30 days of prior authorization request
  - Current weight
  - Attestation that the beneficiary is ordered a Phe-restricted diet
- Initial approvals will be for 30 days. After 30 days, the prescriber must verify that the beneficiary responded to treatment as defined as ≥30% decrease in blood phenylalanine levels from baseline.
  - If the beneficiary was initiated at 10 mg/kg/day dose, then a subsequent trial of 20 mg/kg/day for 30 days can be approved. Then the prescriber must verify that the beneficiary responded to treatment.
  - If the beneficiary does not meet the requirement improvement of 20 mg/kg/day dose after 30 days, then no additional prior authorization approvals will be approved as this beneficiary would be considered a non-responder.

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with ≥ 30% decrease in blood phenylalanine levels from baseline
- Prescriber must submit the following:
  - Current chart notes
  - Updated blood Phe levels
  - Current weight

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Sedative Hypnotics

(Implemented 06/19/2006)
(Updated 1/1/2022)
(Updated 7/20/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents with Criteria in Benzodiazepine Class

- Temazepam 15 mg and 30 mg (generic for Restoril®)
- Triazolam (generic for Halcion®)

Non-Preferred Agents in Benzodiazepine Class

- Estazolam (generic for Prosom®)
- Flurazepam (generic for Dalmane®)
- Halcion® (triazolam)
- Restoril® (temazepam)
- Temazepam 7.5 and 22.5 mg (generic for Restoril®)

Preferred Agents with Criteria in Non-Benzodiazepine Class

- Eszopiclone (generic for Lunesta®)
- Zaleplon (generic for Sonata®)
- Zolpidem (generic for Ambien®)

Non-Preferred Agents in Non-Benzodiazepine Class

- Ambien® (zolpidem)
- Ambien® CR (zolpidem ER)
- Belsomra® (suvorexant)
- Dayvigo® (lemborexant)
- Doxepin (generic for Silenor®)
- Edluar® (zolpidem SL)
- Hetlioz® (tasimelteon)- See Hetlioz Criteria
- Lunesta® (eszopiclone)
- Quviviq® (daridorexant)
- Ramelteon (generic for Rozerem®)
- Silenor® (doxepin)
- Tasimelteon (generic for Hetlioz®) – See Hetlioz Criteria
- Zolpidem 7.5mg capsule

- Zolpidem ER (generic for Ambien CR®)
- Zolpidem SL tablet (generic for Edluar®)

Additional Criteria

- Quantity limits apply

Age Edits

Product	Minimum Age	Product	Minimum Age
DARIDOREXANT (QUVIVIQ®)	18	SUVOREXANT (BELSOMRA®)	18
DOXEPIN (SILENOR®)	18	TEMAZEPAM (RESTORIL®)	18
ESTAZOLAM (PROSOM®)	18	TRIAZOLAM (HALCION®)	N/A
ESZOPICLONE (LUNESTA®)	18	ZALEPLON (SONATA®)	18
FLURAZEPAM (DALMANE®)	18	ZOLPIDEM (AMBIEN®)	18
LEMBOREXANT (DAYVIGO®)	18	ZOLPIDEM ER (AMBIEN CR®)	18
RAMELTEON (ROZEREM®)	18	ZOLPIDEM SL (EDLUAR®)	18

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Seladelpar lysine capsule (Livdelzi®)

(Effective 10/16/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with primary biliary cholangitis (PBC) confirmed by TWO of the following:
  - An alkaline phosphatase (ALP) level of at least 1.67 times (1.67X) the upper limit of normal
  - Presence of antimitochondrial antibodies (AMA) at a tier of 1:40 or higher
  - Histologic evidence of PBC (nonsuppurative destructive cholangitis and destruction of interlobular bile ducts)
- Must be prescribed by or in consultation with a hepatologist or gastroenterologist
- Beneficiary must have had an inadequate response to ursodeoxycholic acid (UDCA) without improvement in LFTs and documented PBC related symptoms after a 1-year trial or the beneficiary must demonstrate intolerance to UDCA (e.g., Ursodiol)
- Beneficiary with an inadequate response to UDCA alone must take Livdelzi® concomitantly with UDCA unless intolerant to UDCA
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy)
  - Is pregnant
  - Has complete biliary obstruction
  - Requires OAT3 inhibitors (e.g., probenecid) or strong CYP2C9 inhibitors
  - Has end-stage renal disease and on dialysis
- Prescriber must submit the following:
  - Current chart notes with beneficiary's specific symptoms
  - Documentation of previous therapies tried with response
  - Labs including liver function tests with baseline alkaline phosphatase
  - Current treatment plan
  - Medical necessity over UDCA taken as monotherapy

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to Livdelzi® with an improvement in symptoms and corresponding labs while experiencing no intolerable side effects
- Beneficiary must remain on ursodeoxycholic acid concomitantly unless there are tolerability issues
- Prescriber must submit the following:
  - Current chart notes

- Documentation of response to therapy with summary of current symptoms
- Current labs including liver function tests with alkaline phosphatase

Quantity Edits

- #30 per 30 days

Top of the document

Semaglutide 0.25 mg, 0.5 mg, 1 mg, 1.7 mg, 2.4 mg injection (Wegovy®)

(Effective 7/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

NOTE: Arkansas Medicaid does not currently cover medications solely for the use of weight loss. PA requests for this medication must demonstrate that the patient has established cardiovascular disease and at risk for a major cardiovascular event.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- For initial approval, beneficiary must meet all of the following:
  - Diagnosed with established cardiovascular disease with at least **ONE** of the following:
    - History of myocardial infarction **OR** history of stent placement or bypass surgery
    - History of stroke
    - Symptomatic peripheral arterial disease
      - Intermittent claudication with an ABI (ankle brachial index) of less than or equal to 0.9; **OR**
      - Peripheral arterial revascularization procedure or amputation due to atherosclerotic disease
  - Considered either obese or overweight (defined as baseline BMI of ≥ 27 kg/m^2)
  - Considered to be at risk for major cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke)
  - Has outlined treatment plan including reduced calorie diet and increased physical activity.
- Beneficiary must not be a current smoker or has started a smoking cessation program
- Beneficiary should not be approved or continue this therapy with any of the following:
  - No documented risk for MACE
  - Not considered overweight or obese (baseline BMI < 27 kg/m^2)
  - Personal or family history of medullary thyroid carcinoma (MTC)
  - Diagnosed with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
  - Requested for weight loss only
  - Current smoker without a cessation plan
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including HbA1c and lipid panel
  - Current and previous therapy for cardiovascular disease
  - Baseline BMI and weight

- Baseline waist circumference, blood pressure, and heart rate
- Current treatment plan including medication therapy, reduced calorie diet, and physical activity plan along with attestation that beneficiary has been counseled on lifestyle modifications needed to assist with weight loss and improvement in cardiovascular disease

Renewal Requirements

- Beneficiary must be compliant on therapy (defined as 75% utilization)
- Renewal requires the following:
  - Improvement in cardiometabolic parameters (e.g., blood pressure, heart rate, labs) and body measurements
  - Continues with lifestyle modifications
- Prescriber must provide the following:
  - Current chart notes
  - Current BMI and weight
  - Current labs including HbA1c and lipid panel
  - Current waist circumference, blood pressure, and heart rate

Quantity Edits

- Max of 4 syringes per 28 days (PA required for each strength)

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Setmelanotide 10 mg/mL solution (Imcivree®)

(Implemented 1/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with monogenic or syndromic obesity due to pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency or Bardet-Biedl syndrome (BBS) OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Confirmation of diagnosis requires:
  - POMC, PCSK1, or LEPR deficiency—genetic testing that confirms variants in the POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance
  - BBS—Confirmed by presence of four major features associated with BBS OR three major features plus two minor features
    - Major features associated with BBS:
      - Rod-cone dystrophy
      - Polydactyly
      - Obesity
      - Learning disabilities
      - Hypogonadism in males
      - Renal abnormalities
    - Minor features associated with BBS:
      - Speech disorder/delay
      - Strabismus/cataracts/astigmatism
      - Brachydactyly/syndactyly
      - Developmental delay
      - Polyuria/polydipsia (nephrogenic diabetes insipidus)
      - Ataxia/poor coordination/imbalance
      - Mild spasticity (especially lower limbs)
      - Diabetes mellitus
      - Dental crowding/hypodontia/small roots/high arched palate
      - Left ventricular hypertrophy/congenital heart disease
      - Hepatic fibrosis
- Beneficiary must meet the following for obesity diagnosis:
  - POMC, PCSK1, or LEPR deficiency must have a baseline body mass index (BMI) ≥ 30 kg/m² or pediatric weight ≥ 95th percentile using growth chart assessment

  - BBS must have a baseline BMI ≥30 kg/m² or pediatric weight ≥ 97th percentile using growth chart assessment
- Must be prescribed by or in consultation with a specialist (e.g., endocrinologist, geneticist, obesity specialist)
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Genetic testing does not confirm POMC, PCSK1, or LEPR deficiency or the variants are classified as benign or likely benign
  - Clinical symptoms do not support the BBS diagnosis
  - Doesn't meet obesity requirements
  - Obesity is not determined to be related to POMC, PCSK1 or LEPR deficiency or BBS
  - End stage renal disease (eGFR < 15 mL/min/1.73 m²)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Current weight and BMI
  - Genetic testing confirming a diagnosis of pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency **OR** clinical symptoms suggesting a BBS diagnosis
  - Current estimated glomerular filtration rate (eGFR)
- Initial PA for 4 months

Renewal Requirements

- Prescriber must submit the following:
  - Current chart notes
  - Current weight and BMI
- Beneficiary diagnosed with POMC, PCSK1, or LEPR deficiency must have lost at least 5% of baseline body weight or 5% of baseline BMI for patients with continued growth potential after 12-16 weeks
- Beneficiary diagnosed with BBS must have lost at least a 5% of baseline body weight or 5% of baseline BMI for patients < 18 years after 1 year with some improvement at 4 month review
- Beneficiary must remain compliant on therapy (defined as at least 75% utilization)
- Beneficiary must continue to meet approval criteria

Quantity Edits

- 9 vials per month

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Sildenafil tablet (Revatio®)

(Implemented 10/11/2005)
(Updated 2/13/17)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Diagnosis of pulmonary heart disease in the last 365 days; **OR**
- Diagnosis of persistent fetal circulation in the last 365 days; **OR**
- Diagnosis of chronic respiratory disease arising in the perinatal period in the last 365 days

Denial Criteria

- One of the following diagnoses in the last 180 days:
  - Cavernosal fibros; **OR**
  - Hypotension; **OR**
  - Leukemia; **OR**
  - Life-threatening arrhythmia; **OR**
  - Malignant hypertension; **OR**
  - Multiple myeloma; **OR**
  - Myocardial infarction; **OR**
  - Peyronie's disease; **OR**
  - Retinitis pigmentosa; **OR**
  - Sickle cell disease; **OR**
  - Stroke; **OR**
  - Unstable angina
- History of any of the following in the last 45 days:
  - Alpha-adrenergic blockers
  - Nitrates
  - Tamsulosin
- Concurrent use of any the following:
  - Indinavir
  - Lopinavir-ritonavir
  - Ritonavir

Additional Criteria – See PAH section

Pulmonary Arterial Hypertension

- Quantity limits apply

Top of the document

Sinecatechins 15% ointment (Veregen®)

(Implemented 06/19/2008)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Diagnosis for of Condyloma Acuminata (commonly known as external genital or perianal warts) within the past two months; **AND**
- ≤ 124 days of Veregen therapy in the past 365 days

Additional Criteria

- Limited to 18 years and older
- Max quantity per claim: 30 grams
- Limited to 60 grams per 365 days

Top of the document

Sirolimus 0.2% gel (Hyftor™)

(Implemented 1/18/2023))

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or an official Compendia
- Beneficiary is diagnosed with tuberous sclerosis with facial angiofibromas OR a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Beneficiary must have at least 3 angiofibromas measuring ≥2 mm in diameter
- Beneficiary should not be approved or continued on this therapy with any of the following:
  - Pregnancy
  - Requires live vaccine (should be completed prior to therapy initiation)
  - No improvement after 12 weeks of treatment
  - Does not have at least 3 angiofibromas measuring ≥2 mm in diameter
- Prescriber must submit **ALL** of the following:
  - Current chart notes documenting a diagnosis of tuberous sclerosis
  - Baseline description of facial angiofibromas
- If approved, PA duration will be 3 months

Renewal Requirements

- Prescriber must submit current chart notes with documented change from baseline
- Beneficiary must have a least a 50% reduction in angiofibroma size and redness by 3 months of use.

Quantity Edits

- 2 tubes/ 31 days

Top of the document

Skeletal Muscle Relaxants

(Implemented 03/20/2006)
(Updated 10/1/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Preferred Agents

- Baclofen 5 mg, 10 mg, 20 mg tablet (generic for Lioresal®)
- Chlorzoxazone 500 mg tablet (generic for Parafon®)
- Cyclobenzaprine tablet (generic for Flexeril®)
- Metaxalone 400 mg, 800mg tablet (generic for Skelaxin®)
- Methocarbamol tablet (generic for Robaxin®)
- Tizanidine HCl tablet (generic for Zanaflex®)

Non-Preferred Agents

- Amrix® ER capsule (cyclobenzaprine)
- Baclofen suspension (generic for Fleqsuvy®)
- Baclofen suspension (generic for Ozobax®)
- Baclofen 15 mg tablet
- Carisoprodol tablet (generic Soma®)
- Chlorzoxazone 250 mg, 375 mg, 750 mg tablet (generic for Lorzone®)
- Cyclobenzaprine HCl 5 mg, 7.5 mg tablet (generic for Fexmid®)
- Cyclobenzaprine HCl extended-release capsule (generic for Amrix®)
- Dantrolene capsule (generic for Dantrium®)
- Fexmid® tablet (cyclobenzaprine 7.5 mg)
- Fleqsuvy® suspension (baclofen)
- Lyvispah® granule (baclofen)
- Lorzone® tablet (generic for chlorzoxazone)
- Metaxalone 640 mg tablet
- Norgesic Forte® tablet (orphenadrine/aspirin/caffeine)
- Orphenadrine citrate tablet (generic for Norflex®)
- ~~Ozobax® solution (baclofen) *~~no longer rebateable
- Soma® tablet (carisoprodol)
- Tanlor® 1,000 mg tablet (methocarbamol)
- Tizanidine HCL capsule (generic for Zanaflex®)
- Zanaflex® (tizanidine)

Quantity Edits

- Methocarbamol 500 mg and 750 mg, up to 8 tablets/24 hours; #248/31 days' supply

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Sodium Chloride 7% inhalation solution (Hyper-Sal 7%)

(Implemented 05/24/2011)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Diagnosis of cystic fibrosis within the past three years

Additional Criteria

- Quantity limits apply

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Sodium zirconium cyclosilicate powder pack (Lokelma®)

(Implemented 01/01/2019)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with hyperkalemia
- Beneficiary has either discontinued or decreased the dose on medications known to cause hyperkalemia to the lowest effective dose [e.g., aldosterone antagonists, nonsteroidal anti-inflammatory drugs (NSAIDs)]
- Beneficiary must be prescribed a low potassium diet
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has severe constipation, bowel obstruction or impaction, including abnormal post-operative bowel motility disorders
  - Prescribed as an emergency treatment
  - Develops clinically significant hypokalemia
- Prescriber must submit the following:
  - Current chart notes
  - Previous treatments tried
  - Current potassium levels
  - Letter of medical necessity over other products available for lowering potassium that do not require prior authorization (e.g., sodium polystyrene, potassium-depleting diuretics)

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must have a positive response to therapy with a decrease in potassium levels
- Prescriber must submit the following:
  - Current chart notes
  - Current potassium level

Top of the document

Sofpironium bromide 12.45% gel (Sofdra™)

(Implemented 4/16/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with primary axillary hyperhidrosis with excessive sweating for at least 6 months despite the use of topical antiperspirants
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Diagnosed with secondary focal hyperhidrosis or Frey's Syndrome
  - Diagnosed with generalized hyperhidrosis, night sweats, or excessive sweating
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of products tried with response
  - Medical necessity over aluminum chloride-containing topical antiperspirants or has documented intolerance
- Initial approval would be for 3 months, subsequent approvals may be up to 6 months

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response to treatment with documentation of decreased sweating compared to baseline
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to treatment

Quantity Edits

- 1 bottle (50 ml)/ 30 days

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Somatropin vial (Serostim®)

(Implemented 10/18/2006)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with HIV and exhibits wasting or cachexia with at least **TWO** of the following symptoms:
  - Chronic weakness or diarrhea
  - Fever that lingers for at least 1 month
  - Fatigue
  - Loss of more than 10% of body weight
  - Loss of both lean body mass and fat mass
- Beneficiary must be compliant with antiretroviral therapy in the previous 120 days
- Beneficiary's Medicaid profile must indicate previous trials of medications used to increase appetite (e.g., megestrol, dronabinol)
- Prescriber must submit the following:
  - Current chart notes
  - Documentation that supports wasting/cachexia
  - Letter of medical necessity
- Initial PA for 3 months then rest for 8 weeks before re-evaluating for continued necessity. Treatment should not exceed 48 weeks

Renewal Requirements

- Beneficiary must be compliant with therapy
- Beneficiary must demonstrate improvement with increase in lean body mass and weight and decrease in fat mass.
- Treatment should not exceed 48 weeks.
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to therapy

Quantity Edits

- Each strength #30/ 30 days

Top of the document

Sotalol Solution (Sotylize®)

(Implemented 07/22/2015)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with life-threatening ventricular arrhythmias or atrial fibrillation/atrial flutter who is currently in sinus rhythm
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including renal function tests (dose should adjust if there is renal impairment)
- Letter of medical necessity outlining the need for SOTYLIZE solution over sotalol tablets that are available without prior authorization

Top of the document

Sotatercept injection (Winrevair™)

(Implemented 10/16/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) Functional Class (FC) II or III **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Initially, must be prescribed by or in consultation with a cardiologist or pulmonologist
- Beneficiary has tried and failed a preferred medication from each of the following categories given as triple therapy for at least 90 days unless contraindicated:
  - Phosphodiesterase Inhibitors
  - Endothelin Receptor Antagonists
  - Prostacyclin Analogues
- Beneficiary should not be approved or continue the medication if meet one of the following:
  - Beneficiary is diagnosed with pulmonary hypertension WHO groups 2, 3, 4, or 5
  - Baseline platelet count is < 50,000/mm^2
  - Experiencing serious bleeding
  - Pregnant
  - Breastfeeding
  - Current smoker without a smoking cessation plan
  - Has restrictive, constrictive, or congestive cardiomyopathy
  - Left ventricular ejection fraction < 45% on an echocardiogram within the previous 6 months
  - Any symptomatic coronary disease events in the previous 6 months
  - Considered Functional Class I or IV
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies
  - Current labs including hemoglobin (Hgb) and platelets
  - Attestation that Hgb and platelet levels are monitored before each dose for the first 5 doses, or longer if values are unstable, and periodically thereafter, to determine if dose adjustments are required
  - Attestation that the patient has been counseled on signs and symptoms of blood loss
  - Attestation that a patient of reproductive potential has been counseled that WINREVAIR can impair fertility (male or female)
  - Attestation that a female patient of reproductive potential has been counseled to use contraception due to embryo-fetal toxicity

- Attestation that a female patient has been counseled that breastfeeding is not recommended during treatment with WINREVAIR, and for 4 months after the final dose.
- Baseline 6-minute walk distance (6MWD)
- Baseline echocardiogram

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response with stabilization of PAH
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including Hgb and platelets
  - Current 6-minute walk distance
  - Documentation that female of reproductive potential is continuing contraception and is not pregnant

Quantity Edits

- Each strength #4 injections per month (for doses of 90 mg or 120 mg every 3 weeks

Top of the document

Sparsenten 200 mg, 400 mg tablet (Filspari™)

(Implemented 5/10/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary is diagnosed with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary must discontinue any prescriptions of renin-angiotensin, aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), and aliskiren
- Beneficiary, prescriber, and pharmacy must all be certified with the FILSPARI REMS program
- Beneficiary should have tried and failed an angiotensin-converting enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB) at maximally tolerated doses unless contraindicated
- Beneficiary should not be approved with any of the following:
  - Baseline elevated aminotransferases > 3x ULN
  - Pregnancy (should be tested monthly)
  - Prescribed concomitant ACEI or ARB (cannot be on an ACEI or ARB with this med)
  - Clinically significant decrease in kidney function compared to baseline
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Previous therapies
  - Current labs including LFTs, eGFR, urine protein or UPCR
  - Confirmation of the IgAN diagnosis with renal biopsy results and labs
  - Attestation that patient has tested negative for pregnancy if of reproductive potential

Renewal Requirements

- Beneficiary has been compliant with therapy (defined as: 75% utilization based on Medicaid claims)
- Beneficiary has documented improvement in proteinuria with a reduction in UPCR or urine protein from baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including LFTs, eGFR, urine protein or UPCR
  - Attestation that patient has tested negative for pregnancy if of reproductive potential

Quantity Edits

- 200 mg - #31/31 days
- 400 mg - #31/31 days

Spironolactone suspension (Carospir®)

(Implemented 10/18/2017)
(Effective 1/17/2018)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary is an adult age ≥ 18 years of age; **AND**
- Beneficiary has an NPO (Appendix A) diagnosis in Medicaid medical history in the previous 365 days

Denial Criteria

- Hyperkalemia diagnosis in the previous 60 days
- Beneficiary has concomitant administration with potassium supplementation drug claim in previous 60 days; **OR**
- Addison's disease diagnosis in the previous 2 years; **OR**
- Concomitant use of eplerenone claim in previous 60 days; **OR**
- Beneficiary has lithium drug claim in history in the previous 60 days; **OR**
- Beneficiary is pregnant

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Sucralfate suspension (Carafate®)

(Implemented 10/11/2011)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- < 7 years of age; **OR**
- NPO (Appendix A) within the past 365 days.

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Sulfamethoxazole-Trimethoprim 800-160/20 ml unit dose cup

(Implemented 04/08/2014)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Currently LTC

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Tacrolimus (Astagraf XL® and Envarsus XR®)

(Implemented 12/10/2013)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must have received a kidney transplant
- Beneficiary must be prescribed to take this product concomitantly with other immunosuppressants
- Prescriber must submit the following:
  - Chart notes
  - Previous therapies tried
  - Letter of medical necessity over immediate release formulations that are available without prior authorization

Top of the document

Tafenoquine tablet (Krintafel®)

Quantity Limits

- #2 tablets per claim

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Tadalafil (Adcirca)

(Implemented 09/15/2009)
(updated 2/13/17)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Diagnosis of pulmonary heart disease in the last 365 days; **OR**
- Diagnosis of persistent fetal circulation in the last 365 days; **OR**
- Diagnosis of chronic respiratory disease arising in the perinatal period in the last 365 days

Denial Criteria

- One of the following diagnoses in the last 180 days:
  - Cavernosal fibros; **OR**
  - Hypotension; **OR**
  - Leukemia; **OR**
  - Life-threatening arrhythmia; **OR**
  - Malignant hypertension; **OR**
  - Multiple myeloma; **OR**
  - Myocardial infarction; **OR**
  - Peyronie's disease; **OR**
  - Retinitis pigmentosa; **OR**
  - Sickle cell disease; **OR**
  - Stroke; **OR**
  - Unstable angina
- History of any of the following in the last 45 days:
  - Alpha-adrenergic blockers
  - Nitrates
  - Tamsulosin
- Concurrent use of any the following:
  - Indinavir
  - Lopinavir-ritonavir
  - Ritonavir

Additional Criteria – See PAH section

Pulmonary Arterial Hypertension

- Quantity limits apply

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Tafamidis (Vydaqel® and Vyndamax®)

(Implemented 7/17/2019)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis ≥18 years old
- Negative pregnancy test if applicable
- Medical history of Heart Failure (HF) with at least 1 prior hospitalization for HF or clinical evidence of HF (without hospitalization) manifested by signs or symptoms of volume overload or elevated intracardiac pressures
- Baseline NYHA class
- Documentation of variant TTR genotype and/or TTR precursor protein identification by immunohistochemistry, scintigraphy and mass spectrometry
- Baseline 6-Minute Walk Test
- Baseline Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score.

Denial Criteria

- NYHA class IV
- Does not meet the approval criteria
- Prior liver or heart transplant or has implanted cardiac mechanical assist device
- Pregnant

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Tapinarof cream (Vtama®)

(Implemented 10/19/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating plaque psoriasis
- Beneficiary has a documented diagnosis of moderate to severe atopic dermatitis or plaque psoriasis
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must trial ≥ 6 months of topical drug therapy with either corticosteroids, calcipotriene, calcitriol, tazarotene, or a combination
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried with duration and response
  - Current BSA
  - Current Investigator's Global Assessment (IGA) score
  - Current Worst Itch-Numeric Rating Score (WI-NRS)
  - Medical necessity over all other topical treatment options

Quantity Edits

- 1 tube (60 gm)/30 days

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Targeted Immune Modulators

(Implemented 10/17/2007)
(Updated 11/27/2017, effective 1/1/18)
(Updated 9/25/2018)
(Updated 1/1/2021)
(Updated 10/19/2022)
(Updated 7/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Preferred Agents with Criteria

- Enbrel® syringe/pen/cartridge/vial (etanercept)
- Humira® syringe/pen (adalimumab)
- Otezla® tablet (apremilast)
- Taltz® syringe/autoinjector (ixekizumab)*
- Xeljanz®, Xeljanz XR® tablet (tofacitinib)*

*Taltz® **AND** Xeljanz®/Xeljanz XR® must have trial and failure of at least **ONE** preferred tumor necrosis factor (TNF) blocker (i.e., Humira® or Enbrel®) unless there is a contraindication to the use of a TNF blocker

Continuation Criteria for Preferred Agents

- **Enbrel®:** Look back in pharmacy claims history 45 days for ≥ 1 paid claims for Enbrel®
- **Humira®:** Look back in pharmacy claims history 45 days for ≥ 1 paid claims for Humira®
- **Otezla®:** Look back in pharmacy claims history 45 days for ≥ 1 paid claims for Otezla®
- **Taltz®:** Look back in pharmacy claims history 45 days for ≥ 1 paid claims for Taltz®
- **Xeljanz®** or **Xeljanz XR®:** Look back in pharmacy claims history 45 days for ≥ 1 paid claims for Xeljanz® or Xeljanz XR®

Non-Preferred Agents (**Designates biosimilar)

- Abrilada™ syringe/pen (adalimumab-afzb)**
- Actemra® syringe/autoinjector (tocilizumab)
- Adalimumab-aacf syringe/pen (generic for Idacio®)**
- Adalimumab-aaty syringe/autoinjector (generic for Yuflyma®)**
- Adalimumab-adaz syringe/pen (generic for Hyrimoz®)**
- Adalimumab-adbm syringe/pen (generic for Cyltezo®)**
- Adalimumab-fkjp syringe/pen (generic for Hulio®)**
- Adalimumab-ryvk syringe/autoinjector (generic for Simlandi®)**
- Amjevita™ syringe/autoinjector (adalimumab-atto)**
- Arcalyst® vial (rilonacept)
- Bimzelx® syringe/autoinjector (bimekizumab-bkzx)
- Cimzia® syringe (certolizumab)
- Cosentyx® syringe/pen (secukinumab)
- Cyltezo® syringe/pen (adalimumab-adbm)**
- Enspryng® syringe (satralizumab-mwge)

- Entyvio® pen(vedolizumab)
- Hadlima™ syringe/autoinjector (adalimumab-bwwd)**
- Hulio® syringe/pen (adalimumab-fkjp)**
- Hyrimoz® syringe/pen (adalimumab-adaz)**
- Idacio® syringe/pen (adalimumab-aacf)**
- Ilaris® vial (canakinumab)
- Ilumya® syringe (tildrakizumab-asmm)
- Imuldosa® syringe (ustekinumab-srlf)**
- Kevzara® syringe/pen (sarilumab)
- Kineret® (anakinra)
- Leqselvi™ tablet (deuruxolitinib)
- Litfulo™ capsule (ritlecitinib)
- Olumiant® tablet (baricitinib)
- Omvoh® syringe/pen (mirikizumab-mrkz)
- Orencia® syringe/autoinjector (abatacept)
- Otulfi™ syringe (ustekinumab-aauz)**
- Pyzchiva® syringe/45 mg vial (ustekinumab-ttwe)**
- Rinvoq® tablet/solution (upadacitinib)
- Selarsdi™ syringe (ustekinumab-aekn)**
- Siliq® syringe (brodalumab)
- Simlandi® syringe/autoinjector (adalimumab-ryvk)**
- Simponi® syringe/pen (golimumab)
- Skyrizi® syringe/on-body injector/pen (risankizumab-rzaa)
- Sotyktu™ tablet (deucravacitinib)
- Spevigo® syringe (spesolimab-sbzo)
- Stelara® syringe/45 mg vial (ustekinumab)
- Steqeyma® syringe (ustekinumab-stba)**
- Tremfya® syringe/pen/autoinjector (guselkumab)
- Tyenne® syringe/autoinjector (tocilizumab-aazg)**
- Ustekinumab syringe/45 mg vial (generic for Stelara®)
- Ustekinumab-aekn syringe (generic for Selarsdi™)**
- Ustekinumab-ttwe syringe (generic for Pyzchiva®)**
- Velsipity™ tablet (etrasimod)
- Xeljanz® solution (tofacitinib)
- Yesintek™ syringe/45 mg vial (ustekinumab-kfce)**
- Yuflyma® syringe/autoinjector (adalimumab-aaty)**
- Yusimry™ pen (adalimumab-aqvh)**
- Zymfentra® syringe/pen (infliximab-dyyb)**

Agents Covered Under Medical Claims Only – Please refer to AFMC for PA Criteria

- Actemra® vial (tocilizumab)
- Avsola® vial (infliximab-axxq)**
- Cosentyx® vial (secukinumab)
- Entyvio® vial (vedolizumab)
- Imuldosa® vial (ustekinumab-srlf)**
- Inflectra® vial (infliximab-dyyb)**
- Infliximab vial (generic for Remicade®)
- Omvoh® vial (mirikizumab-mrkz)
- Orencia® vial (abatacept)
- Otulfi™ vial (ustekinumab-aauz)**
- Pyzchiva® vial (ustekinumab-ttwe)**

- Remicade® vial (infliximab)
- Renflexis® vial (infliximab-abda)**
- Selarsdi™ vial (ustekinumab-aekn)**
- Simponi Aria® vial (golimumab)
- Skyrizi® vial (risankizumab-rzaa)
- Spevigo® vial (spesolimab-sbzo)
- Stelara® vial (ustekinumab)
- Steqeyma® vial (ustekinumab-stba)**
- Tofidence™ vial (tocilizumab-bavi)**
- Tremfya® vial (guselkumab)
- Tyenne® vial (tocilizumab-aazg)**

NOTE: Bolded medications below are preferred on the Arkansas Medicaid Preferred Drug List (PDL).

(Updated 7/16/2025)

APPROVAL CRITERIA FOR PLAQUE PSORIASIS

(Abrilada, Amjevita, Bimzelx, Cimzia, Cosentyx, Cyltezo, **Enbrel,** Hadlima, Hulio, **Humira,** Hyrimoz, Idacio, Ilumya, **Otezla,** Otulfi, Pyzchiva, Selarsdi, Siliq, Simlandi, Skyrizi, Sotyktu, Stelara, Steqeyma, **Taltz**, Tremfya, Yesintek , Yuflyma, or Yusimry)

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating plaque psoriasis
- Beneficiary has a documented diagnosis of moderate to severe plaque psoriasis
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Beneficiary must trial ≥ 6 months with at least **ONE** product from each of the following (6 months of topical and 6 months of systemic):
  - Topical drug therapy with corticosteroids, calcipotriene, calcitriol, tazarotene, roflumilast, or tapinarof
  - Systemic drug therapy with methotrexate, acitretin, or cyclosporine
- Beneficiary must have tried and failed phototherapy or have a contraindication
- Beneficiary continues to have symptoms after trial of conventional therapy with at least **ONE** of the following:
  - Involvement of ≥ 10% body surface area (BSA)
  - Psoriasis Area and Severity Index (PASI) score ≥ 12
  - Plaque location severely impacts quality of life (i.e., head/neck, palms, soles of feet, genitalia)
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous therapies
  - Current psoriasis description with BSA and PASI score
- For Taltz®, the beneficiary has a history of at least 3 months of **ONE** preferred tumor necrosis factor (TNF) blocker (i.e., Humira® or Enbrel®) unless there is a contraindication (i.e., lupus) to the use of a TNF blocker
- Non-preferred medications require a trial and failure of at least **TWO** preferred agents with this indication for at least 3 months each, or a contraindication or intolerance to preferred agents

- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR PSORIATIC ARTHRITIS AND RHEUMATOID ARTHRITIS

Psoriatic Arthritis:
Abrilada, Amjevita, Bimzelx, Cimzia, Cosentyx, Cyltezo, **Enbrel,** Hadlima, Hulio, **Humira,** Hyrimoz, Idacio, Orencia, **Otezla,** Otulfi, Pyzchiva, Rinvoq, Rinvoq LQ, Selarsdi, Simlandi, Simponi, Skyrizi, Stelara, Steqeyma, **Taltz,** Tremfya, **Xeljanz, Xeljanz XR,** Yesintek, Yuflyma, or Yusimry

Rheumatoid Arthritis:
Abrilada, Actemra, Amjevita, Cimzia, Cyltezo, **Enbrel,** Hadlima, Hulio, **Humira,** Hyrimoz, Idacio, Kevzara, Kineret, Olumiant, Orencia, Rinvoq, Simlandi, Simponi, Tyenne, **Xeljanz, Xeljanz XR,** Yuflyma, or Yusimry

- Prescribed by or in consultation with a rheumatologist or other specialist treating psoriatic arthritis
- Beneficiary has a documented diagnosis of psoriatic arthritis
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with NSAIDs
- Trial and failure with ≥ 6 months of any of the following:
  - Hydroxychloroquine
  - Methotrexate
  - Sulfasalazine
  - Leflunomide
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous therapies
  - Current labs as baseline (e.g., Erythrocyte Sedimentation Rate, C-Reactive Protein level)
- For Taltz®, Xeljanz IR® and Xeljanz XR®, the beneficiary has a history of at least 3 months of **ONE** preferred tumor necrosis factor (TNF) blocker (i.e., Humira® or Enbrel®) unless there is a contraindication (i.e., lupus) to the use of a TNF blocker
- Non-preferred medications require a trial and failure of at least **TWO** preferred agents with this indication for at least 3 months each, or a contraindication or intolerance to preferred agents
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ULCERATIVE COLITIS

(Abrilada, Amjevita, Cyltezo, Entyvio, Hadlima, Hulio, **Humira,** Hyrimoz, Idacio, Omvoh, Otulfi, Pyzchiva, Rinvoq, Selarsdi, Simlandi, Simponi, Skyrizi, Stelara, Steqeyma, Tremfya, Velsipity, **Xeljanz, Xeljanz XR,** Yesintek, Yuflyma, Yusimry, or Zymfentra)

- Prescribed by or in consultation with a gastroenterologist
- Beneficiary has a documented diagnosis of moderate to severe ulcerative colitis as defined by **ONE** of the following:
  - Fecal calprotectin > 150 µg/g

  - Endoscopy Mayo subscore ≥ 2 or modified Mayo score (mMS) ≥ 5
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Beneficiary has been hospitalized for ulcerative colitis **OR** had a trial and failure with of ≥ 2 months of standard of care drug therapy with at least **TWO** of the following for induction or maintenance of remission:
  - Immunosuppressants (e.g., azathioprine, 6-mercaptopurine, cyclosporine)
  - Oral/rectal glucocorticoids (e.g., enteric coated budesonide, prednisone, hydrocortisone)
  - Oral/rectal 5-aminosalicyclic acid agents (e.g., mesalamine, sulfasalazine)
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous therapies
  - Current labs including inflammatory markers (i.e., fecal calprotectin, endoscopic Mayo subscore)
- Beneficiary has no therapeutic duplication with any other monoclonal antibodies or cytokine & CAM antagonists
- For Xeljanz IR® and Xeljanz XR®, the beneficiary has a history of at least 3 months of **ONE** preferred tumor necrosis factor (TNF) blocker (i.e., Humira®) unless there is a contraindication (i.e., lupus) to the use of a TNF blocker
- Non-preferred medications require a trial and failure of at least **TWO** preferred agents with this indication for at least 3 months each, or a contraindication or intolerance to preferred agents
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR CROHN'S DISEASE

(Abrilada, Amjevita, Cimzia, Cyltezo, Entyvio, Hadlima, Hulio, **Humira**, Hyrimoz, Idacio, Omvoh, Otulfi, Pyzchiva, Rinvoq, Selarsdi, Simlandi, Skyrizi, Stelara, Steqeyma, Tremfya, Yesintek, Yuflyma, Yusimry, or Zymfentra)

- Prescribed by or in consultation with a gastroenterologist
- Beneficiary has a documented diagnosis of moderate to severe Crohn's Disease confirmed by assessment of stool frequency, abdominal pain score, and Simple Endoscopic Score for Crohn's Disease (SES-CD). Information for diagnosis is based on endoscopy and imagining results as well as elevated CRP and fecal calprotectin.
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Beneficiary has been hospitalized with Crohn's Disease **OR** been diagnosed with a fistula or abscess **OR** had a trial and failure with ≥ 2 months of standard of care drug therapy with at least **TWO** of the following for induction or maintenance of remission:
  - Immunosuppressants (e.g., azathioprine, 6-mercaptopurine, cyclosporine)
  - Oral/rectal glucocorticoids (e.g., enteric coated budesonide, prednisone, hydrocortisone)
  - Oral/rectal 5-aminosalicyclic acid agents (e.g., mesalamine, sulfasalazine)
  - Methotrexate

- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous therapies and surgeries
  - Current labs including CBCs and inflammatory markers (i.e., fecal calprotectin, C-reactive protein)
  - Colonoscopy or imaging reports
  - Baseline stool frequency and abdominal pain score
  - Baseline Crohn's Disease Activity Index (CDAI) (clinical trials included patients with score ≥ 220) or Simple Endoscopic Score for Crohn's disease (SES-CD) (clinical trials included patients with score ≥ 6 or ≥4 for isolated ileal disease)
- Beneficiary has no therapeutic duplication with any other monoclonal antibodies or cytokine & CAM antagonists
- Non-preferred agents require a 3-month trial and failure or a contraindication or intolerance to at least **ONE** preferred agent with this indication
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS

(Abrilada, Actemra, Amjevita, Cimzia, Cyltezo, **Enbrel**, Hadlima, Hulio, **Humira**, Hyrimoz, Idacio, Kevzara, Orencia, Rinvoq, Rinvoq LQ, Simlandi, Tofidence, Tyenne, **Xeljanz tablet**, Xeljanz oral solution, Yuflyma, or Yusimry)

- Prescribed by or in consultation with a rheumatologist or other specialist
- Beneficiary has a documented diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (JIA)
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with NSAIDs (unless contraindication or intolerance)
- Trial and failure with ≥ 3 months of disease modifying anti-rheumatic drugs (DMARDs) with any of the following (unless contraindication or intolerance):
  - Methotrexate
  - Leflunomide
  - Cyclosporine
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous therapies with description of current symptoms
  - Current labs including CBCs and inflammatory markers
- For Xeljanz IR®, the beneficiary has a history of at least 3 months of **ONE** preferred tumor necrosis factor (TNF) blocker (i.e., Humira®) unless there is a contraindication (i.e., lupus) to the use of a TNF blocker
- Non-preferred medications require a trial and failure of at least **TWO** preferred agents with this indication for at least 3 months each, or a contraindication or intolerance to preferred agents
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR DEFICIENCY OF IL-1 RECEPTOR ANTAGONIST:
(Arcalyst & Kineret)

- Prescribed by or in consultation with a rheumatologist or other specialist
- Beneficiary has a documented diagnosis of deficiency of IL-1 receptor antagonist (DIRA)
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with NSAIDs (unless contraindication or intolerance)
- Trial and failure with ≥ 3 months of disease modifying anti-rheumatic drugs (DMARDs) with any of the following (unless contraindication or intolerance):
  - Methotrexate
  - Leflunomide
  - Cyclosporine
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous therapies with description of current symptoms
  - Current labs including CBCs and inflammatory markers
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ANKYLOSING SPONDYLITIS
(Abrilada, Amjevita, Bimzelx, Cimzia, Cosentyx, Cyltezo, **Enbrel**, Hadlima, Hulio, **Humira**, Hyrimoz, Idacio, Rinvoq, Simlandi, Simponi, **Taltz**, **Xeljanz tablet, Xeljanz XR**, Yuflyma, or Yusimry)

- Prescribed by or in consultation with a rheumatologist or other specialist
- Beneficiary has a documented diagnosis of ankylosing spondylitis
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with ≥ 3 months of standard of care drug therapy (unless contraindication or intolerance) with nonsteroidal anti-inflammatory drugs at maximum doses (e.g., naproxen, celecoxib, ibuprofen)
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous therapies
- For Taltz®, Xeljanz IR® and Xeljanz XR®, the beneficiary has a history of at least 3 months of **ONE** preferred tumor necrosis factor (TNF) blocker (i.e., Humira® or Enbrel®) unless there is a contraindication (i.e., lupus) to the use of a TNF blocker
- Non-preferred medications require a trial and failure of at least **TWO** preferred agents with this indication for at least 3 months each, or a contraindication or intolerance to preferred agents
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR NONRADIOGRAPHIC AXIAL SPONDYLOARTHRITIS:
(Bimzelx, Cimzia, Cosentyx, Rinvoq, or **Taltz**)

- Prescribed by or in consultation with a rheumatologist or other specialist
- Beneficiary has a documented diagnosis of nonradiographic axial spondyloarthritis
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with ≥ 3 months of standard of care drug therapy (unless contraindication or intolerance) with nonsteroidal anti-inflammatory drugs at maximum doses (e.g., naproxen, celecoxib, ibuprofen)
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous therapies
- Non-preferred agents require a 3-month trial and failure or a contraindication or intolerance to at least **ONE** preferred agent with this indication.
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES
(Arcalyst, Ilaris, or Kineret)

- Prescribed by or in consultation with a specialist in treating CAPS
- Beneficiary must have a diagnosis of cryopyrin-associated periodic syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) **OR** neonatal onset multisystem inflammatory disease (NOMID)
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Prescribers must submit the following:
  - Current chart notes
  - Confirmation of the diagnosis with genetic test results if available
  - Baseline symptoms
  - Previous therapies tried
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR GIANT CELL ARTERITIS
(Actemra, Rinvoq, or Tyenne)

- Prescribed by or in consultation with a rheumatologist or other specialist
- Beneficiary has a confirmed diagnosis of giant cell arteritis based on clinical symptoms and **ONE** of the following:
  - Temporal artery biopsy
  - Ultrasound of vessels
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Prescribers must submit the following:
  - Current chart notes
  - Documentation to confirm diagnosis with biopsy results and/or ultrasound report along with labs (i.e., CRP, ESR)

  - Medical necessity over high dose corticosteroids
  - Treatment plan for potential discontinuation in the future
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE

(Actemra)

- Prescribed by or in consultation with a rheumatologist, pulmonologist, or other specialist
- Beneficiary has a confirmed diagnosis of SSc-ILD based on clinical symptoms and the following:
  - PFTs indicate a decreased lung volume and decreased DLCO
  - High resolution CT indicates ground glass or reticular opacities
  - Lab work consistent with scleroderma
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure of immunosuppressant therapy with mycophenolate or cyclophosphamide unless a contraindication or intolerance
- Prescribers must submit the following:
  - Current chart notes
  - Current PFTs
  - High resolution CT report
  - Current labs
  - Baseline 6-minute walk test
  - Medical necessity over immunosuppressant therapy +/- glucocorticoids
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR RECURRENT PERICARDITIS

(Arcalyst)

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is diagnosed with recurrent pericarditis based on previous episode of acute pericarditis and has developed pleuritic chest pain. Lab work should support an inflammatory phenotype (elevated CRP, WBC, or ESR).
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Beneficiary should not receive this medication if not diagnosed with an inflammatory phenotype.
- Beneficiary should have trial and failure with ALL of the following (unless there is a contraindication):
  - Colchicine + NSAID or aspirin—first line therapy
  - Colchicine + glucocorticoid—second line therapy
  - Colchicine + glucocorticoid + aspirin—third line therapy
- Prescribers must submit the following:
  - Current chart notes
  - Previous treatment for acute pericarditis
  - Electrocardiogram and echocardiogram results

  - Current labs including CBC, ESR, and CRP
  - Treatment plan including taper
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR UVEITIS
(Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, **Humira**, Hyrimoz, Idacio, Simlandi, or Yusimry)

- Prescribed by or in consultation with a rheumatologist, ophthalmologist, or other specialist for treating uveitis
- Beneficiary must be diagnosed with non-infectious intermediate, posterior, or panuveitis
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with ALL of the following:
  - Topical glucocorticoid (e.g., prednisolone, triamcinolone)
  - Systemic glucocorticoid at the maximum indicated dose unless a contraindication or intolerance (e.g., prednisone)
  - Immunosuppressant (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine)
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried
- Non-preferred agents require a 3-month trial and failure or a contraindication or intolerance to at least **ONE** preferred agent with this indication.
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR TUMOR NECROSIS FACTOR RECEPTOR ASSOCIATED PERIODIC SYNDROME OR HYPERIMMUNOGLOBULIN D SYNDROME/MEVALONATE KINASE DEFICIENCY
(Ilaris)

- Prescribed by or in consultation with a rheumatologist or other rare disease specialist for treating TRAPS or HIDS/MKD
- Beneficiary must be diagnosed with ONE of the following:
  - TNF Receptor Associated Periodic Syndrome (TRAPS) after infectious or neoplastic causes of recurrent fevers are excluded
  - Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure of NSAIDs and oral glucocorticoids at the maximum indicated dose unless a contraindication or intolerance
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of symptoms and criteria used for diagnosis
  - Previous therapies tried
  - Current weight for dose determination
  - Medical necessity for the use of this medication over NSAIDs and oral glucocorticoids

- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR FAMILIAL MEDITERRANEAN FEVER
(Ilaris)

- Prescribed by or in consultation with a rheumatologist or other rare disease specialist for treating FMF
- Beneficiary must be diagnosed with Familial Mediterranean Fever (FMF)
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure of colchicine unless a contraindication or intolerance (treatment recommended indefinitely)
- Prescribers must submit the following:
    - Current chart notes
    - Documentation of symptoms and criteria used for diagnosis
    - Previous therapies tried
    - Current weight for dose determination
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR STILL'S DISEASE
(Actemra, Ilaris, or Tyenne)

- Prescribed by or in consultation with a rheumatologist or other specialist
- Beneficiary must be diagnosed with active Still's Disease (either Adult-Onset Still's Disease (AOSD) or Systemic Juvenile Idiopathic Arthritis (SJIA))
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- New onset AOSD
    - Trial and failure of NSAIDs OR oral glucocorticoids at the maximum indicated dose unless a contraindication or intolerance for mild to moderate disease
    - If macrophage activation syndrome is suspected, a biologic is warranted (UpToDate® recommends anakinra in these patients)
- Established AOSD still needing therapy
    - Trial and failure with ≥ 3 months of disease modifying anti-rheumatic drugs (DMARDs) with any of the following (unless contraindication or intolerance):
        - Methotrexate
        - Leflunomide
- Prescribers must submit the following:
    - Current chart notes
    - Documentation of symptoms and criteria used for diagnosis
    - Previous therapies tried
    - Current weight for dose determination
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ALOPECIA AREATA

(Leqselvi, Litfulo, or Olumiant)

- Prescribed by or in consultation with a dermatologist
- Beneficiary has a documented diagnosis of alopecia areata with > 50% scalp hair loss or refractory disease
- Beneficiary does not have another cause of hair loss (i.e., androgenetic alopecia, chemotherapy-induced hair loss, or causes of hair loss other than alopecia areata)
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Beneficiary request would be denied if taking any of the following concomitantly:
  - JAK inhibitor
  - Other monoclonal antibodies or cytokine & CAM antagonists
  - Immunosuppressant
- Trial and failure of topical and/or intralesional corticosteroids
- Trial and failure with ≥ 6 months of disease modifying anti-rheumatic drugs (DMARDs) with any of the following (unless contraindicated):
  - Methotrexate
  - Leflunomide
  - Cyclosporine
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried with duration
  - Medical necessity over intralesional corticosteroids, topical steroids, and DMARDs
  - Letter of medical necessity
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR POLYMYALGIA RHEUMATICA

(Kevzara)

- Prescribed by or in consultation with a rheumatologist or other specialist
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or official Compendia
- Beneficiary has no therapeutic duplication with any other cytokine & CAM antagonists
- Beneficiary must be diagnosed with polymyalgia rheumatica based on clinical symptoms and supporting lab findings with the following:
  - Elevated ESR and/or CRP
  - Pain and morning stiffness about the shoulders, hip girdle, and neck
  - Limited range of motion in shoulders, cervical spine, or hips causing difficulties with activities of daily living (such as pulling on a shirt, putting on socks/shoes, or transfer from lying to seated position)
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of symptoms
  - Current labs including ESR and CRP

- Medical necessity over corticosteroids at maximum tolerated doses
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR HIDRADENITIS SUPPURATIVA

(Abrilada, Amjevita, Bimzelx, Cimzia, Cosentyx, Cyltezo, Hadlima, Hulio, **Humira**, Hyrimoz, Idacio, Simlandi, Yuflyma, or Yusimry)

- Some medications/treatments recommended in Hidradenitis Suppurativa (HS) guidelines may not be a covered product/procedure by Arkansas Medicaid. Refer to the respective provider manual for additional information.
- Beneficiary with diagnosis of Hurley Stage I HS should use options from the following list (biologics are not recommended for Hurley Stage I):
  1) Topical clindamycin
  2) Oral tetracyclines (tetracycline, doxycycline, minocycline)
  3) Antiandrogenic agents (combined oral contraceptives, spironolactone, finasteride)
  4) Metformin
  5) Alternatives for refractory patients—clindamycin with rifampin, acitretin, dapsone
  6) Laser therapy
  7) Intralesional corticosteroids
  8) Topical resorcinol
  9) Surgical drainage
- Beneficiary with diagnosis of Hurley Stage II:
  - Beneficiary should follow treatment guidelines (e.g., Journal of the American Academy of Dermatology) https://www.jaad.org/action/showPdf?pii=S0190-9622%2819%2930368-8
  - Prior to beginning biologics, the beneficiary should have tried at least 2 of the following:
    - Oral tetracyclines for a minimum of 3 months (unless contraindicated)
    - Combination of rifampin and clindamycin for a minimum of 3 months (unless contraindicated)
    - Oral contraceptives for a minimum of 3 months (females only)
    - Oral retinoids for a minimum of 3 months (unless contraindicated)
    - Refractory after treatment—antibiotic therapy with adjunctive treatment of an antiandrogen, metformin, or oral contraceptives (when choosing adjunctive options, consideration the beneficiary's comorbidities)
- Beneficiaries who are refractory after at least two 3-month therapies or have progressed to Stage III during treatment may be considered for therapy with biologics
- Prescribers must submit the following:
  - Chart notes
  - Documentation of previous therapies tried including surgery or laser treatment
  - Comorbidities that can increase HS severity must be addressed (list not all inclusive)
    - Tobacco use
    - Obesity
    - PCOS
- Non-preferred agents require a 3-month trial and failure or a contraindication or intolerance to at least **ONE** preferred agent with this indication.
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ENTHESITIS-RELATED ARTHRITIS

(Cosentyx)

- Prescribed by or in consultation with a rheumatologist or other specialist
- Beneficiary has a documented diagnosis of enthesitis-related arthritis
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with NSAIDs
- Trial and failure with ≥ 3 months of disease modifying anti-rheumatic drugs (DMARDs) with any of the following (unless contraindicated):
  - Methotrexate
  - Leflunomide
  - Cyclosporine
  - Sulfasalazine
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR GOUT FLARES

(Ilaris)

- Prescribed by or in consultation with a rheumatologist or other specialist.
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication.
- Maximum dose based on support in manufacturer's package insert or official Compendia.
- Beneficiary has no therapeutic duplication with any other cytokine & CAM antagonists.
- Beneficiary must be diagnosed with gout flares.
- Beneficiary must have tried and failed non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and colchicine (unless contraindicated or not tolerated). (Repeated courses of corticosteroids are not appropriate.)
- Beneficiary with frequent gout flares (defined as 3 or more gout flares in the previous year) must be on a urate-lowering medication (e.g., allopurinol, febuxostat, probenecid).
- Prescribers must submit ALL of the following:
  - Current chart notes
  - Documentation of symptoms
  - Current labs including serum urate concentration and documentation of urate crystals in the synovial fluid (if available)
- PA will be approved for 1 dose.
- Renewal requires prescribers to submit updated notes with documentation of continued gout flare. Ilaris® requires at least 12 weeks between doses.

APPROVAL CRITERIA FOR BEHCET'S DISEASE

(Otezla)

- Prescribed by or in consultation with a rheumatologist or other specialist in the treatment of Behçet's Disease
- Beneficiary has a documented diagnosis of Behçet's Disease with oral ulcers

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or MicroMedex®
- Trial and failure with ≥ 3 months of the following:
  - Topical corticosteroids (e.g., triamcinolone acetonide cream 0.1% in orabase); **AND**
  - ≥ 1 of the following conventional oral therapies
    - Colchicine
    - Azathioprine
    - Sulfasalazine
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous therapies tried with duration
  - Medical necessity over topical corticosteroids and conventional oral therapies
- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR NEUROMYELITIS OPTICA SPECTRUM DISORDER
(Enspryng)

- Prescribed by a specialist experienced with NMOSD
  - Beneficiary is diagnosed with neuromyelitis optica spectrum disorder (NMOSD) and is anti-aquaporin-4 (AQP4) antibody positive and confirmed with the following:
  - Test indicating beneficiary is seropositive for AQP4-IgG antibodies
  - Beneficiary has at least one core clinical characteristic (i.e., optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or symptomatic cerebral syndrome with NMOSD-typical brain lesions)
  - Exclusion of alternative diagnosis (i.e., Lupus, multiple sclerosis, sarcoidosis, cancer, chronic infection like HIV)
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Maximum dose based on support in manufacturer's package insert or an official Compendia
- Beneficiary must have a history of at least one documented relapse (including first attack) in the last 12 months
- Beneficiary must have an Expanded Disability Status Scale (EDSS) score ≤ 6.5
- Beneficiary is not prescribed medication for the treatment of multiple sclerosis (i.e., interferon, dimethyl fumarate, fingolimod, glatiramer, etc.)
- Beneficiary is not prescribed other treatment options for NMOSD concomitantly (i.e., eculizumab or inebilizumab)
- Prescribed to prevent future attacks (not meant to treat an acute attack)
- Prescribers must submit ALL of the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Confirmation of NMOSD diagnosis
  - Baseline Expanded Disability Status Scale score
  - Medical necessity over the use of immunotherapy (e.g., rituximab, azathioprine, mycophenolate, or methotrexate)
  - Results for Hepatitis B virus and tuberculosis screens (should be negative for approval)

Renewal Requirements

- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy which is defined by any of the following:
  - Decrease in acute relapses
  - Improvement in EDSS
  - Reduced hospitalizations
  - Reduction/discontinuation in plasma exchange treatments or corticosteroids

Quantity Edits

- #1/28 days (first month will require a quantity override to allow 3 injections)

APPROVAL CRITERIA FOR GENERALIZED PUSTULAR PSORIASIS

(Spevigo)

- Prescribed by or in consultation with a dermatologist
- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Maximum dose based on support in the manufacturer's package insert or Micromedex®
- Beneficiary must have a diagnosis of generalized pustular psoriasis (GPP) with a history of at least two GPP flares of moderate-to-severe intensity in the past 5 years. Those two flares must meet the following criteria from the Effisayil-1 trial to be considered moderate-to-severe. Documentation of those flares must be provided.
  - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate); AND
  - GPPGA pustulation subscore of ≥ 2 (mild); AND
  - Presence of fresh pustules (new appearance or worsening of pustules)
  - ≥ 5% of BSA covered with erythema and the presence of pustules
- Beneficiary must have one of the following treatment options. Please document the correct treatment plan for the beneficiary.
  - Treatment and maintenance following an acute GPP flare
    - 900 mg IV infusion loading dose over 90 minutes; may repeat once after one week (requires medical prior authorization request review)
    - Followed by 300 mg SQ every 4 weeks
    - Any subsequent flares would require a medical prior authorization request review
  - Treatment and maintenance when not experiencing a GPP flare
    - 600 mg SQ loading dose
    - Followed by 300 mg SQ every 4 weeks
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has no history of at least two GPP flares of moderate-to-severe intensity as defined above
  - Active tuberculosis
- Prescribers must submit the following:
  - Current chart notes
  - Documentation of previous biologics or disease-modifying antirheumatic drugs (DMARDs) that have been tried with response
  - Documentation of other autoimmune diagnoses for the beneficiary and treatment plan
  - Documentation that the beneficiary has been evaluated for tuberculosis
  - Clarification if this will be billed as a medical claim through "buy and bill" or billed as a pharmacy claim through a specialty pharmacy.

NOTE: If billing as a medical claim, contact AFMC for PA processing.

- Renewal requires prescribers to submit updated notes with documentation of a positive response to therapy

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Tasimelteon capsule and suspension (Hetlioz®)

(Implemented 09/23/2014)
(Updated 7/21/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary with Non-24 diagnosis must be ≥ 18 years of age, and beneficiary with SMS diagnosis must be ≥ 3 years of age; AND
- Beneficiary must have a diagnosis of either Non-24-Hour Sleep-Wake Disorder OR Nighttime Sleep Disturbances in Smith-Magenis Syndrome OR a diagnosis consistent with FDA indications; AND
- Non-24-hour Sleep-Wake Disorder
  - Blind patient
    - Clinical trials provided in the package insert included totally blind patients and reference the Diagnostic and Statistical Manual of Mental Disorders 5 (DSM-5) diagnostic criteria
    - A persistent or recurrent pattern of sleep disruption that is primarily due to an alteration of the circadian system or to a misalignment between the endogenous circadian rhythm and the sleep-wake schedule required by an individual's physical environment or social or professional schedule; AND
    - The sleep disruption leads to excessive sleepiness or insomnia, or both; AND
    - The sleep disturbance causes clinically significant distress or impairment in social, occupational, and other important areas of functioning; AND
    - Beneficiary must have tried and failed melatonin and other sleep aids
  - Sighted patient
    - Beneficiary must have tried and failed melatonin and other sleep aids; AND
    - Beneficiary must have tried and failed timed light exposure; AND
    - Sleep disturbance cannot be explained by other causes (i.e., neurological disorder, mental disorder, medication use, or substance use disorder)
- For Nighttime Sleep Disturbances in SMS requests:
  - Need confirmed diagnosis of SMS; AND
  - Need history of sleep disturbances; AND
  - Prescriber must submit the following:
  - Current chart notes; AND
  - Documentation of medications and therapies tried to improve sleep patterns; AND
  - Documentation as listed above to confirm diagnosis; AND
  - Daily sleep logs or actigraphy for confirmation of sleep disruption; AND
  - Initial PA for 3 months

Denial Criteria

- Beneficiary does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**

- Beneficiary requires the use of strong CYP1A2 inhibitors or strong CYP3A4 inducers; **OR**
- Beneficiary has severe hepatic impairment

Quantity Edits

- 20 mg capsules #31/31 days
- Suspension
  - 48 mL—3 bottles/31 days
  - 158 mL—1 bottle/31 days

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Tazarotene gel/cream (Tazorac®)

(Implemented 06/19/2006)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Approval Criteria (New Start)

- Diagnosis of psoriasis in Medicaid history in previous 365 days; **AND**
- 2 paid claims of a topical corticosteroid in previous 27-60 days; **AND**
- At least one paid claim for a topical corticosteroid must be from the Class 1 (one) potency category.

Approval Criteria (Continuation)

- Diagnosis of psoriasis in Medicaid history in previous 365 days; **AND**
- The incoming claim matches claim in history in the previous 45 days of TAZORAC; **AND**
- At least two claims of a topical corticosteroid in previous 60 days in drug claim history with at least one topical corticosteroid claim 14-60 days back in history.

Denial Criteria

- History of acne vulgaris in the last 60 days

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Tedizolid (Sivextro®)

(Implemented 01/13/2015)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- No therapeutic duplication between a claim of the tablets and claim of the vials within the same month

Additional Criteria

- Age >/= 18 years of age
- Quantity limits apply

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Teduglutide kit (Gattex®)

(Implemented 07/09/2013)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with Short Bowel Syndrome (SBS) and is dependent on parenteral support
  - adult patients require parenteral nutrition at least 3 times per week
  - pediatric patients must have parenteral nutrition to account for at least 30% of caloric/and/or fluid/electrolyte needs
- Beneficiary must have a history of using supportive therapies (e.g., anti-motility agents, proton pump inhibitors, bile acid sequestrants, and octreotide)
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Weighs < 10 kg
  - Has intestinal or stomal obstruction; restart when obstructive presentation resolves
  - Diagnosed with gastrointestinal cancer
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried with response
  - Baseline volume of parenteral nutrition/intravenous support
  - Current labs including eGFR (dosage adjustment required for eGFR <60 mL/min/1.73m^2); bilirubin and alkaline phosphatase (to monitor for biliary tract disease); lipase and amylase (to monitor for pancreatic disease)
  - Test results required 6 months prior to starting treatment
    - Adult - colonoscopy and upper gastrointestinal (GI) endoscopy with removal of polyps
    - Pediatric patients - fecal occult blood testing; if there is new or unexplained blood in the stool perform colonoscopy/sigmoidoscopy and upper GI endoscopy

Renewal Requirements

- Beneficiary has been compliant on therapy (defined as 75% utilization)
- Beneficiary has a positive response to therapy with at least a 20% reduction in weekly parenteral nutrition/IV volume
- Prescriber must submit the following:
  - Current chart notes
  - Current volume of parenteral nutrition/intravenous support
  - Current labs to monitor kidney function, pancreatic disease, and biliary tract disease

- After 1 year of treatment, adults require colonoscopy and upper GI endoscopy, and pediatric patients require at least a fecal occult blood test

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Testosterone Replacement Products (Topical and Injectable)

(Implemented 01/18/2011)
(Updated 2/20/2020)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents with Criteria

- Testosterone cypionate 100 mg/ml injection
- Testosterone cypionate 200 mg/ml injection
- Testosterone enanthate 200 mg/ml injection
- Testosterone gel pump (generic for Androgel®)

Non-Preferred Agents

- Testosterone cypionate (Azmiro® 200 mg/ml syringe)
- Testosterone cypionate (DEPO-TESTOSTERONE® - **BRAND ONLY**)
- Testosterone enanthate (Xyosted® autoinjector)
- Testosterone undecanoate (Tlando®, Undecatrex®)
- Testosterone gel packet (Androgel®, Vogelxo®)
- Testosterone gel pump (Androgel® pump - **BRAND ONLY**)
- Testosterone gel pump (Vogelxo®)
- Testosterone gel tube (Testim®, Vogelxo®)
- Testosterone nasal gel (Natesto® nasal gel)
- Testosterone patch (Androderm® patch)
- Testosterone pump (Axiron®)
- Testosterone undecanoate injection (Aveed® injection)

Approval Criteria for Preferred Agents with Criteria

- Male
- Diagnosis of one of the following diagnoses in the previous 3 years:
  - Hypospadias
  - Klinefelter Syndrome
  - Kallmann Syndrome
  - Orchiectomy
  - Panhypopituitarism
  - Prader-Willi Syndrome
  - Testicular cancer

Denial Criteria

- Diagnosis of one of the following diagnoses in the previous 3 years:
  - Decreased libido
  - Impotence
  - Any other sexual dysfunction diagnoses

Additional Criteria

- Quantity Limits Apply

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Thrombopoiesis Stimulating Proteins

(Updated 1/20/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents with Manual Review Criteria

Promacta® (eltrombopag olamine) – BRAND ONLY

Approval Criteria:

- Beneficiary must have a diagnosis of thrombocytopenia with chronic immune thrombocytopenia with insufficient response to corticosteroids, immunoglobulin, or splenectomy, **OR** chronic hepatitis C in which thrombocytopenia prevents the initiation of interferon-based therapies, **OR** severe aplastic anemia in combination with standard immunosuppressive therapy as first-line therapy, **OR** severe aplastic anemia with insufficient response to immunosuppressive therapy, **OR** a diagnosis consistent with FDA indications; **AND**
- Beneficiary has a baseline platelet count of < 50,000/µL; **AND**
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies tried with response; **AND**
  - Current labs:
    - LFTs prior to therapy initiation, every 2 weeks during dose adjustment, then monthly once dosing is stable (If abnormal, monitor weekly); **AND**
    - CBC with differential (including platelets) prior to therapy, every week until platelet count is stable, then monthly; **AND**
  - Documentation of medical necessity over other options for increasing platelets (e.g., steroids, IVIG, platelet transfusion); **AND**
  - If used previously, provide chart notes and labs with documentation of response; **AND**
  - Documentation that other causes for low platelets have been ruled out including myelodysplastic syndrome; **AND**
  - Verify required dose - dose reductions may be needed for patients with mild, moderate, or severe hepatic impairment and patients with Asian ancestry (such as Chinese, Japanese, Taiwanese, Korean, or Thai) with ITP or severe aplastic anemia; **AND**
- Initial PA for one month only.

Chronic Immune Thrombocytopenia

- Beneficiary must be ≥ 1 year of age; **AND**
- Dose requirements
  - 1-5 years of age begin with 25 mg once daily
  - ≥ 6 years of age begin with 50 mg once daily
  - Max of 75 mg daily
    - Asian ancestry OR hepatic impairment, begin with 25 mg once daily
    - Asian ancestry AND hepatic impairment, begin with 12.5 mg once daily

Interferon Treatment for Hepatitis C patients

- Beneficiary must be ≥ 18 years of age; **AND**
- Dose requirements; **AND**
  - Begin with 25 mg once daily
  - Max of 100 mg once daily
- Beneficiary must be prescribed interferon-based therapies.

Severe Aplastic Anemia

- Beneficiary must be ≥ 2 years of age; **AND**
- Dose requirements; **AND**
- First-line with immunosuppressive therapy—
  - 2-5 years of age begin with 2.5 mg/kg
  - 6-11 years of age begin with 75 mg daily
  - ≥ 12 years of age begin with 150 mg daily
  - Do not exceed the initial dose (above are beginning and max doses per age)
- Refractory—
  - Begin with 50 mg once daily
  - Titrate based on platelet count
  - Max of 150 mg once daily ▪ If no hematologic response after 16 weeks, discontinue PROMACTA
- Asian ancestry or hepatic impairment—
  - ≥ 12 years of age begin with 75 mg daily
  - 6-11 years of age begin with 37.5 mg daily
  - 2-5 years of age begin with 1.25 mg/kg daily
  - Refractory begin with 25 mg once daily
- Treatment duration is maximum of 6 months.

Promacta® Denial Criteria:

- Beneficiary does not meet approval criteria **OR** have a diagnosis supported in the official Compendia; **OR**
- Beneficiary has a diagnosis of myelodysplastic syndrome; **OR**
- Hepatitis C patient is not being treated for HCV infection or the beneficiary has been prescribed a direct-acting antiviral agent instead of interferon; **OR**
- Beneficiary platelet count is ≥ 50,000/µL at time of PA request; **OR**
- Beneficiary has a history of arterial or venous thrombosis **OR** congenital or acquired thrombotic disease; **OR**
- Platelet count is > 400,000/µL after 2 weeks at lowest PROMACTA dose; **OR**
- Aplastic anemia patient is not prescribed standard immunosuppressive therapy along with PROMACTA for first-line treatment; **OR**
- Prescriber has requested a dose >150 mg daily for aplastic anemia, or >75 mg daily for ITP, or >100 mg daily for interferon treatment of hepatitis C; **OR**
- Prescriber requests PROMACTA for longer than 6 months in aplastic anemia

Non-Preferred Agents with Manual Review Criteria

- Alvaiz® (eltrombopag choline)
- Doptelet® tablet (avatrombopag maleate)

- Eltrombopag olamine (generic for Promacta®)
- Mulpleta® tablet (lusutrombopag)
- Promacta® suspension (eltrombopag) **– BRAND PREFERRED OVER GENERIC if approved**
- Tavalisse® tablet (fostamatinib disodium)

Quantity Limits for Promacta®

- 50 mg #62/31 days
- All other strengths #31/31 days

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Thyroid, pork 15 mg, 30 mg, 60 mg, 90 mg, 120 mg tablet (Adthyza™)

(Implemented 4/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with hypothyroidism or require TSH suppression **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have tried and failed levothyroxine and Armour™ Thyroid
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including TSH and serum T4
  - Medical necessity over levothyroxine and Armour™ Thyroid
  - Medical necessity for patients who are pregnant or have cardiovascular disease
- Initial approval for 6 months

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Tirzepatide 10 mg and 15 mg injection (Zepbound®) – OSA only

(Implemented 04/16/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Arkansas Medicaid does not cover medications solely for weight loss. The criteria listed below pertain to the obstructive sleep apnea indication only.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with moderate to severe obstructive sleep apnea (OSA) defined as apnea-hypopnea index (AHI) ≥ 15 respiratory events per hour based on polysomnography (PSG) results.
- Beneficiary must have a baseline diagnosis of obesity defined as body mass index (BMI) ≥ 30 kg/m^2 **AND** at least **ONE** of the following weight-related comorbid conditions:
  - Cardiovascular disease; **OR**
  - Type II diabetes mellitus; **OR**
  - Dyslipidemia; **OR**
  - Hypertension
- Medication must be prescribed by, or in consultation with, a neurologist, pulmonologist, otolaryngologist, or other sleep medicine specialist. PA requests are not required from a specialist, but the specialist should have performed the sleep study and provided a report.
- Beneficiary must have been participating in a comprehensive weight management program for at least 6 months with documented counseling on behavioral modification, reduced-calorie diet, and increased physical activity.
- Beneficiary should not be approved or continue the medication if meets one of the following:
  - Has not been on a weight management program for at least 6 months
  - Has not been compliant with nightly CPAP use
  - Prescribed another tirzepatide-containing product or any glucagon-like peptide 1 (GLP1) receptor agonist to be used concurrently
  - Personal or family history of medullary thyroid carcinoma (MTC)
  - Diagnosed with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
  - Requested for weight loss only
  - Has been diagnosed with severe gastrointestinal disease including gastroparesis
  - Has a history of pancreatitis
  - Has a history of suicidal attempts or active suicidal ideation
- Beneficiary must have at least a 6-month history of compliant positive airway pressure (CPAP or BiPAP) use without a decrease in AHI below 15 events per hour.
- Prescriber must submit the following:
  - Current chart notes

- Most recent polysomnography (PSG) results including AHI after CPAP or BiPAP trial
- Patient specific symptoms attributable to OSA (e.g., self-reported daytime sleepiness, snoring episodes, and AHI events)
- CPAP/BiPAP usage report
- Current weight and body mass index (BMI)

- If approved, the PA will be approved for 6 months

Renewal Requirements

- Beneficiary must be compliant with Zepbound® usage (defined as 75% utilization) and compliant with positive airway pressure (CPAP or BiPAP) usage
- Beneficiary must demonstrate a positive response in OSA self-reported symptoms as compared to baseline (e.g., reduction in daytime sleepiness, reduction in snoring, or reduction in AHI) and decrease in weight/ body mass index (BMI)
- Beneficiary continues with comprehensive weight management program with behavioral modification, reduced-calorie diet, and increased physical activity.
- Prescriber must submit the following:
  - Current chart notes
  - Current weight and body mass index (BMI)
  - Documentation of patient specific symptoms improvement compared to baseline
  - Current CPAP or BiPAP usage report

Quantity Edits

- #4 injections/28 days

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Tolvaptan (Jynarque™)

(Implemented 7/18/2018)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary is an adult ≥18 years of age
- Beneficiary has diagnosis of Autosomal Dominant Polycystic Kidney Disease (ADPKD)and is at risk of rapidly progressing in the disease
- Prescriber must submit chart notes indicating the beneficiary's PKD stage
- Beneficiary is not receiving kidney dialysis
- Prescriber must submit initial liver test results for ALT, AST, and bilirubin for the 1st one month PA
- Beneficiary has normal serum sodium concentrations prior to starting drug; Prescriber to submit initial blood sodium test results
- The initial recommended dose is 60 mg/day (using the 45 mg-15 mg package). If dose is tolerated, the dose can be up-titrated at weekly intervals. The prescriber should work with the patient during up-titration using the tablet strengths in the package before requesting the PA for the next strength.
  - 45 mg – 15 mg tablets
  - 60 mg – 30 mg tablets
  - 90 mg – 30 mg tablets
- Reduced dose adjustment as stated in package insert is required for co-administration with moderate CYP 3A inhibitors

Denial Criteria

- Beneficiary is already receiving kidney dialysis
- Beneficiary is not adherent to prescribed dose
- Beneficiary does not meet approval criteria
- Beneficiary has history of signs or symptoms of significant liver impairment or injury, does not include uncomplicated polycystic liver disease
- Beneficiary has concomitant use of strong CYP 3A inhibitors, which is contraindicated
- Beneficiary has uncorrected abnormal blood sodium concentrations
- Beneficiary is unable to sense or respond to thirst
- Beneficiary has hypovolemia
- Beneficiary has hypersensitivity to tolvaptan or any of its components
- Beneficiary has uncorrected urinary outflow obstruction
- Beneficiary has anuria
- Beneficiary is breast feeding

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Topical Antiparasitic Medications (Lice Treatment)

(Updated 02/13/2017)
(Effective 4/1/17)
(Updated 10/1/2019)
(Updated 1/1/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976

Preferred Agents

- Permethrin 1% topical liquid OTC (e.g., Lice Killing liquid, Lice Treatment)
- Piperonyl butoxide 4% /Pyrethrum extract 0.33% OTC (e.g., Lice Killing Shampoo, Complete Lice Treatment, Lice Killing shampoo)
- Permethrin 5% cream (generic for Elimite™)
- Natroba 0.9%™ suspension (spinosad)* - **BRAND ONLY**

*BRAND Natroba may be filled once every 60 days. This medication should not, in general, require retreatment. However, if retreatment is required additional chart notes documenting reason for retreatment (re-infestation, product did not completely kill all nits, etc) will be needed.

Non-Preferred Agents

- Croton® 10% lotion (crotamiton)
- Elimite™ cream (permethrin)
- Eurax® 10% cream/lotion (crotamiton)
- Ivermectin lotion 0.5% (generic for Sklice®)
- Lindane 1% shampoo
- Malathion lotion 0.5% (generic for Ovide®)
- Ovide®) 0.5% lotion (malathion)
- Sklice®) 0.5% lotion (ivermectin)
- Spinosad suspension 0.9% - **GENERIC ONLY**
- Vanalice™ gel (piperonyl butoxide, pyrethrins)

Additional Criteria

- Quantity limits apply

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Tobacco-cessation Products

(Implemented 11/15/2005)
(*Updated 1/1/2020)*

All smoking cessation products eligible for rebate are currently covered without a PA through Arkansas Medicaid. In addition, these products do not contribute toward the use of a slot nor do they have a copay. This includes the following:

- Zyban (Wellbutrin)
- Chantix (Varenicline)
- Nicotine gum
- Nicotine patches
- Nicotine inhalers
- Nicotine lozenges

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Tranexamic Acid (Lysteda™)

(Implemented 06/21/2011)
(Updated and Effective 7/15/2020)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Point-Of-Sale (POS) Approval Criteria

- Diagnosis in Medicaid medical history in previous 3 years of cyclic heavy menstrual bleeding; **AND**
- Beneficiary's Medicaid pharmacy drug history indicates paid claims of contraceptives or hormonal therapy with any of the following
  - 84 days' supply of oral, vaginal or patch contraceptive claims from 30-180 days in profile history (three pharmacy claims); **OR**
  - 90 days' supply of injectable birth control from 90-180 days in profile history (one pharmacy claim); **OR**
  - 91 days' supply for extended cycle oral contraceptive from 90-180 days in profile history (one pharmacy claim)
- Beneficiary's lab results in the Prime system for the previous 30 days indicates a hemoglobin (Hgb) level of ≤ 12 g/dL.

Denial Criteria

- Medicaid profile indicates a pharmacy claim for a combination hormonal contraception (estrogen and progestin combination) in the previous 30 days; **OR**
- Medicaid profile indicates a pharmacy claim for anticoagulants in the previous 30 days

Additional Criteria

- Quantity limits apply - #30/21 days

Manual review PA will be on a case-by-case basis if the above requirements are not found in the Medicaid system for POS approval. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

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Transdermal Scopolamine Patches

(Implemented 03/09/2010)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- ≥ 12 years of age; **OR**
- History of at least one paid claim in the past 60 days for transderm scopolamine

Additional Criteria

- Quantity limits apply

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Trientine capsule (Syprine®)

(Implemented 09/18/2013)
(Updated 1/15/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Manual review on a case-by-case basis
- Beneficiary must be diagnosed with Wilson's disease and be intolerant of penicillamine with intolerable or life endangering side effects
- Dose may be increased only when the clinical response is not adequate or the concentration of free serum copper is persistently above 20 mcg/dL.
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Response to penicillamine
  - If dose needs to be increased when the clinical response is not adequate, free serum copper should be checked and be above 20 mcg/dL.

Renewal Requirements

- Beneficiary must remain compliant on therapy (defined as 75% utilization)
- Beneficiary must demonstrate a positive response
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of response to treatment

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Triheptanoin liquid (Dojolvi®)

(Implemented 10/21/2020)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary has a confirmed diagnosis of long-chain fatty acid oxidation disorder **OR** a diagnosis consistent with FDA indication; **AND**
- Beneficiary is under the care of a clinical specialist knowledgeable in appropriate disease- related dietary management based upon current nutritional recommendations; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Documentation confirming the diagnosis of LC-FAOD with one of the following:
    - Acylcarnitine profiles from a newborn screen; **OR**
    - Fatty acid oxidation probe studies in cultured fibroblasts (low enzyme activity); **OR**
    - Mutation analysis containing one of the following mutations—CPT2, ACADVL, HADHA, or HADHB;
  - Total daily dose based on required daily caloric intake (DCI) X target % of DCI; **AND**
  - Documentation of symptoms; **AND**
  - Documentation of diet plan; **AND**
  - Baseline echocardiogram with documented left ventricular ejection fraction; **AND**
  - Medical necessity over other available options

Denial Criteria

- Beneficiary does not meet the FDA approved indication OR have a diagnosis supported in the official Compendia; **OR**
- Beneficiary has pancreatic insufficiency; **OR**
- Beneficiary requires concomitant pancreatic lipase inhibitors (e.g. orlistat); **OR**
- Beneficiary is receiving another medium-chain triglyceride product; **OR**
- Beneficiary has a feeding tube manufactured of polyvinyl chloride (PVC).

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Trofinetide 200 mg/mL solution (Daybue™)

(Effective 7/19/2023)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with Rett syndrome OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Prescriber must be a specialist with experience in Rett Syndrome (e.g., neurologist, geneticist) or prescriber must be in consultation with a specialist
- Provider must submit a detailed baseline clinical presentation of Rett syndrome including, but not limited to the following:
  - Abnormal muscle tone/dystonia
  - Abnormal respiration pattern
  - Feeding difficulties
  - Intellectual disability (i.e., I.Q. score < 70)
  - Loss of mobility or gait abnormalities
  - Partial or complete loss of acquired hand skills
  - Partial or complete loss of speech
  - Seizures
  - Stereotypic hand movements such as hand wringing/squeezing, clapping/tapping, mouthing, and washing/rubbing automatisms
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Moderate to severe renal impairment
  - Intolerable diarrhea
  - No improvement in clinical presentation compared to baseline
  - Dose requested is not consistent with weight based dose recommendation
- Prescriber must submit **ALL** of the following:
  - Current chart notes with description of specific symptoms present in this beneficiary
  - Documentation of the MECP2 mutation (if available)
  - Attestation of a clinical diagnosis of RTT in the absence of a MECP2 mutation
  - Current weight
  - Current dose requested
  - Current labs to determine renal function
  - Treatment plan for severe diarrhea and weight loss
  - Baseline Rett Syndrome Behavior Questionnaire (RSBQ) and the Clinical Global Impression-improvement (CGI-I) score if available
- Initial PA for 6 months

Renewal Requirements

- Beneficiary remains compliant with therapy (defined as: 75% utilization based on Medicaid claims)
- Prescriber must submit the following:
  - Current chart notes with documentation of current clinical presentation
  - Current RSBQ and/or CGI-I if available
- Beneficiary continues to lack intolerable side effects
- Beneficiary must demonstrate an improvement in clinical presentation compared to baseline

Quantity Edits

- 3600 mL per 30 days

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Urea Cycle Disorder Agents

(Implemented 4/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Preferred Agents with Criteria

- Carbaglu® tablet (carglumic acid) - **BRAND NAME**
- Pheburane® pellet (sodium phenylbutyrate)

Non-Preferred Agents

- Buphenyl® powder (sodium phenylbutyrate)
- Buphenyl® tablet (sodium phenylbutyrate)
- Carglumic Acid tablet (generic for Carbaglu®) - **GENERIC**
- Olpruva™ pellet (sodium phenylbutyrate)
- Ravicti® liquid (glycerol phenylbutyrate)
- Sodium phenylbutyrate powder (generic for Buphenyl®)
- Sodium phenylbutyrate tablet (generic for Buphenyl®)

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with:
  - Buphenyl® - urea cycle disorders involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccunic acid synthetase (AS)
  - Carbaglu® -
    - Acute or chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency
    - Adjunctive therapy to standard of care for the treatment of acute hyperammonemia

    OR
    - Maintenance therapy for the treatment of chronic hyperammonemia
    - Acute hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA) as adjunctive therapy **(BRAND NAME ONLY)**
  - Olpruva™ - urea cycle disorders involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccunic acid synthetase (AS) and weigh at least 20 kg or have a body surface area of at least 1.2 m^2
  - Pheburane® - urea cycle disorders involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccunic acid synthetase (AS)
  - Ravicti® - urea cycle disorders and cannot be managed by dietary protein restriction and/or amino acid supplementation alone

- Medication must be prescribed by or in consultation with a provider experienced in managing UCDs (e.g., geneticist)
- Beneficiary is unable to maintain a plasma ammonia level within normal range with standard of care treatment (i.e., protein restriction and essential amino acid supplementation when appropriate)
- Beneficiary must continue dietary management with protein restriction with dietary plan provided
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Previous therapies tried with response
  - Current weight and body surface area (BSA)
  - Current labs including plasma ammonia and complete metabolic panel
  - Dose requested must fall within the parameters from the individual product package insert
    - Pheburane® pellet or Buphenyl® tablet/powder (maximum daily dose of 20 gm)
      - 450 to 600 mg/kg/day orally in patients weighing < 20 kg
      - 9.9 5o 13 g/m²/day orally in patients weighing ≥ 20 kg
    - Carbaglu® tablet
      - Acute treatment for NAGS – 100-250 mg/kg
      - Chronic treatment for NAGS – 10-100 mg/kg
      - Acute treatment for PA or MMA – 150 mg/kg/day for ≤ 15 kg OR 3.3 g/m²/day for > 15 kg
      - If diagnosed with PA or MMA, provide number days treated while hospitalized. Patient should have a maximum of 7 days total.
    - Olpruva™ pellet (maximum daily dose of 20 gm)
      - 9.9 to 13 g/m²/day
    - Ravicti® liquid (maximum daily dose of 17.5 mL (19 gm))
      - 4.5 to 11.2 mL/m²/day (5 to 12.4 g/m²/day)
- For non-preferred products, beneficiary must have tried and failed preferred products with documented uncontrolled hyperammonemia despite compliance in the previous year or have documented contraindication/intolerance to preferred products.
- If the beneficiary has a G-tube, the medical necessity of Ravicti® over sodium phenylbutyrate powder will need to be provided.

Renewal Requirements

- Prescriber must submit the following:
  - Current chart notes with documentation of current clinical presentation
  - Current plasma ammonia level
  - Current weight and/or BSA and dose requested
- Beneficiary must demonstrate an improvement in clinical presentation and/or decrease in plasma ammonia compared to baseline
- Beneficiary must continue to meet approval criteria

Quantity Edits

- None since dose based on BSA

Ulcerative Colitis Agents (excluding biologics)

(Added to PDL 4/1/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Apriso® capsule (mesalamine ER) - **BRAND NAME**
- Mesalamine suppository (generic for Canasa®)
- Pentasa® capsule (mesalamine ER) – **BRAND NAME**
- Sulfasalazine tablet (generic for Azulfidine®)
- Sulfasalazine DR tablet (generic for Azulfidine EN-tab®)

Preferred Agents with Criteria

- Budesonide ER 9 mg tablet (generic for Uceris®)

UCERIS (budesonide extended-release) tablets are indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.
The recommended dosage for the induction of remission in adult patients with active, mild to moderate ulcerative colitis is 9 mg taken orally once daily in the morning with or without food for up to 8 weeks.

Point-of-Sale Approval Criteria for Budesonide ER 9 mg tablet

- Beneficiary must have a billed diagnosis of ulcerative colitis in the past 2 years; **AND**
- Beneficiary must have a pharmacy claim in their Arkansas Medicaid history over the last 186 days for one of following:
  - Oral or rectal mesalamine
  - Sulfasalazine
- Beneficiary will be limited to 2 claims of budesonide ER 9 mg tablets every 186 days for a total of 60 tablets.

For beneficiaries not meeting the above point-of-sale approval criteria, prior authorization approvals will be for 2 months only as indicated in the package insert dosing.

Non-Preferred Agents

- Azulfidine® tablet (sulfasalazine)
- Azulfidine® EN-tab (sulfasalazine DR)
- Balsalazide capsule (generic for Colazal®)
- Budesonide foam (generic for Uceris®)
- Canasa® suppository (mesalamine)
- Colazal® capsule (balsalazide)
- Delzicol® capsule (mesalamine DR)

- Dipentum® capsule (olsalazine)
- Lialda® tablet (mesalamine DR)
- Mesalamine DR tablet (generic for Asacol HD®)
- Mesalamine DR capsule (generic for Delzicol®)
- Mesalamine DR tablet (generic for Lialda®)
- Mesalamine enema (generic for sfRowasa®)
- Mesalamine ER capsule (generic for Apriso®)
- Mesalamine ER capsule (generic for Pentasa®)
- Mesalamine kit (generic for Rowasa®)
- Rowasa® kit (mesalamine)
- sfRowasa® enema (mesalamine)
- Uceris® foam (budesonide)
- Uceris® tablet (budesonide)

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Vaginal Hormones

(Implemented 10/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Estradiol cream (generic for Estrace®)
- Premarin® cream (estrogens, conjugated)

Non-Preferred Agents

- Estrace® cream (estradiol)
- Estradiol tablet (generic for Vagifem® and Yuvafem®)
- Estring® vaginal ring (estradiol)
- Femring® vaginal ring (estradiol acetate)
- Imvexxy® vaginal insert (estradiol)
- Vagifem® vaginal tablet (estradiol)
- Yuvafem® vaginal tablet (estradiol)

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Valganciclovir oral solution (Valcyte®)

(Implemented 01/18/2011)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Less than 9 years of age; **OR**
- History of diagnosis of NPO (Appendix A) within the past 365 days.

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Vericiguat (Verquvo®)

(Updated 7/21/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must be ≥ 18 years of age; **AND**
- Beneficiary must be diagnosed with symptomatic chronic heart failure (New York Heart Association class III-IV) with an ejection fraction < 45% following a worsening HF event **OR** a diagnosis consistent with FDA-approved indications; **AND**
- Beneficiary must have previously been hospitalized for heart failure in the last 6 months or required outpatient IV diuretics in the last 3 months; **AND**
- Beneficiary must remain on standard of care therapy; **AND**
- Beneficiary of reproductive potential should use contraception and have a negative pregnancy test; **AND**
- Beneficiary has continued heart failure symptoms while on Entresto®; **AND**
- Prescriber must submit the following:
  - Current chart notes; **AND**
  - Discharge summary from hospital if recently hospitalized; **AND**
  - Documentation of previous therapies tried with outcomes; **AND**
  - Documentation of ejection fraction; **AND**
  - Pro-BNP confirms heart failure diagnosis; **AND**
  - Negative pregnancy test results for beneficiaries of reproductive potential

Denial Criteria

- Beneficiary does not meet approval criteria OR have a diagnosis supported on the official Compendia; **OR**
- Beneficiary is pregnant; **OR**
- Beneficiary is taking another soluble guanylate cyclase (sGC) stimulator (i.e., Adempas); **OR**
- Beneficiary taking a PDE-5 inhibitor is not recommended to take with this product; **OR**
- Beneficiary has severe hepatic impairment (Child-Pugh C) or severe renal impairment (eGFR)

Quantity Edits

- #31/31 days for each strength

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Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors

(Effective 1/1/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents with Criteria

- **Austedo® tablet (deutetrabenazine)**
- **Austedo XR® tablet (deutetrabenazine)**
- **Austedo XR® titration kit (deutetrabenazine)**
- **Ingrezza® capsule and sprinkle (valbenazine)**
- **Ingrezza® initiation pack (valbenazine)**
- **Tetrabenazine tablet (generic for Xenazine®)**

Non-Preferred Agents

- **Xenazine® tablet (tetrabenazine)**

Approval Criteria for Preferred Agents with Criteria

Tetrabenazine tablet (POS edits)

- Requires a billed diagnosis of Huntington's Disease with Chorea in the past 3 years
- Quantity edits apply

Austedo®/Austedo XR® tablet (deutetrabenazine) - requires a PA

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have one of the following diagnoses:
  - Chorea associated with Huntington's disease
  - Moderate to severe tardive dyskinesia (must also meet ALL the following DSM-5 criteria)
    - Involuntary athetoid or choreiform movements
    - History of treatment with dopamine receptor blocking agent (DRBA) (e.g., antipsychotics or metoclopramide)
    - Symptoms duration lasting longer than 4 to 8 weeks
- Must be prescribed by or in consultation with a neurologist, psychiatrist, or gastroenterologist (chorea due to metoclopramide)
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Congenital long QT syndrome or cardiac arrhythmias associated with a prolonged QT interval
  - Hepatic impairment

  - Requires monoamine oxidase inhibitors (MAOIs), any other VMAT2 inhibitor, or reserpine
  - Requires strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion)
  - Poor CYP2D6 metabolizer requires a dose reduction to 36 mg daily
  - Pregnant or breastfeeding
  - Dose requested is > 48 mg/day
  - Develops Neuroleptic Malignant Syndrome
  - Chorea associated with Huntington's disease beneficiary that is suicidal or has untreated or inadequately treated depression
- Prescriber must submit ALL the following:
  - Current chart notes with documentation on the impact of TD or chorea symptoms with activities of daily living
  - Completed Medicaid Ingrezza®/Austedo® Statement of Medical Necessity form with the initial request: Forms & Documents - Arkansas (primetherapeutics.com)
  - Baseline Abnormal Involuntary Movement Scale (AIMS) form for tardive dyskinesia
  - Data documenting the response to benztropine or other agent of EPS symptoms if applicable
  - Tapering plan with each PA request until beneficiary reaches a stable, maintenance dose
- The initial Austedo® PA will be approved for two (2) months to allow time for titration. Austedo® 6 mg can be approved up to a maximum of #240 tablets (8 tablets per day) during the initial two (2) months of treatment for titration. If additional titration time is needed beyond the original two (2) months, another PA with quantity override would be required. Once compliant on a maintenance dose, PAs may be approved for a maximum of 6 months.

Renewal Requirements

- Prescriber must submit the following:
  - Current chart notes
  - Current AIMS score
- Beneficiary must have an improvement from baseline AIMS score or has a positive clinical response

Ingrezza® capsule and sprinkle (valbenazine) - requires a PA

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have one of the following diagnoses:
  - Chorea associated with Huntington's disease
  - Moderate to severe tardive dyskinesia (must also meet **ALL** the following DSM-5 criteria)
    - Involuntary athetoid or choreiform movements
    - History of treatment with dopamine receptor blocking agent (DRBA) (e.g., antipsychotics or metoclopramide)
    - Symptoms duration lasting longer than 4 to 8 weeks
- Must be prescribed by or in consultation with a neurologist, psychiatrist, or gastroenterologist (chorea due to metoclopramide)
- Beneficiary should not be approved or continue on this therapy with any of the following:

- Has violent behavior or is suicidal
- Pregnant or breastfeeding
- Requires monoamine oxidase inhibitors (MAOIs), any other VMAT2 inhibitor, or concomitant strong CYP3A4 inducers (e.g., rifampin, carbamazepine, and phenytoin)
- Dose requested is > 80 mg/ day
- Dose requested is > 40 mg/ day when requires strong SYP3A4 inhibitors (e.g., itraconazole, ketoconazole, and clarithromycin) OR has moderate to severe hepatic impairment (Child Pugh score 7-15)
- Congenital long QT syndrome or cardiac arrhythmias associated with a prolonged QT interval
- Severe renal impairment (creatinine clearance <30 ml/min)

- Prescriber must submit ALL the following:
  - Current chart notes with documentation on the impact of TD or chorea symptoms with activities of daily living
  - Completed Medicaid Ingrezza®/Austedo® Statement of Medical Necessity form with the initial request: Forms & Documents - Arkansas (primetherapeutics.com)
  - Baseline Abnormal Involuntary Movement Scale (AIMS) form for tardive dyskinesia
  - Data documenting the response to benztropine or other agent of EPS symptoms if applicable
  - Requests for the sprinkle formulation should include documentation of the medical necessity over the capsule
- Initial Ingrezza® PA should not exceed 3 months. Once compliant on maintenance dose, PAs may be approved for a maximum of 6 months.

Renewal Requirements

- Prescriber must submit the following:
  - Current chart notes
  - Current AIMS score for patients with tardive dyskinesia
- Beneficiary must have an improvement from baseline AIMS score or has a positive clinical response

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Voclosporin capsule (Lupkynis®)

(Implemented 4/21/2021)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must have a diagnosis of biopsy-proven active lupus nephritis (Class III, IV or V) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must also take mycophenolate mofetil (MMF) and corticosteroids concomitantly with LUPKYNIS
- Beneficiary must have an elevated urine protein to creatinine (UPCR) ratio
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Pregnant
  - Baseline eGFR ≤ 45 mL/min/1.73 m^2
  - Baseline blood pressure >165/105 mmHg or with hypertensive emergency
  - Not taking concomitant mycophenolate mofetil and corticosteroids
  - Taking cyclophosphamide
  - Requires concomitant strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin)
  - Dose requested > 23.7 mg twice daily **OR** < 7.9 mg twice daily
  - Hepatic impairment
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including liver function tests, urine protein to creatinine (UPCR) ratio, serum potassium levels, and baseline estimated glomerular filtration rate (eGFR). eGFR must be assessed every two weeks for the first month, and every four weeks thereafter.
  - Current blood pressure

Renewal Requirements

- Beneficiary is compliant on therapy (defined as 75% utilization)
- If approved, beneficiary has not experienced therapeutic benefit by 24 weeks.
- Prescriber must submit the following:
  - Current chart notes with response to treatment
  - Current labs
  - Current blood pressure

Quantity Edits

- #180/ 30 days

Voltage-Gated Sodium Channel Selective Inhibitors

(Effective 2/10/2025)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Agents

- Journavx™ tablet (suzetrigine)

Non-Preferred Agents

- None

Quantity Edits

- #30 tablets every 60 days

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Vonoprazan tablet, Dual Pak, Triple Pak (Voquezna®)

(Implemented 4/17/2024)
(Updated 10/16/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary prescribed a VOQUEZNA Dual or Triple Pak must be diagnosed with *Helicobacter pylori* or beneficiary prescribed VOQUEZNA must be diagnosed with **ONE** (1) of the following:
  - For healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
  - To maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
  - For the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.
  - In combination with amoxicillin and clarithromycin for the treatment of *Helicobacter pylori (H. pylori)* infection in adults.
  - In combination with amoxicillin for the treatment of *H. pylori* infection in adults.
- Beneficiary with erosive esophagitis or heartburn must have had previous treatment failure with or a contraindication to all preferred proton pump inhibitors
- Beneficiary with *H. pylori* must have tried and failed (defined as failure to eradicate *H. pylori* infection after 14-day course of therapy) **ONE** (1) of the following:
  - Bismuth quadruple therapy unless contraindicated (e.g., bismuth, metronidazole, tetracycline and proton pump inhibitor); **OR**
  - Clarithromycin-based therapy unless contraindicated (e.g., clarithromycin, amoxicillin, and proton pump inhibitor)
- Prescribed by or in consultation with a gastroenterologist or infectious disease specialist
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Requested duration of treatment for healing erosive esophagitis or relief of heartburn associated with erosive esophagitis exceeds 8 weeks
  - Requested duration of maintenance therapy for healed erosive esophagitis and relief of heartburn exceeds 6 months
  - Requested duration of treatment for heartburn associated with non-erosive gastroesophageal reflux disease exceeds 4 weeks
  - Requested duration of treatment for *H. pylori* exceeds 14 days
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried

- Confirmation of *H. pylori* if that is the diagnosis
- Letter of medical necessity requesting VOQUEZNA over guideline-recommended first-line treatment
- VOQUEZNA requests require an endoscopy report confirming:
  - Current erosive esophagitis with treatment prescribed to heal erosive esophagitis; **OR**
  - Confirmed healed erosive esophagitis with treatment prescribed as maintenance therapy; **OR**
  - Confirmed lack of esophageal erosions but heartburn persists

- PA duration will be consistent with duration per the package insert

Renewal Requirements

- Prescriber must submit the following:
  - Current chart notes
  - Letter of medical necessity outlining the rationale for exceeding FDA approved treatment duration

Quantity Edits

- 10 mg and 20 mg - #31/31 days; Dual and Triple Pak - #112/14 days

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Vosoritide (Voxzogo®)

(Implemented 01/19/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary must have a diagnosis of achondroplasia (ACH) **OR** a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must have open epiphyses
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Has closed epiphyses
  - Has a diagnosis of hypochondroplasia or short stature condition other than ACH
  - Has been treated with growth hormone in the previous 6 months
- Prescriber who specializes in skeletal dysplasia (orthopedics, geneticist, or endocrinologist) must submit the following:
  - Current chart notes
  - Genetic test results and radiologic findings confirming the diagnosis of achondroplasia
  - Baseline standing height
  - Current weight (must be at least 3kg)
  - Requested dose
  - X-ray report demonstrating epiphyses status for patients yearly

Quantity Edits

- Each strength - #30 vials/30 days (packaged in 10 vials per kit)

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Vutrisiran Syringe (Amvuttra®)

(Effective 10/19/2022)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Prescribed by or in consultation with a neurologist or other specialist that treats polyneuropathy due to hATTR
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is diagnosed with polyneuropathy due to hereditary transthyretin-mediated (hATTR) amyloidosis OR a diagnosis consistent with any updated FDA approved indications
- Beneficiaries with multisystem symptoms and/or family history must have the diagnosis confirmed with ONE of the following:
  - Confirmation of a TTR variant by genetic testing
  - Tissue biopsy confirming the presence of amyloid deposits
- Beneficiary does not have any of the following:
  - Severe renal impairment or end-stage renal disease
  - Moderate or severe hepatic impairment
- Prescriber must submit the following:
  - Current chart notes
  - Medical necessity over preferred neuropathic pain agents
  - Attestation that Vitamin A is being monitored for possible supplementation
  - Baseline modified Neuropathy Impairment Score +7 (mNIS+7)
  - Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score
  - Previous therapies tried
  - Current labs including LFTs and BMP
- Renewal requires prescriber to submit updated notes and labs with documentation of a positive response to therapy

Quantity Edits

- 1 syringe every 3 months

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Zilucoplan sodium 16.6 mg, 23 mg, 32.4 mg syringe (Zilbrysq®)

(Implemented 04/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with generalized myasthenia gravis (gMG) and are antiacetylcholine receptor (AChR) antibody positive OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Must be prescribed by, or in consultation with, a neurologist or other specialist knowledgeable in treating gMG
- Prior to initiating treatment with ZILBRYSQ, the beneficiary must have a baseline Myasthenia Gravis Foundation of America (MGFA) Clinical Classification class II to IV and a MG-Activities of Daily Living (MG-ADL) total score ≥ 6
- Beneficiary must have completed or updated meningococcal vaccination (for serogroups A, C, W, and Y, and serogroup B) at least 2 weeks prior to first dose of ZILBRYSQ or the provider must administer the meningococcal vaccine as soon as possible and begin antibacterial drug prophylaxis
- Beneficiary must have tried and failed an acetylcholinesterase (AChE) inhibitor (e.g., pyridostigmine) AND immunosuppressive therapies (e.g., glucocorticoids, azathioprine, or mycophenolate) while on a stable dose or have a documented contraindication or intolerance to those agents
- Prescribers and pharmacies must be certified in the ZILBRYSQ Risk Evaluation Mitigation Strategy (REMS) program
- Beneficiary should not be approved or continue this therapy with any of the following:
  - Dose requested is not consistent with weight based dosing from the package insert
  - Beneficiary is not AChR antibody positive
  - Beneficiary has a current unresolved *Neisseria meningitidis* infection
  - Beneficiary has suspected or confirmed pancreatitis
  - Baseline MG-ADL total score is < 6 or designated as MGFA class I or class V
- Prescriber must submit the following:
  - Current chart notes

  - Documentation of previous therapies tried with response
  - Serologic test confirming the presence of anti-AChR antibodies
  - Baseline lipase and amylase levels
  - Current body weight
  - Dose requested
  - Baseline MG-ADL total score and MGFA class
- Initial PA will be for 3 months

RENEWAL REQUIREMENTS:

- Beneficiary must demonstrate a positive clinical response compared to baseline with an improvement in symptoms and/or improvement in the MG-ADL total score
- Prescriber must submit the following:
  - Current chart notes
  - Current MG-ADL total score
  - Current body weight
  - Dose requested
- Renewal PAs can be approved for 6 months

Quantity Edits

- 16.6 mg/0.416 mL - #28 per 28 days
- 23 mg/0.574 mL - #28 per 28 days
- 32.4 mg/0.81 mL - #28 per 28 days

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Zuranolone 20 mg, 25 mg, 30 mg capsule (Zurzuvae®)

(Implemented 04/17/2024)

Prescribers with questions on how to obtain a PA should call the Prime Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Approval Criteria

- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary is prescribed no more than the maximum dose or treatment duration from the manufacturer's package insert or based on support from the official Compendia
- Beneficiary must be diagnosed with moderate to severe postpartum depression (PPD) with onset of symptoms no earlier than the third trimester and no later than 4 weeks following delivery OR a diagnosis consistent with any new FDA-approved indications. Any off-label requests will be reviewed on a case-by-case basis.
- Beneficiary must be ≤12 months postpartum (< 365 days)
- Beneficiary should not be approved with any of the following:
  - More than 12 months postpartum
  - Currently pregnant
  - Requesting more than one (1) 14-day course
- Prescriber must submit the following:
  - Current chart notes
  - Previous therapies tried
  - Date of delivery
  - Dose requested
    - Typical dose is 50 mg once daily in the evening for 14 days
    - If patient experiences CNS depressant effects within the 14-day period, dose may be decreased to 40 mg once daily in the evening for the remainder of the 14-day period. The prescriber should contact the specialty pharmacy that filled the member's initial ZURZUVAE prescription to obtain the 20mg capsules from the manufacturer for the remainder of the member's treatment course.
    - Dose should be reduced to 30 mg for the following:
      - Concomitant use with strong CYP3A4 inhibitor (e.g., ketoconazole)
      - Severe hepatic impairment (Child-Pugh C)
      - Moderate or severe renal impairment (eGFR < 60 mL/min/1.73 m^2)
  - Attestation that the beneficiary has been counseled on CNS depression risk for infants during breastfeeding. Breastfeeding should be temporarily stopped during the 14 day treatment and for 7 days after if possible.
  - Attestation that the beneficiary is not currently pregnant

Quantity Edits

- One (1) 14-day course

Appendix A – Nil per os (NPO)

Procedure codes	Description
B4034, B4035, B4036	Enteral feeding supplies
B4149, B4151-B4156	Enteral formula
B4160-B4162	Enteral formula for pediatrics
43752	Naso/Oro-gastric tube placement
43510	Surgical opening of stomach
43760	Change gastrostomy tube
43762	Replacement of stomach stoma tube accessed through skin
43763	Replacement of stomach stoma tube accessed through skin with revision of stoma opening
43831	Insertion of stomach feeding tube, open procedure for newborn feeding
44021	Incision of small bowel for insertion of tube
44300	Insertion of small bowel tube, open procedure
44310	Creation of small bowel feeding tube
49440	Insertion of stomach tube, accessed through skin using fluoroscopic guidance with contrast
49441	Insertion of small bowel tube, accessed through skin using fluoroscopic guidance with contrast
49442	Insertion of large bowel tube, accessed through skin using fluoroscopic guidance with contrast
49446	Conversion of stomach tube to stomach-to-small bowel tube, accessed through skin using fluoroscopic guidance with contrast
49452	Replacement of stomach-to-small bowel tube, accessed through skin using fluoroscopic guidance with contrast
43830, 43832	Gastrostomy tube
43761	G-tube repositioning
44373, 44372, 44015	J-Tube
43246 , 43750	PEG placement
43820	Partial removal of stomach, without vagotomy
43810	Removal of end portion of stomach with attachment to upper small bowel
43845	Partial removal of stomach, with partial gastrectomy
43825	Partial removal of stomach and severing of vagus nerve
B4087	Gastrostomy/Jejunostomy tube, standard
74350	G-tube placement

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Appendix B – Approved Tracheostomy Codes

Code	Description
V44.0	Tracheostomy status
V55.0	Attention to tracheostomy
31.1	Temporary tracheostomy
31.2X	Permanent tracheostomy
31.74	Revision of tracheostomy
519.0X	Tracheostomy complications
31600	Tracheostomy, planned (separate procedure)
31601	Tracheostomy, planned (separate procedure); younger than two years
31603	Tracheostomy, emergency procedure; transtracheal
31605	Tracheostomy, emergency procedure; cricothyroid membrane
31610	Tracheostomy, fenestration procedure with skin flaps

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Appendix D – Congestive Heart Failure Diagnoses

Description
Hypertensive heart disease with heart failure
Hypertensive heart disease with heart failure
Hypertensive heart disease with heart failure
Hypertensive heart and renal disease with heart failure
Hypertensive heart and renal disease with heart and renal failure
Hypertensive heart and renal disease with heart failure
Hypertensive heart and renal disease with heart and renal failure
Hypertensive heart and renal disease with heart failure
Hypertensive heart and renal disease with renal failure
Hypertensive heart and renal disease with heart and renal failure
Congestive heart failure, unspecified

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Appendix E – Malignant cancer diagnoses

Description
Malignant neoplasm of lip
Malignant neoplasm of major salivary gland
Malignant neoplasm of oropharynx
Malignant neoplasm of nasopharynx
Malignant neoplasm of hypopharynx
Malignant neoplasm of other and ill-defined sites within the lip, oral cavity, and pharynx
Malignant neoplasm of esophagus
Malignant neoplasm of stomach
Malignant neoplasm of small intestine including duodenum
Malignant neoplasm of colon
Malignant neoplasm of rectum rectosigmoid junction
Malignant neoplasm of liver and intrahep
Malignant neoplasm of gall bladder and extrahepatic bile duct
Malignant neoplasm of pancreas
Malignant neoplasm of retroperitoneum and peritoneum
Malignant neoplasm of other and ill-defined sites within the digestive organs and peritoneum
Malignant neoplasm of nasal cavities middle ear and accessory sinuses
Malignant neoplasm of larynx
Malignant neoplasm of trachea bronchus and lung
Malignant neoplasm of pleura
Malignant neoplasm of thymus, heart, and mediastinum
Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs
Malignant neoplasm of bone and articular cartilage
Malignant neoplasm of connective and other soft tissue
Malignant melanoma of skin
Malignant neoplasm of female breast
Malignant neoplasm of male breast
Kaposis sarcoma
Malignant neoplasm of uterus, part unspecified
Malignant neoplasm of cervix uteri
Malignant neoplasm of placenta
Malignant neoplasm of body of uterus
Malignant neoplasm of ovary and other uterine adnexa
Malignant neoplasm other and unspecified female genital organs
Malignant neoplasm of prostate
Malignant neoplasm of testis
Malignant neoplasm of penis and other male genital

Description
Malignant neoplasm of bladder
Malignant neoplasm of kidney and other and unspecified urinary organs
Malignant neoplasm of eye
Malignant neoplasm of brain
Malignant neoplasm other and unspecified parts nervous system
Malignant neoplasm of thyroid gland
Malignant neoplasm of other endocrine glands and related structures
Malignant neoplasm of other and ill-defined sites
Secondary and unspecified malignant neoplasm of lymph
Secondary malignant neoplasm of respiratory and digestive
Secondary malignant neoplasm of other specified sites
Malignant neoplasm without specification
Lymphosarcoma and reticulosarcoma
Hodgkins disease
Other malignant neoplasms lymphoid and histiocytic tissue
Multiple myeloma and immunoproliferative neoplasms
Lymphoid leukemia
Myeloid leukemia
Monocytic leukemia
Other specified leukemia
Leukemia of unspecified cell type

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Appendix I – Approved endoscopy codes

Endoscopy	
CPT	**Procedure**
43201	ESPHGSC RGD/FLX DIRED SBMCSL NJX ANY SBST
43234	UPR GI NDSC SMPL PRIM XM SPX
43235	UPR GI NDSC DX +-COLLJ SPEC BR/WA SPX
43236	UPR GI NDSC DIRED SBMCSL NJX ANY SBST
43237	UPR GI NDSC NDSC US XM LMTD ESOPH
43238	UPR GI NDSC TNDSC US FINE NDL ASPIR/BX ESOPH
43239	UPR GI NDSC BX 1/MLT
43240	UPR GI NDSC TRANSMURAL DRG PSEUDOCST
43241	UPR GI NDSC TNDSC INTRAL TUBE/CATH PLMT
43242	UPR GI NDSC TNDSC US FINE NDL ASPIR/BX W/US XM
43243	UPR GI NDSC NJX SCLEROSIS ESOPHGL&/GSTR VARC
43244	UPR GI NDSC BAND LIG ESOPHGL&/GSTR VARC
43245	UPR GI NDSC DILAT GSTR OUTLET FOR OBSTRCJ
43246	UPR GI NDSC DIRED PLMT PRQ GASTROSTOMY TUBE
43247	UPR GI NDSC RMVL FB
43248	UPR GI NDSC INSJ GD WIRE DILAT ESOPH GD WIRE
43249	UPR GI NDSC BALO DILAT ESOPH <30 MM DIAM
43250	UPR GI NDSC RMVL LES HOT BX/BIPOLAR CAUT
43251	UPR GI NDSC RMVL TUM POLYP/OTH LES SNARE TQ
43255	UPR GI NDSC CTRL BLD ANY METH
43256	UPR GI NDSC TNDSC STENT PLMT W/PREDILAT
43257	UPR GI NDSC DLVR THERMAL NRG SPHNCTR/CARDIA
43258	UPR GI NDSC ABLTJ LES X RMVL FORCEPS/CAUT/SNARE
43259	UPR GI NDSC W/US XM
43200	Esophagoscopy, rigid or flexible; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)
43201	...with directed submucosal injection(s), any substance
43202	...with biopsy, single or multiple
43204	…with injection sclerosis of esophageal varices
43205	...with band ligation of esophageal varices
43220	...with balloon dilation (less than 30 mm diameter)
43226	...with insertion of guide wire followed by dilation over guide wire
43227	...with control of bleeding (e.g., injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator)
43228	...with ablation of tumor(s), polyp(s), or other lesion(s), not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique
43216	... with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery
43217	...with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
43219	...with insertion of plastic tube or stent
43231	...with endoscopic ultrasound examination
43232	...with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s)

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