Prescription Drug Program Prior Authorization Criteria

Revised 1/1/2025

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 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.

Drugs that require manual review for prior authorization

- Soriatane

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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% (Abreva) cream

Drugs that require manual review for prior authorization

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

Additional criteria

- Quantity edits apply

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Albuterol Oral Tablets and Syrup

(Implemented 03/18/2014)

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

- Albuterol 2mg/5ml Syrup
- Albuterol 2mg IR
- Albuterol 4mg IR
- Albuterol 4mg ER
- Vospire 4mg ER
- Albuterol 8mg ER
- Vospire 8mg ER

Additional criteria

Quantity limits apply

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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:

- Recipient must be ≥ 2 years of age; AND
- Recipient 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.)
        - Recipient <6 years—max of 50 mg daily
        - Recipient 6-17 years of age—50 mg daily for at least 24 weeks before increasing to 125 mg daily
        - Recipient ≥18 years of age—max of 250 mg daily

DENIAL CRITERIA:

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

QUANTITY EDITS:

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

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 ≤ 80mg/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®)
- Namenda® XR capsule (memantine ER)
- Namzaric® capsule (memantine/donepezil)
- Razadyne® ER capsule (galantamine)
- Rivastigmine patch (generic for Exelon®)
- Rivastigmine capsule (generic for Exelon®)

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Amifampridine (Firdapse/Ruzurgi)

(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

- Firdapse
- Ruzurgi

Approval Criteria

- Manual review on a case-by-case basis
- ≥18 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

- < 18 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 recipient
- 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 tablets

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

NON-PREFERRED AGENTS
- Auvi-Q® 0.1 mg, 0.15 mg, and 0.3 mg
- Epinephrine 0.15 mg and 0.3 mg (generic for Adrenaclick®)
- Epinephrine 0.15 mg and 0.3 mg (non-authorized generic for EpiPen Jr® and EpiPen®)
- Neffy® 2 mg/0.1 ml nasal spray
- Symjepi® 0.15 mg and 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 II Converting Enzyme (ACE) Inhibitors AND Combination Products

PREFERRED

- BENAZEPRIL (generic for LOTENSIN)
- BENAZEPRIL/AMLODIPINE (generic for LOREL)
- 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

- ACCUPRIL
- ACCURETIC
- ALTACE
- CAPTOPRIL/HCTZ (generic for CAPOZIDE)
- ENALAPRIL solution (generic for EPANED)
- EPANED (enalapril solution)
- LOTENSIN
- LOTENSIN HCT
- LOTREL
- MOEXIPRIL (generic for UNIVASC)
- MOEXIPRIL/HCTZ (generic for UNIRETIC)
- PERINDOPRIL (generic for ACEON)
- QBRELIS (lisinopril solution)
- TARKA
- TRANDOLAPRIL (generic for MAVIK)
- TRANDOLAPRIL/VERAPAMIL (generic for TARKA)

- VASOTEC
- ZESTORETIC
- ZESTRIL

NON-PREFERRED WITH CRITERIA STATUS

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

Direct Renin Inhibitors

PREFERRED

- **NONE**

NON-PREFERRED

- ALISKIREN (generic for TEKTURNA)
- TEKTURNA
- TEKTURNA HCT

Angiotensin II Receptor Blockers (ARB) and ARB Combination Products

PREFERRED-

- 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 (generic for DIOVAN)
- VALSARTAN/HCTZ (generic for DIOVAN HCT)
- VALSARTAN/AMLODIPINE (generic for EXFORGE)
- VALSARTAN/AMLODIPINE/HCT (generic for EXFORGE HCT)

PREFFERED AGENTS WITH CRITERIA:

- ENTRESTO (valsartan/sacubitril) – **BRAND PREFERRED**
  - 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 recipient is currently pregnant

NON-PREFERRED ARB and ARB Combination Products

- ATACAND
- ATACAND HCT
- AVALIDE
- AVAPRO
- AZOR
- BENICAR
- BENICAR HCT

- CANDESARTAN (generic for ATACAND)
- CANDESARTAN/HCTZ (generic for ATACAND HCT)
- COZAAR
- DIOVAN
- DIOVAN HCT
- EDARBI
- EDARBYCLOR
- EPROSARTAN (generic for TEVETAN)
- EXFORGE HCT
- HYZAAR
- MICARDIS
- MICARDIS HCT
- OLMESARTAN/HCTZ (generic for BENICAR HCT)
- OLMESARTAN/AMLODIPINE/HCTZ (generic for TRIBENZOR)
- SACUBITRAL/VALSARTAN (generic for ENTRESTO)
- TELMISARTAN (generic for MICARDIS)
- TELMISARTAN/AMLODIPINE (generic for TWYNSTA)
- TELMISARTAN/HCTZ (generic for MICARDIS HCT)

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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

- Eliquis® tablet (apixaban)
- Enoxaparin injection (generic for Lovenox®)
- Pradaxa® capsule (dabigatran) **BRAND ONLY**
- Warfarin tablet (generic for Coumadin®)
- Xarelto® tablet (rivaroxaban)

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
- Dabigatran capsule (generic for Pradaxa®)
- Dalteparin injection (generic for Fragmin®)
- Fondaparinux injection (generic for Arixtra®)
- Lovenox® injection
- Pradaxa pellet pack (dabigatran)
- Savaysa® tablet (edoxaban)
- Xarelto® Suspension (rivaroxaban)

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)
- 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®)

NONPREFERRED ANTICONVULSANT AGENTS

- Aptiom® (eslicarbazepine acetate)
- Banzel® suspension (rufinamide) (BRAND PREFERRED OVER GENERIC when approved)
- Banzel® tablet (rufinamide) (BRAND PREFERRED OVER GENERIC when approved)
- 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)
- 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)
- Gabapentin solution (generic for Neurontin®)**
- 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®)

NONPREFERRED ANTICONVULSANT AGENTS (CONTINUED)

- 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®)
- 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**
- 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 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 ER)
- Duloxetine (generic for Cymbalta)
- Escitalopram oxalate tablet and solution (generic for Lexapro)
- Fluoxetine HCl 10mg, 20mg capsule, 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

- 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 tablets (paroxetine mesylate)
- Phenelzine tablet (generic for Nardil)
- Pristiq ER tablets (desvenlafaxine)
- Prozac capsule (fluoxetine)
- Remeron SolTab and tablet (mirtazapine)
- Savella tablets (milnacipran HCl)
- Sertraline capsule (generic for Zoloft)
- Spravato nasal spray (esketamine) (manual review criteria)
- Tranylcypromine tablet (generic for Parnate)
- Trazodone 300mg tablet
- Trintellix tablets (vortioxetine HBr)
- Venlafaxine ER tablet (generic for Effexor)
- Viibryd tablets (vilazodone)
- Vilazodone HCl tablets (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 resulting from 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 nonpreferred 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

Antidiabetic Agents

(Implemented 01/01/2009)
(Updated 8/12/20)
(Effective 10/1/2020)
(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 PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976

Preferred agents: Alpha Glucosidase Inhibitors

- Acarbose (generic for Precose®)

Non-Preferred agents: Alpha Glucosidase Inhibitors

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

Preferred agents: Amylin Analogues

- None

Non-Preferred agents: Amylin Analogues

- Symlin® (pramlintide)

Preferred agents: DPP-4 Inhibitors (manual review)

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

Non-Preferred agents: DPP-4 Inhibitors

- Alogliptin (generic for Nesina®)
- Alogliptin/metformin (generic for Kazano®)
- Alogliptin/pioglitazone (generic for Oseni®)
- Glyxambi® (linagliptin/empagliflozin)
- Janumet® XR (sitagliptin/metformin extended release)
- Jentadueto® and Jentadueto XR® (linagliptin/metformin)
- Kazano® (alogliptin/metformin)
- Kombiglyze® XR (saxagliptin/metformin ER)
- Nesina® (alogliptin)
- Onglyza® (saxagliptin)
- Oseni® (alogliptin/pioglitazone)
- Qtern® (saxagliptin/dapagliflozin)
- Saxagliptin/metformin ER (generic for Kombiglyze® XR)
- Sitagliptin (generic for Zituvio®)
- Sitagliptin/metformin (generic for Zituvimet®)

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

Preferred agents- GLP-1 Agonists

- ~~Bydureon® pen/vial (exenatide ER)-~~ off market
- Byetta® pen (exenatide)
- Victoza® pen (liraglutide) **– BRAND ONLY**

Point of Sale (POS Approval Criteria for preferred GLP-1 Agonists

- Diagnosis of type 2 diabetes mellitus; AND
  - Metformin claim in the last 90 days; OR
  - Diagnosis of ASCVD
- Medicaid pharmacy profile indicates a paid claim in the last 60 days for a GLP-1 receptor agonist

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

Non-Preferred agents- GLP-1 Agonists

- Adlyxin™ injection (lixisenatide)
- Bydureon® BCise (exenatide ER)
- Exenatide (Byetta®)
- Liraglutide (generic for Victoza®)
- Mounjaro® injection (tirzepatide)
- Ozempic® injection (semaglutide)
- Rybelsus® tablet (semaglutide)
- Soliqua® injection (lixisenatide/insulin glargine)
- Trulicity® pen (dulaglutide)
- Xultophy® injection (insulin degludec/liraglutide)

Insulins – Please see Insulins

Preferred agents - Meglitinides

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

Non-Preferred agents - Meglitinides

- Repaglinide/metformin (generic for Prandimet®)
- Prandin® (repaglinide)
- Starlix® (nateglinide)

Preferred agents - Metformins

- Metformin 500mg (generic for Glucophage®)
- Metformin 850mg (generic for Glucophage®)

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

Non-Preferred agents - Metformins

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

Preferred agents – SGLT-2 Inhibitors

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

Point of Sale (POS) Approval Criteria for preferred SGLT-2 Inhibitors

- Diagnosis of type 2 diabetes mellitus; AND
  - Metformin claim in the last 90 days OR
  - Diagnosis of ASCVD
- Diagnosis of heart failure
- Diagnosis of CKD (Farxiga® and Jardiance® only)
- Medicaid pharmacy profile indicates a paid claim in the last 60 days for a SGLT-2 inhibitor

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

Non-Preferred agents – SGLT-2 Inhibitors

- Bexagliflozin (generic for Brenzavvy®)
- Brenzavvy® (bexagliflozin)
- 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)

Preferred agents-Sulfonylureas

- 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-Sulfonylureas

- Amaryl® (glimepiride)
- Duetact®
- Glimepiride 3 mg tablet
- Glucotrol® /Glucotrol XL® (glipizide)
- Glynase® (glyburide micronized)

Preferred agents-Thiazolidinediones

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

Non- Preferred agents-Thiazolidinediones

- ActoPlus Met®
- Actos® (pioglitazone)
- Avandia® (rosiglitazone)
- Duetact®

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Antiemetic Agents - (HT3 or NK1 Receptor Antagonists)

(Implemented 09/14/2009)
(Updated 08/18/2015)

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 PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

Preferred agents with criteria

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

Non-preferred agents

- Aprepitant (Emend)
- Dolasetron (Anzemet)
- Granisetron (Kytril, Sancuso)
- Netupitant-Palonosetron HCl (Akynzeo)
- Palonosetron HCl (Aloxi)
- Ondansetron 16 mg oral-disintegrating tablet
- Ondansetron 24mg tablet (Zofran)
- Ondansetron 32mg/50ml bag (Zofran)
- Ondansetron 4mg/2ml ampule and syringe (Zofran)
- Ondansetron 4mg/5ml solution (Zofran)
- Ondansetron Soluble Film (Zuplenz)

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)

Prescribers with questions on how to obtain a PA should call 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

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

Non-Preferred Topical Antifungal Agents

- Butenafine 1% cream (Mentax®)
- Ciclopirox 0.77% cream, 1% shampoo (Ciclodan, Loprox)
- Clotrimazole 1% Rx solution
- Clotrimazole-Betamethasone Rx lotion
- Econazole 1% cream, foam
- Ketoconazole 2% cream, foam (Extina® Foam)
- Klayesta® powder
- Luliconazole cream 1% (Luzu™)
- Oxiconazole 1% cream, lotion (Oxistat®)
- Sertaconazole 2% cream (Ertaczo®)
- Sulconazole 1% solution, cream (Exelderm®)
- Miconazole 0.25%/zinc oxide 15%/white petrolatum ointment 81.35% (Vusion® Ointment)
- Naftifine cream and gel (Naftin®)
- Nystatin emollient cream (Pediaderm® AF)
- Nystatin/triamcinolone cream

Non-Preferred Topical Antifungal Agents for Onychomycosis

- ciclopirox 8% topical nail solution (Penlac® Nail Lacquer)
- efinaconazole 10% topical nail solution (Jublia®)
- tavaborole 5% topical nail solution (Kerydin®)

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Antihistamine- Oral (Second-generation)

(Implemented 11//2007)
(updated 2/21/18)
(Effective 4/1/18)

Prescribers with questions on how to obtain a PA should call 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 (Zyrtec)
- Loratadine (Claritin)

Nonpreferred agents

- Acrivastine w/Pseudoephedrine (Semprex-D)
- Desloratidine syrup (Clarinex)
- Cetirizine 5 mg swallow table, 10 mg chewable tablet (Zyrtec)
- Desloratadine tablet (Clarinex)
- Fexofenadine 180 mg tablet (Allegra)
- Levocetirizine (Xyzal)

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Anti-Hyperuricemics

(Implemented 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 products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800- 424-7976.

PREFERRED AGENTS

- Allopurinol tablet
- Colchicine tablet (generic for Colcrys®)
- Probenecid tablet
- Probenecid/colchicine tablet

NONPREFERRED AGENTS

- Colchicine capsule (generic for Mitigare®)
- Colcrys® tablet
- Febuxostat tablet (generic for Uloric®)
- Gloperba (colchicine) solution
- Mitigare® capsule
- Uloric® tablet
- Zyloprim® tablet

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Anti-inflammatory Agents (NSAIDs)

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

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

- Celecoxib (Celebrex)
- Diclofenac sodium 25mg, 50mg, and 75 mg tablet (Voltaren)
- Diclofenac sodium topical (**Voltaren gel 1% only**)
- Ibuprofen 100mg/5ml suspension
- Ibuprofen 400mg, 600mg, 800mg tablets
- Meloxicam 7.5mg and 15mg tablets
- Nabumetone (Relafen)
- Naproxen 250mg, 375mg, 500mg tablets (Naprosyn)
- Naproxen 375mg, 500mg, Enteric coated tablets (EC-Naprosyn)
- Naproxen 275mg, 550mg tablets (Anaprox)

Preferred agent with criteria

- Ketorolac tablet (Toradol)

Nonpreferred agents

- Celebrex (celecoxib)
- Coxanto (oxaprozin)
- Diclofenac epolamine (Flector)
- Diclofenac epolamine (Licart)
- Diclofenac potassium (Cataflam, Zipsor)
- Diclofenac sodium topical **1.5%, 2% and 3% (Pennsaid, Solaraze,etc)**
- Diclofenac sodium/Misoprostol (Arthrotec)
- Diclofenac submicronized (Zorvolex)
- Diflunisal (Dolobid)
- Etodolac (Lodine)
- Fenoprofen (Nalfon)
- Flurbiprofen (Ansaid)
- Ibuprofen 40mg/ml suspension
- Ibuprofen/famotidine (Duexis)
- Indomethacin 75mg SA Capsule
- Indomethacin 20mg, 25mg and 40 mg capsules (Tivorbex)
- Indomethacin 50mg suppository
- Indomethacin 25mg/5ml suspension (Indocin)
- Ketoprofen 200mg extended-release capsule (Oruvail)
- Ketoprofen capsules

- Ketorolac nasal spray (Sprix)Meclofenamate sodium (Meclomen)
- Mefenamic acid (Ponstel)
- Meloxicam tablet, orally disintegrating tablet (QMIIZ)
- Naproxen/Esomeprazole magnesium (Vimovo)
- Naproxen Suspension (Naprosyn)
- Naproxen sodium 375mg and 500mg extended-release tablet (Naprelan)
- Naproxen sodium 750 mg controlled release
- Oxaprozin (Daypro)
- Oxaprozin (Coxanto)
- Piroxicam (Feldene)
- Salsalate (Disalcid)
- Sulindac (Clinoril)
- Tolmetin sodium (Tolectin)

Nonpreferred agents with criteria

- Diclofenac Sodium 3% Gel (Solaraze)
- Naproxen 125mg/ml suspension (Naprosyn suspension)

Approval criteria for nonpreferred agents with criteria

- Diclofenac Sodium 3% Gel (Soloraze)
  Diagnosis of Actinic Keratosis in the past two months
- Naproxen 125mg/ml suspension (Naprosyn suspension)
  < 7 years of age, OR NPO (Appendix A) in the past year.

Denial criteria for preferred agent with criteria

- Ketorolac
  - 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

- Erzofri® (paliperidone palmitate)
- Risperidone ER microspheres (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 prior to approval to assess tolerability with a 2 year look back in Medicaid pharmacy claim history
• 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 90 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 prior to approval to assess tolerability with a 2 year look back in Medicaid pharmacy claim history
• 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 90 days

Aristada® 441mg, 662mg, 882mg and 1064mg
• 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 prior to approval to assess tolerability with a 2 year look back in Medicaid pharmacy claim history
• Initiation of treatment after tolerability has been established requires one of the following: ○ Administer Aristada Initio® 675mg injection and one dose of oral aripiprazole 30mg 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 90 days.

Aristada Initio® 675 mg
• Requires at least two weeks of oral aripiprazole prior to approval to assess tolerability with a 2 year look back in Medicaid pharmacy claim history
• 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 to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

Criterion 2
• Fluphenazine decanoate claim in the last 180 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 to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

Criterion 2
• Haloperidol decanoate claim in the last 45 days

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

Criterion 1
• Request requires adequate treatment of Invega Sustenna® for at least 4 months OR Invega Trinza® for at least one 3-month course

Criterion 2
• Invega Hafyera® claim in the last 7 months

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 to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

Criterion 2
• Invega Sustenna® claim in the last 45 days, Invega Hafyera® in the last 7 months, or Invega Trinza® in the last 120 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 4 months

Criterion 2
• Invega Trinza® claim in the last 120 days, Invega Hafyera® in the last 7 months, or Invega Sustenna® in the last 45 days

Perseris® 90 mg and 120 mg

• Monthly dosing

Criterion 1
• Requires previous history of oral risperidone to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

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 90 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 to assess tolerability with a 2 year look back in Medicaid pharmacy claim history
• 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 90 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 to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

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 90 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 to assess tolerability with a 2 year look back in Medicaid pharmacy claim history

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 Agent(s) with Criteria

- Vraylar® capsule (cariprazine)

Vraylar® will have the following point-of-sale 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

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*)

- Therapeutic Duplication
    - TD with three or more oral antipsychotic agents will deny for new starts

    - TD 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

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 - 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. (Effective 11/8/2011)
    - 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 recipients < 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 – 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 recipients < 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 recipients < 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 LDl cholesterol)

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Aprocitentan (Tryvio™) 12.5 mg tablet

(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 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 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

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Apremilast (Otezla)

(Implemented 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 manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Otezla (apremilast) is Manual Review for Behçet's Disease only. For other approval criteria please see: Targeted Immune Modulators

Approval Criteria for Behçet's Disease:

- 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
- Prescriber 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 prescriber to submit updated notes with documentation of a positive response to therapy

QUANTITY EDITS:

- #62/31 days

Asfotase Alfa (Strensiq) Injection

(Implemented 07/13/2016)

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.

Drugs that require manual review for prior authorization

- Strensiq

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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)
• Eucrisa® ointment (crisaborole)
• Opzelura®* cream (ruxolitinib)
• Pimecrolimus cream (generic for Elidel®)
• Protopic® ointment (tacrolimus)
• Rinvoq®* tablet (upadacitinib)

APPROVAL CRITERIA FOR ATOPIC DERMATITIS FOR 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)
    - o 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
    - o At least one trial of a TCI over a minimum of 30 days (i.e., tacrolimus, pimecrolimus)
• Prescriber must submit **ALL** of the following:
    - o Current chart notes
    - o Documentation of previous therapies
    - o Current IGA score
    - o 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 (Adbry®, Cibinqo®, Dupixent®, 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):
    o Baseline impacted body surface area (BSA) ≥ 10%
    o Baseline Eczema Area and Severity Index (EASI) total score of ≥ 16
    o Baseline weekly averaged peak pruritis Numeric Rating Scale (NRS) ≥ 7
    o Baseline Investigator's Global Assessment (IGA) score ≥ 3
    o 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:
    o 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**
    o 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:
    o Current chart notes
    o Documentation of previous therapies with trial length of each medication
    o BSA prior to topical/systemic therapies and current impacted BSA
    o Baseline EASI, NRS, IGA and/or SCORAD and updated score with previous treatment
    o Drug claims data or retail pharmacy printout if the drug claims are not available in Medicaid drug claims history
    o 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:
    - o Decrease in severity scores; OR
    - o Decrease in BSA impacted; OR
    - o Decrease in need for systemic or topical rescue treatment
- Prescriber must submit:
    - o Current chart notes
    - o Current BSA and EASI, NRS, IGA or SCORAD (compared to baseline severity score)

Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder (ADD/ADHD) Agents for Children (Less than 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 INTUNIVE ER)
- METHYLPHENIDATE TABLET (generic for METHYLIN, RITALIN IR)
- METHYLPHENIDATE ER TABLET (generic for CONCERTA)
- VYVANSE CHEW TABLET **(BRAND ONLY)**
- VYVANSE CAPSULE **(BRAND ONLY)**

Nonpreferred 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 TABLETS
- JORNAY PM CAPSULE
- KAPVAY ER TABLET
- LISDEXAMFETAMINE CAPSULES (generic for VYVANSE)
- LISDEXAMFETAMINE CHEWABLE TABLETS (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 TABLETS
- 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 TABLETS (generic for ADDERALL IR)
- ATOMOXETINE CAPSULE (generic for STRATERRA)
- CLONIDINE IR TABLET (generic for CATAPRES)
- CLONIDINE ER TABLET (generic for KAPVAY ER)
- CONCERTA TABLET
- DAYTRANA PATCH **(BRAND ONLY)**
- DEXMETHYLPHENIDATE ER CAPSULE (generic for FOCALIN XR)
- DESMETHYLPHENIDATE 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 INTUNIVE 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 SUSPENSION)
- 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)
- DYNAVEL XR SUSPENSION
- DYNAVEL XR TABLET
- EVEKEO TABLETS
- EVEKEO ODT
- INTUNIV ER TABLETS
- JORNAY PM CAPSULES
- KAPVAY ER TABLET
- LISDEXAMFETAMINE CAPSULES (generic for VYVANSE)
- LISDEXAMFETAMINE CHEWABLE TABLETS (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 ER CAPSULES
- QUILLICHEW ER CHEWABLE TABLETS
- 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 recipients ≥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 (Ridaura) Capsule

(Implemented 09/18/2013)

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 require manual review for prior authorization

- Ridaura Capsule

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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:

- Recipient must be ≥18 years of age; AND
- Recipient 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
- Recipient had previous therapy with an immunosuppressant (i.e., rituximab or cyclophosphamide) and corticosteroids based on treatment guidelines; AND
- Recipient 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:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official
- Compendia; OR
- Recipient has severe hepatic impairment OR AST/ALT >5X ULN OR AST/ALT >3X ULN with bilirubin >2X ULN; OR
- Recipient 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
- Recipient develops reactivation of HBV while on TAVNEOS; OR
- Recipient has an active, serious infection including localized infections; OR
- Recipient is pregnant or breastfeeding

QUANTITY EDITS:

- #180 capsules/ 30 days

Azithromycin (Azithromycin Powder Packets)

(Implemented 4/12/2011)

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 manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization:

- Azithromycin 1 gm powder packets

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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 manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

APPROVAL CRITERIA:

- Beneficiary is age 12 years or older;
- Beneficiary has positive flu test who have been symptomatic for no more than 48 hours;
- Prescriber to submit beneficiary's weight at time of PA request;
- Prescriber to submit documentation to substantiate medical necessity of beneficiary receiving XOFLUZA™ over TAMIFLU® (oseltamivir) that does not require a PA

DENIAL CRITERIA:

- Beneficiary does not have active flu;
- Beneficiary is < 12 years of age;
- Quantity requested is greater than one dose;

QUANTITY LIMIT:

- 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, or
  - XOFLUZA™ 40 mg tablet, packaged as 2 tablets for single dose of 80 mg

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Bedaquiline Fumarate Tablet (Sirturo)

(Implemented 12/10/2013)

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 require manual review for prior authorization

- Sirturo

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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
- Recipient 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 Recipient 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 recipient, serum potassium levels, and baseline estimated glomerular filtration rate (eGFR) for LN recipient. 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 REEQUIREMENTS:

- 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

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®)
- Entadfi® (finasteride/tadalafil) capsule
- Flomax® capsule (tamsulosin)
- Jalyn® capsule (dutasteride/tamsulosin)
- Proscar® tablet (finasteride)
- Rapaflo® capsule (silodosin)
- Silodosin capsule (generic for Rapaflo®)
- Tadalafil tablet (generic for Cialis®)‡

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

‡Denial for diagnosis of erectile dysfunction

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Benznidazole Tablet and Nifurtimox tablet (Lampit)

(Implemented 03/01/2018)

(Updated 9/19/2020)

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.

Drugs that require manual review for prior authorization

- Benznidazole 12.5mg Tablet
- Benznidazole 100mg Tablet
- Lampit 30mg
- Lampit 120mg

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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 anyage.

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Beremagene geperpavec (Vyjuvek™) gel

(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

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

- Recipient must be ≥12 years of age; AND
- Recipient must have a laboratory diagnosis of Type 1 or Type 2 hereditary angioedema OR a diagnosis consistent with FDA indications; AND
- Recipient 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; AN
    - Initial PA maximum 3-month trial if approved

Denial Criteria

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Prescriber intends for recipient to use for the treatment of acute attacks of HAE; OR
- Prescriber requests a dose of >150 mg per day; OR
- Recipient 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 (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 tablets (generic for Betapace)

Nonpreferred agents

- Betapace
- Betaxolone (generic for Kerlone)
- Bystolic
- Carvedilol phosphate CR capsule (Coreg CR)
- Coreg
- Coreg CR
- Corgard
- Hemangeol (propranolol) suspension
- Inderal LA (propranolol ER)
- Labetalol HCL 400 mg (generic for Normodyne)
- Kapspargo (metoprolol) sprinkle
- Lopressor
- 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

- Tenormin
- Timolol Maleate (generic for Blocadren)
- Toprol XL
- Ziac

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Betaine (Cystadane) Powder for Oral Solution

(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 (Zinplava) Solution, injection for IV infusion

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

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Birch triterpenes (Filsuvez) 10% gel

(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 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 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.

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 1/1/17)
(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 Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Short Acting Beta Agonists agents

- 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® (albuterol) HFA- **BRAND ONLY**
- Xopenex® HFA (levalbuterol) - **BRAND ONLY**

Nonpreferred Short Acting Beta Agonists agents

- 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 agents with Criteria

- Serevent Diskus® (salmeterol xiafoate disk with device)

Non-Preferred Long-Acting Beta-Agonists agents

- 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

- 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 recipient is ≥ 40 years of age

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)
- Bevespi Aerosphere® (formoterol/glycopyrrolate)
- Stiolto Respimat® (tiotropium/olodaterol)

Non-Preferred Agents

- Duaklir Pressair® (aclidinium/formoterol)

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 ICS/LABA 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 Approval Criteria for Symbicort®, Dulera®, Advair HFA/Diskus®, and AirDuo RespiClick®

- **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 last120 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 at this time

Non-Preferred agents

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

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Budesonide Extended-Release 9mg (Uceris)

(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 state pharmacy unit at 1-800-424-5851.

Approval criteria

- Submitted Diagnosis of Ulcerative Colitis in the past 2 years

Additional criteria

Quantity limits apply

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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 state pharmacy unit at 1-800-424-5851.

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:

- Recipient must be ≥18 years of age; AND
- Must be prescribed by or in consultation with a nephrologist; AND
- Recipient must have a diagnosis of immunoglobulin A nephropathy (IgAN) with proteinuria OR a diagnosis consistent with the FDA approved indication; AND
- Recipient 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
- Recipient must be on a stable dose of maximally tolerated RAS inhibitor unless contraindicated for at least 90 days; AND
- Recipient must be prescribed in combination with an ACEi or ARB; AND
- Recipient must have trialed and failed corticosteroids; AND
- Recipient 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:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient 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 (Crysvita®) 10 mg, 20 mg, and 30 mg injection

(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.

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

Recipient must be at least 12 Years of Age or greater

Quantity Edit

- 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 93 units per 31 days' supply
  Additional information listed under Exemptions
- The butalbital products that contain 750mg 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

Exemptions

- Patients who have a diagnosis of malignant cancer in the past 12months:
  - 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.

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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.

Drugs that require manual review for prior authorization

- Berinert

Approval Criteria

- 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.

Drugs that require manual review for prior authorization

- Cinryze

Approval criteria

- 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.

Drugs that require manual review for prior authorization

- Haegarda

Approval criteria

- 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 manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drug Dovonex
Sorilux Vectical

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 potency category.

Approval criteria (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 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

Link to Memorandum

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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 PDL drugs may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred agents- Dihydropyridine and Combination Products

- 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- Dihydropyridine AND Combination Products

- AMLODIPINE/ATORVASTATIN (generic for CADUET)
- AMLODIPINE/OLMESARTAN/HCTZ (generic for TRIBENZOR)
- EXFORGE
- EXFORGE HCT
- FELODIPINE ER (generic for PLENDIL)
- ISRADIPINE (generic for DYNACIRC)
- ISRADIPINE ER (generic for DYNACIRC CR)
- KATERZIA suspension
- LEVAMLODIPINE (generic for CONJUPRI)
- NICARDIPINE (generic for CARDENE)
- NORLIQVA (amlodipine suspension)
- NIMODIPINE (generic for NYMALIZE)
- NISOLDIPINE ER (generic for SULAR) •
- NORVASC
- NYMALIZE SOLUTION
- PROCARDIA XL

Preferred agents- Non-Dihydropyridine AND Combination Products

- DILTIAZEM HCl ER capsule (generic for DILACOR XR, TIAZAC)
- DILTIAZEM TABLET (generic for CARDIZEM)
- VERAPAMIL tablet (generic for CALAN)
- VERAPAMIL ER tablet ((generic for CALAN)

Non-Preferred agents- Non-Dihydropyridine AND Combination Products

- CALAN SR
- CARDIZEM, CARDIZEM CD, LA
- DILTIAZEM CD, ER, LA, XR, XT (generic for CARDIZEM AND MATZIM)
- MATZIM LA
- TIAZAC
- VERAPAMIL ER CAPSULES (generic for VERELAN, VERELAN PM
- VERELAN
- VERELAN PM

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Cannabidiol (CBD) Extract – (Epidiolex Oral Solution)

(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:

- The starting dosage is 2.5 mg/kg twice daily (5 mg/kg/day). After one week, the dosage can be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day)
- If further reduction of seizures is necessary, dose may be increased to a maximum of 10 mg/kg twice daily (20 mg/kg/day)
- 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 (Qutenza®) 8% kit

(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
- Recipient 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.
- Recipient 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)
- Recipients being treated for PHN pain must have continued pain at least 6 months after healing of herpes zoster rash
- Recipient 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:

- Recipient must be ≥ 2 years of age; AND
- Recipient must have a diagnosis of neurotrophic keratitis OR a diagnosis consistent with FDA approved indication or Compendia support; AND
- Recipient 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

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)

Cholic Acid (Cholbam)

(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

- Cholbam

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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)

NONPREFERRED AGENTS

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

Approval criteria for Amitiza

Criterion 1:

- ≥ 18 years of age, AND
- Paid drug claim for Lubiprostone (Amitiza) within the past 60 days

Criterion 2:

- Recipient must be ≥ 18 years of age; AND
- Recipient'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, MOVANTIK tablet, SYMPROIC tablet, TRULANCE tablet, ZELNORM tablet, AMITIZA capsule of different strengths, or new agents to market.

Denial criteria for Amitiza

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

Approval Criteria for Linzess:

Criterion 1:

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

Criterion 2:

- Recipient must be ≥ 6 years of age for Linzess 72mcg and ≥ 18 years old for Linzess 145mcg and 290mcg; AND
- Recipient'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, AMITIZA capsule, or new agents to market.

Denial Criteria for Linzess:

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

Approval Criteria for Movantik:

Criterion 1:

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

Criterion 2:

- Recipient must be ≥ 18 years of age; AND
- Recipient'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, AMITIZA capsule of different strengths, or new agents to market; AND
- Recipient has a paid claim for an opioid (includes buprenorphine) in the last 60 days.

Denial Criteria for Movantik

- Absence of approval criteria; OR
- Recipient has a history of mechanical gastrointestinal obstruction; OR
- Recipient is < 18 years of age; OR
- Recipient 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 > 10mg/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 on the basis of 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 for:
  "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 (Xaciato) 2% gel

(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:

- Recipient is a female 12 years of age and older OR updated age allowance if indication changes
- Recipient 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 5000mcg/10ml
- Clonidine HCl PF vials 1000mcg/10ml

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Colony Stimulating Factors

(Reviewed 5/10/18)
(Effective 7/1/18)
(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 (pegrilgrastim-pbbk) syringe
- NEUPOGEN (filgrastim) vial and syringe

NONPREFERRED AGENTS

- FULPHILA (pegfilgrastim-jmbd) syringe
- GRANIX (tbo-filgrastim) syringe
- LEUKINE (sargramostim) vial
- NEULASTA (pegfilgrastim) syringe
- NEULASTA ONPRO® KIT (pegfilgrastim)
- NIVESTYM (filgrastim-aafi)
- NYVEPRIA (pegfilgrastim-apgf)
- RELEUKO (filgrastim-ayow)
- ROLVEDON (eflapegrastim-xnst) syringe
- STIMUFEND (pegfilgrastim-fpgk)
- UDENYCA (pegfilgrastim -cbqv) syringe and autoinjector
- ZARXIO (filgrastim-sndz) syringe
- ZIEXTENZO (pegfilgrastim-bmez) syringe

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)
- 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®)
- Pulmicort Respules® (budesonide)

Non-preferred agents WITH criteria

- Fluticasone HFA (generic for Flovent HFA®)

Approval criteria for Budesonide Respules (Point-of-Sale 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 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 Fluticasone HFA (Point-of-Sale 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 7/1/17)
(Updated 7/1/2020)

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.

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 0.05% solution, 50ml
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
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% lotion (Impeklo®)
Clobetasol propionate 0.05% shampoo
Clobetasol propionate 0.05% spray
Desoximetasone 0.25% spray
Diflorasone diacetate 0.05% ointment
Halobetasol propionate 0.05% foam (Lexette™)
Halobetasol propionate 0.01% lotion (Bryhali ™)
Halobetasol propionate 0.05% lotion
Halobetasol propionate 0.05% ointment, 15 gm, 50 gm

Potency Class 2 – Potent, *Preferred Status* only for package sizes noted:
Betamethasone dipropionate Aug. 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:
Amcinonide 0.1% ointment
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 0.1% ointment

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
Amcinonide 0.1% lotion
Betamethasone dipropionate 0.05% cream (not augmented)
Betamethasone dipropionate 0.05% ointment (not augmented)
Betamethasone dipropionate 0.05% spray emulsion (not augmented)
Betamethasone valerate 0.12% foam
Fluocinonide 0.05% emollient cream
Fluticasone propionate 0.005% ointment
Triamcinolone 0.1% ointment **454 gm**

Potency Class 4 – Mid Strength, *Preferred Status* only for package sizes noted:
Fluocinolone 0.025% ointment, 15 gm, 60 gm, 120 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, 28.4 gm, 30 gm, 45 gm, 80 gm, 85.2 gm

Potency Class 4 – Mid Strength, *Non-Preferred Status* for all package sizes unless otherwise noted:
Clocortolone pivalate 0.1% cream and cream pump
Desoximetasone 0.05% cream
Desoximetasone 0.05% ointment
Flurandrenolide 0.05% ointment
Hydrocortisone valerate 0.2% ointment
Triamcinolone 0.1% cream, **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, 120 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:
Betamethasone valerate 0.1% lotion
Desonide 0.05% lotion
Desonide 0.05% ointment
Fluocinolone shampoo
Flurandrenolide 0.05% cream
Flurandrenolide 0.05% lotion
Flurandrenolide 4 mcg/sq. cm tape, small and large size
Fluticasone propionate 0.05% lotion
Hydrocortisone butyrate 0.1% cream
Hydrocortisone butyrate 0.1% cream emollient
Hydrocortisone butyrate 0.1% ointment
Hydrocortisone butyrate 0.1% solution
Hydrocortisone valerate 0.2% cream
Hydrocortisone probutate 0.1% cream
Prednicarbate 0.1% cream emollient
Prednicarbate 0.1% ointment
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
Desonide 0.05% gel
Fluocinolone scalp/body oil 0.01%
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 0.5% oint (covered OTC), 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**
Hydrocortisone 1% ointment, **453.6 gm**
Hydrocortisone 2.5% cream **453.6 gm**
Hydrocortisone 2.5% ointment, **453.6 gm, 454 gm**
Hydrocortisone 1% ointment in absorbase
Hydrocortisone 2.5% lotion
Hydrocortisone 2.5% solution

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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

- Recipient must be ≤ 2 years of age; **AND**
- Recipient 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**
- Recipient 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 timeof discharge with specific taper directions; **AND**
- PA will be approved at the time of discharge for the amount needed for completion of the taper. Recipients cannot fill Acthar as a pharmacy benefit and use during hospitalization.

Denial Criteria:

- Recipient 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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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 : Approve > 2 years of age

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Cysteamine 0.44% and 0.37% Ophthalmic Drop (Cystaran, Cystadrops)

(Implemented 12/10/2013)

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 require manual review for prior authorization

- Cystaran Ophthalmic Drop
- Cystadrops Ophthalmic Drop

Additional criteria

Quantity limits apply

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Cysteamine DR Capsule (Procysbi)

(Implemented 03/18/2014)

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

- Procysbi 25mg DR Capsule
- Procysbi 75mg DR Capsule

Additional criteria

Quantity limits apply

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Cystic Fibrosis Transmembrane Conductance Regulator Agents (CFTR) – 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 manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

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 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 (Voydeya™) 50 mg and 100 mg tablet

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

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Deferasirox Tablet (Jadenu)

(Implemented 04/13/2015)

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.

Drugs that require manual review for prior authorization

- Jadenu

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Deferiprone Tablet (Ferriprox)

(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 manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Ferriprox tablet

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Deflazacort (Emflaza)

(Implemented 4/19/2017)
(Updated 7/18/2018)
(Updated 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 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:

- 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

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Delafloxacin Meglumine (Baxdela)

(Implemented 03/14/2018)

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.

Drugs that require manual review for prior authorization

- Baxdela 450mg Tablet
- Baxdela 300mg Vial

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Denosumab- (Xgeva)

(Implemented 01/21/2011)

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 require manual review for prior authorization

- Xgeva

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Desmopressin (DDAVP) Nasal Spray and Solution

(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 tablets (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.

Drugs that require manual review for prior authorization

- Nocdurna®

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 LIMIT and other claim edits:

- 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.

Drugs that require manual review for prior authorization

- Ryclora™

APPROVAL CRITERIA:

- 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

(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 HBr/Quinidine Capsule (Nuedexta)

(Implemented 06/21/2011)

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 require manual review for prior authorization

- Nuedexta capsule

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Dichlorphenamide (Keveyis)

(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 manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Keveyis Tablet
- Dichlorphenamide tablet

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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 > two claims for a steroidal product (Class 5 or higher) in the past 60 days

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Doxycycline hyclate (Lymepak™) 100 mg tablet

(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 is diagnosed with early Lyme disease (as evidenced by erythema migrans) due to *Borrelia burgdorferi* **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 infectious disease specialist
- Beneficiary should not be approved with any of the following:
    - Doesn't meet the minimum age and weight per the package insert
    - Medical necessity over generic doxycycline was not established
- Prescriber must submit the following:
    - Current chart notes with rationale for the Lyme disease diagnosis
    - Culture report confirming diagnosis of Lyme disease
    - Medical necessity over generic doxycycline tablets or capsules

QUANTITY EDITS:

- #42 per 21 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 (Periostat®)
- Doxycycline hyclate 50 mg capsule (Vibramycin®)
- Doxycycline hyclate 100 mg capsule (Vibramycin®)
- Doxycycline hyclate 100 mg tablet (Vibra-tab®)
- Doxycycline monohydrate 50 mg capsule (Monodox®)
- Doxycycline monohydrate 100 mg capsule (Monodox®)
- Minocycline HCl 50 mg capsule (Minocin®)
- Minocycline HCl 75 mg capsule (Dynacin®)
- Minocycline HCl 100 mg capsule (Minocin®)

Drugs that require manual PA

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

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Doxylamine Succinate and Pyridoxine (Diclegis DR 10- 10)

(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 Approval Criteria

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

QUANTITY EDITS:

- #124/31 days

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Doxylamine Succinate and 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.

Bonjesta Criteria

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

QUANTITY EDITS:

- #62/31 days

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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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Droxidopa (Northera) Capsule

(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.

Drugs that require manual review for prior authorization

- Northera
- Droxidopa

Elafibranor (Iqirvo®) Tablet

(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

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Elagolix (Orilissa and Oriahnn) Tablet

(Implemented 01/01/2019)

(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.

APPROVAL CRITERIA for both ORILISSA and ORIAHNN unless specified:

- Recipient must be ≥ 18 years of age; AND
- Recipient has a diagnosis of moderate to severe pain associated with endometriosis for ORILISSA requests OR a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas/fibroids for ORIAHNN requests OR a diagnosis consistent with FDA indications; AND
- Recipient must be premenopausal; AND
- Attestation that recipient of reproductive potential will use effective non-hormonal contraception during treatment and for 1 week after discontinuing therapy; AND
- Recent dual-energy X-ray absorptiometry (DXA) scan results for documentation of baseline bone mineral density for patients at high risk of osteoporosis. Examples of high-risk patients include but are not limited to the following:
    - History of low-trauma fracture
    - Taking other medications that may decrease BMD (i.e., corticosteroids, anticonvulsants, PPIs)
    - Parent or sibling with osteoporosis
- Documentation of negative pregnancy status by one of the following:
    - Current negative pregnancy test results in patient with reproductive potential; OR
    - Documentation of beginning medication within 7 days of onset of menses; OR
    - Documentation of tubal ligation

Provider must submit the following for ORILISSA requests:

- Current chart notes documenting symptom history, all previous treatments for endometriosis, and that the pelvic pain is not due to other causes; AND
- Current labs including CBC and LFTs; AND
- Confirmation of endometriosis by pelvic exam results AND at least one of the following:
    - Transvaginal ultrasound; OR
    - Magnetic Resonance Imaging; OR
    - Laparoscopy or laparotomy; OR
    - Biopsy report confirming diagnosis.
- Documentation that recipient has tried and failed at least 2 medications in the following drug classes with at least a 3-month history of each:
    - NSAID and/or acetaminophen usage
    - Contraceptives (Combined estrogen-progestin treatments include combined oral

contraceptive pills, transdermal patches, and vaginal rings)
    - Progesterone-only therapy (e.g., medroxyprogesterone, norethindrone, dienogest)
    - Intrauterine device
    - Letter outlining the medical necessity of ORILISSA over other treatment options (i.e., OTC pain medications, hormonal contraception, progestin therapy, and surgery); AND
- Recipient must use the lowest effective dose possible but may titrate taking into account severity of symptoms
- Documentation of initial starting dose from one of the following:
    - 150 mg once daily for 24 months--Recipient has no hepatic impairment or dyspareunia
    - 200 mg twice daily for 6 months—Recipient has dyspareunia
    - 150 mg once daily for 6 months—Recipient has moderate hepatic impairment (ChildPugh B)

Provider must submit the following for ORIAHNN requests:

- Current chart notes documenting symptom history and all previous treatments for uterine leiomyomas/fibroids with heavy menstrual bleeding/painful menstrual cycles; AND
- Current labs including CBC and LFTs; AND
- Confirmation of uterine fibroids by pelvic exam results AND at least one of the following:
    - Transabdominal or transvaginal ultrasound; OR
    - Magnetic Resonance Imaging; OR
    - Computerized Tomography scan; OR
    - Hysterosalpingogram or sonohysterogram; OR
    - Laparoscopy or hysteroscopy
- Letter outlining the medical necessity of ORIAHNN over other treatment options (i.e., OTC pain medications, hormonal contraception, IUD, and surgery); AND
- Documentation that recipient has tried and failed at least 2 medications in the following drug classes with at least a 3-month history of each:
    - NSAID and/or acetaminophen usage
    - Contraceptives (Combined estrogen-progestin treatments include combined oral contraceptive pills, transdermal patches, or vaginal rings)
    - Progesterone-only therapy (e.g., medroxyprogesterone, norethindrone, dienogest)
    - Intrauterine device
    - Tranexamic acid

DENIAL CRITERIA for both ORILISSA and ORIAHNN unless specified

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient is postmenopausal; OR
- Recipient has a diagnosis of osteoporosis or osteopenia (T-score < -1.0 SD); OR
- Recipient has history of major depression or PTSD in last 2 years OR history of major psychiatric disorder (i.e., schizophrenia or bipolar) OR history of suicide attempt in the last year; OR
- Recipient is pregnant; OR
- Recipient has severe hepatic impairment (Child-Pugh C), and dose modifications may be needed for moderate hepatic impairment; OR
- Recipient requires concomitant use of strong organic anion transporting polypeptide

(OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil); OR

- Prescriber requests for > 24 months of treatment for ORIAHNN and ORILISSA patients with no coexisting conditions; requests for > 6 months of treatment for ORILISSA patients with either dyspareunia or moderate hepatic impairment; OR
- ORILISSA recipient has chronic pelvic pain that is not caused by endometriosis (e.g., pelvic inflammatory disease, inflammatory bowel disease, ovarian cysts); OR
- ORIAHNN recipient with any of the following:
    - Over 35 years of age and currently smokes; OR
    - History of breast cancer or other hormonally-sensitive malignancies; OR
    - History of or high risk for arterial, venous thrombotic or thromboembolic disorder OR
    - Deep vein thrombosis or pulmonary embolism; OR
    - Vascular disease; OR
    - Thrombogenic valvular or thrombogenic rhythm disease of the heart; OR
    - Inherited or acquired hypercoagulopathies; OR
    - Uncontrolled hypertension; OR
    - Headaches with focal neurological symptoms or have migraine headaches with aura (over 35 years of age); OR
    - History of heavy bleeding associated with uterine fibroids that has not caused anemia (hemoglobin level ≤ 12 g/dL); OR
    - Undiagnosed abnormal uterine bleeding

QUANTITY EDITS:

- ORILISSA • 150 mg--#28/28 days (max of 24 months)
    - 200 mg--#56/28 days (max of 6 months)
- ORIAHNN 300-1-0.5 mg/ 300 mg • #56/28 (max of 24 months)

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Eliglustat (Cerdelga) Capsule

(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.

Drugs that require manual PA

- Eliglustat (Cerdelga) Capsule

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Ensifentrine (Ohtuvayre™) inhalation suspension

(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 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

QUANTITY EDITS:

- #60 ampules (1 carton)/30 days

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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:

- Flovent (fluticasone)—no point-of-sale criteria required for EoE
- Budesonide Respules
    - Criteria 1: Recipient < 4 years of age (maximum dose is 2 mg/day) OR
    - Criteria 2: Regardless of age, recipient 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 Edits 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

- 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

Eplontersen sodium (Wainua) 45 mg/0.8 mL injection

(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

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 treatment resistant depression (TRD) or have depressive symptoms with major depressive disorder with acute suicidal ideation or behavior **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary must have failed treatment with a minimum of THREE (3) separate therapeutic trials including antidepressants from at least TWO (2) different drug classes (SSRI, SNRI and bupropion) as well as at least ONE (1) 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 (8) weeks EACH for the nonconcurrent monotherapies at maximally tolerated doses
- Beneficiary's profile must indicate a current fill of oral antidepressant at maximally tolerated dose and must remain on concurrent oral antidepressant therapy
- 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 should not be approved or continue on this therapy with any of the following:
    - Pregnant or breastfeeding
    - Active moderate to severe substance or alcohol use disorder
    - Has one of the following contraindications
        - Aneurysmal vascular disease
        - History of intracerebral hemorrhage
        - Hypersensitivity to esketamine, ketamine or any of the components of the medication
- 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 event during treatment session (i.e., access to emergency care)
- Initial approval for 4 weeks only

QUANTITY EDITS:

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

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

Non-preferred Agents

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

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.

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)

Nonpreferred 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)

Nonpreferred 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 nonpreferred agents with criteria

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 LIMITS:

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

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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 (Vowst™) capsules

(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:
  - o Prescribed concomitant antibacterial therapy
  - o Does not meet the requirements for recurrent CDI
  - o Has not been treated with either vancomycin or fidaxomicin

• Prescriber must submit **ALL** of the following:
  - o Current chart notes
  - o Documentation of treatment for previous CDI episodes
  - o Previous laboratory assay results noting *C difficile*
  - o Medical necessity over vancomycin and fidaxomicin if have not been tried and failed

• PA for 1 claim

QUANTITY EDITS:

#12 per claim

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

- Recipient must be ≥ 2 and ≤ 18 years of age; AND
- Recipient 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 recipient must all be enrolled in the FINTEPLA REMS program; AND
- Recipient 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 recipients NOT taking stiripentol is 0.35 mg/kg twice daily (26 mg per day), and maximum dose for recipients 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 o
    - 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

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

QUANTITY EDITS:

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

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Ferric maltol (Accrufer) 30 mg capsule

(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

Fezolinetant (Veozah™) 45mg tablet

(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:
    o Spontaneous amenorrhea for ≥ 12 consecutive months
    o Spontaneous amenorrhea for ≥ 6 months with biochemical criteria of menopause (follicle-stimulating hormone [FSH] > 40 IU/L); or
    o 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:
    o Has cirrhosis
    o Has severe renal impairment or end-stage renal disease (eGFR < 30 mL/min/1.73m2)
    o Requires concomitant use with CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine)
• Prescriber must submit **ALL** of the following:
    o Current chart notes
    o Current labs including FSH level, LFTs, and CMP
    o Duration of symptoms
    o 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:

- Recipient must be ≥ 18 years of age; AND
- Recipient must have a diagnosis of Type 2 diabetes mellitus and chronic kidney disease OR a diagnosis consistent with FDA indications; AND
- Recipient 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/1.73m2 and diabetic retinopathy OR
  - UACR of ≥ 300 mg/g and eGFR 25-75 mL/min/1.73m2
- Recipient 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
- Recipient must have tried and failed an aldosterone inhibitor unless contraindicated; AND
- Recipient must be a non-smoker or participating in a tobacco cessation program; AND
- Recipient 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:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official
- Compendia; OR
- Recipient has eGFR < 25 mL/min/1.73m2 OR
- Recipient's baseline serum potassium is > 5 mEq/L; OR
- Recipient is receiving concomitant strong CYP3A4 inhibitors (e.g., fluconazole) and strong or moderate CYP3A4 inducers (e.g., efavirenz, rifampicin); OR
- Recipient has been diagnosed with adrenal insufficiency (Addison's disease)

QUANTITY EDITS:

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

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

- >/= 18 years of age, AND
- At least 1 paid claim in Medicaid history for Vancomycin (oral or injectable compounded for oral use) in the previous 10-30 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 EDITS:

- 1 tube per 31 days

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Fluorouracil Solution/Cream (Efudex)

(Implemented 06/21/2011)
(Updated 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 for Fluorouracil 2% Solution:

- Diagnosis of Actinic Keratosis in Medicaid history in the past 2months, 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], OR

Approval for Fluorouracil 4% Cream:

- Diagnosis of Actinic Keratosis in Medicaid history in the past 2months, 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], OR

Approval 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], OR

Additional criteria Quantity limits apply

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Fluorouracil Cream (Carac 0.5%)

(Updated 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.

Drug that requires manual review for prior authorization

- Fluorouracil 0.5% Cream (Carac)

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Furosemide (Furoscix®) 80mg/mL injection

(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 New York Heart Association (NYHA) Class III chronic heart failure and being treated for congestion due to fluid overload **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 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)
- 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)
- Beneficiary must have had recent renal lab work done
- Prescriber must submit **ALL** of 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 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

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 Prime Therapeutics State Government Solutions at1-800-424-7976.

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 3600mg per day.
- For Gralise, limit to 1800mg per day
- For Horizant, limit to 1200mg per day.

QUANTITY EDITS:

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

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 these products may be faxed to Prime Therapeutics State Government Solutions at 1-800-424-7976.

APPROVAL CRITERIA:

- Recipient must be ≥2 years of age
- Recipient 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
- Recipient's seizures are refractory to current antiepileptic therapy with at least 2 previous trials with different MOA
- Recipients 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 recipient/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)

Glaucoma Agents

(Implemented 7/1/17)

(Updated 7/1/2020)

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 Status only for strengths and package sizes noted:

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

Non-Preferred Status, all package sizes unless otherwise noted:

- Alphagan P® (brimonidine) 0.1% drops
- Apraclonidine 0.5%, 1% solution drops
- Betaxolol 0.25% and 0.5% solution drops
- Betimol® (timolol) 0.5% drops
- Bimatoprost 0.03% solution drops
- Brimonidine (generic for Alphagan/Alphagan P) 0.1%, 0.15% 0.2% drops
- Brimonidine 0.2%/ timolol 0.5% (generic for Combigan®)
- Brinzolamide (AZOPT®) suspension drops 1%
- Cosopt® PF (dorzolamide 2% /timolol) drops
- Dorzolamide 2% /timolol 0.5% (generic for Cosopt® PF) solution drops
- Echothiophate (PHOSPHOLINE IODIDE) kit
- Istalol® (timolol maleate) 0.5% drops
- Iyuzeh® (latanoprost) 0.005% drops
- Metipranolol 0.3% solution drops
- Pilocarpine 1%, 2%, 4% solution drops
- Simbrinza® (Brimonidine 1%/ brinzolamide 0.2%) suspension drops, 8ml
- Tafluprost (generic for Zioptan®) drops 0.0015%
- Timolol (generic for Betimol®) 0.5% drops
- Timolol maleate (generic for Istalol®) 0.5% drops
- Timolol gel forming solution 0.25%, 0.5% (generic for Timoptic-XE®)

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

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Glutamine Powder (Endari)

(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

- Endari® Powder (l-glutamine)
- L-Glutamine Powder

Additional criteria

- Age limits apply
- Quantity limits apply

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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 (Cuvposa)

Drugs that require manual review for prior authorization

- Glycopyrrolate 0.2 mg/ml vial

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

(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 Drugs 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)

Criteria for Preferred Growth Hormones:
In children, we may need to question continuation when growth velocity is ≤ 2.5 cm/year.

Criterion 1:

- Recipient < 18 years of age
- Recipient 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
    - 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:

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

Criterion 3:

- Recipient < 18 years of age
- Recipient has abnormal growth velocity and height below the mean for gender and age
- Recipient 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 recipient 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:

- Recipient > 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:

- Recipient > 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.

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Hemophilia A/B Products

(Implemented 03/01/2018)
(Updated 8/16/2019)
(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.

Drug that requires a manual review for prior authorization

- Feiba
- Hemlibra
- NovoSeven RT
- Sevenfact

APPROVAL CRITERIA for FEIBA:

- Recipient 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
- Recipient 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**
- Recipient 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:

- Recipient 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 recipient is not a candidate for ITI;
    - Attestation that recipient will NOT be receiving concurrent prophylactic treatment with bypassing agents or has possibility of receiving ITI while taking Hemlibra®; AND
    - Attestation that the recipient 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:

- Recipient 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 CBCs 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 recipient will NOT be receiving concurrent prophylaxis factor VIII; AND
    - Attestation that recipient 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 3mg/kg once weekly for 4 weeks; subsequent PAs will be determined on a case-by-case basis

DENIAL CRITERIA for HEMLIBRA

- Recipient does not have a diagnosis of congenital hemophilia A; OR
- Recipient continues to receive prophylaxis doses (e.g., FVIII, FIX, or bypassing agents); OR
- If approved and the recipient 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 recipient has no positive response with the decrease of bleeding episodes and/or decrease of episodic agent use

APPROVAL CRITERIA for NOVOSEVEN RT and SEVENFACT

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

- Recipient 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
- Recipient 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
- Recipient 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 Hemophilia A or B with Inhibitors

Congenital Factor VII Deficiency (NovoSeven RT®)

- Recipient 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®)

- Recipient 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®)

- Recipient 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 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 PDL products may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

Preferred Drugs:

- Hydrocortisone 1% cream
- Hydrocortisone 2.5% cream
- ~~Hydrocortisone- Pramoxine 1%-1% cream (as of 10/1/2021 - only 1 payable NDC 45802-0144-64)~~
- Proctofoam-HC 1-1%
- Procto-Med HC 2.5% cream
- Procto-Sol HC 2.5% cream

Non-Preferred Drugs:

- Anu-Sol HC 2.5% cream
- Proctozone-HC 2.5% cream

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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 Drugs that require manual review for prior authorization

- Mavyret™ tablet (glecaprevir and pibrentasvir)
- sofosbuvir/velpatasvir tablet (generic for Epclusa®)
- Zepatier® tablet (elbasvir/grazoprevir)
- Ribavirin capsule 200mg
- Ribavirin tablet 200mg

Nonpreferred agents

- Epclusa tablet (sofosbuvir/velpatasvir)
- Harvoni® (ledipasvir-sofosbuvir) tablet
- Pegasys® (peginterferon alpha-2a) pen, vial
- PegIntron® (peginterferon alpha-2b) vial kit
- Sovaldi® (sofosbuvir) tablet
- Viekira Pak™ (ombitasvir-paritaprevir-ritonavir & dasabuvir) tablet dosepak
- Vosevi® (sofosbuvir, velpatasvir, and voxilaprevir tablet, film coated) tablet

Link to Hepatitis C prior authorization form—Portable Document Format (.pdf):
Arkansas Medicaid Hepatitis C Prescription Drug Program (ar.primetherapeutics.com)

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 sodium (generic for Pravachol®)
- Rosuvastatin (generic for Crestor®)
- Simvastatin (generic for Zocor®)

Nonpreferred agents

- Altoprev® (lovastatin ER)
- Atorvaliq® suspension (atorvastatin)
- Atorvastatin/Amlodipine (generic for Caduet®)
- Caduet® (atorvastatin/amlodipine)
- Crestor® (rosuvastatin)
- Fluvastatin sodium (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 this product may be faxed to Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

PREFERRED HIV 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)
- 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 HIV AGENTS

- Aptivus capsule (tipranavir)
- Atripla tablet (efavirenz/emtricitabine/tenofovir)
- Combivir tablet (lamivudine/zidovudine)
- Didanosine capsule (generic for Videx EC)
- Efavirenz capsule (generic for Sustiva)
- Efavirenz/lamivudine/tenofovir disoproxil fumarate tablet (generic for Symfi and Symfi Lo)
- Emtricitabine capsule (generic for Emtriva)
- 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 HIV 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)

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 year
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

- Medical necessity over oral PrEP options was not provided

• Prescriber must submit **ALL** of the following:
- Current chart notes
- Current HIV test results
- Medical necessity over oral PrEP options (e.g., generic Truvada® or Descovy®)
- Document if beneficiary will have the 28-day oral lead-in therapy or begin with Apretude®
- Attestation that the prescriber has counseled the patient about the importance of compliance

• Prior authorization will be approved for 12 months.

QUANTITY EDITS

• 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:
    - o Current chart notes

o 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

Hydrocortisone (Alkindi) sprinkle

(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 (Siklos) 100mg Film Coated Tablet

(Implemented 01/01/2019)

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.

Drug that requires a manual review for prior authorization

- Siklos 100mg Film Coated Tablet

Additional Criteria

- Quantity Limits Apply

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Hypoglycemic Agents

(Implemented 10/15/2019)
(Updated 4/1/2020)

(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

- Baqsimi® (glucagon) intranasal powder
- GlucaGen® (glucagon) Hypokit 1mg injection
- Gvoke® (glucagon) pre-filled syringe and autoinjector
- Proglycem® (diazoxide) suspension – BRAND ONLY

Non-Preferred Agents

- Diazoxide suspension (generic for Proglycem®)
- Glucagon 1mg emergency kit
- Gvoke® (glucagon) vial
- Zegalogue® (dasiglucagon) pre-filled syringe and autoinjector

QUANTITY EDITS:

- 2 doses per prescription fill

AGE EDITS:

- FDA approved minimum requirements apply

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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:

- Recipient must be post-menarchal; AND
- Recipient must have a diagnosis of vulvovaginal candidiasis (VVC) OR a diagnosis consistent with FDA approved indication; AND
- Recipient 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:

- Recipient 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
- Recipient is pregnant

QUANTITY EDITS:

#4 tablets / 30 days

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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.

Drugs that require manual review for prior authorization

- Firazyr

Approval Criteria

- 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

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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 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 recipient must have a billed diagnosis for an indication found in Table A in the last 2 years
- Recipients 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 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 agents 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)

POS Criteria for Kesimpta (Briumvi®, Lemtrada®, Ocrevus®, and Tysabri® are excluded from the pharmacy program.) 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 recipient 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
- Recipient 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

- 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
  - 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

- NUCALA:
  - Maintenance treatment of chronic rhinosinusitis with nasal polyps
  - Hypereosinophilic Syndrome
  - Severe asthma with an eosinophilic phenotype
  - Eosinophilic Granulomatosis with Polyangiitis

- TEZSPIRE
  - Severe asthma

- XOLAIR:
  - Moderate to severe asthma with positive skin test or in vitro reactivity to allergen
  - Nasal polyps
  - Chronic Spontaneous Urticaria
  - IgE-Mediated Food Allergies

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. (Current indications as of 8/8/2023.)
    - **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

Continuation Criteria for Asthma

- 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 Idiopathic Urticaria (Xolair®)

- Beneficiaries 12 years of age and older will be based on documentation of CIU diagnosis AND
- Beneficiary meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Beneficiary must have a diagnosis of chronic spontaneous urticaria (CSU) while remaining symptomatic despite H1 antihistamine treatment. CSU was formerly called chronic idiopathic urticaria (CIU)

- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Beneficiary should minimize factors that can exacerbate CSU (i.e., NSAIDs, alcohol, stress, friction from clothing)
- Beneficiary's IgE level and XOLAIR form for asthma are not required
- Beneficiary's baseline Urticaria Activity Score-7 (UAS7) must be ≥ 16 despite previous treatment outlined below
- Beneficiary must have tried and failed the following:
  - 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; AND
  - Alternative nsAH at 4 times the normal daily dose for a minimum of 4 weeks OR H_2 antagonist; AND
  - Add a Leukotriene receptor antagonist to the nsAH or H_2 antagonist for a minimum of 4 weeks; AND
  - Add cyclosporine to the above treatment dosed at 4 mg/kg (based on ideal body weight) for a minimum of 8 weeks.
- Prescriber must submit the following:
  - Current chart notes
  - Baseline description of urticaria
  - Baseline UAS7
  - Previous therapies tried with duration.
  - 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

Continuation Criteria for Chronic Idiopathic Urticaria

- Beneficiary must be compliant on this medication
- Beneficiary must have a positive response with a decrease in UAS7 and decrease in urticaria symptoms
- Prescriber must submit the following:
  - Current chart notes
  - Documentation of current symptoms
  - Current UAS7

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 the following:
  - Nasal corticosteroids for three (3) months (e.g., fluticasone, beclomethasone, budesonide); **AND**
  - Oral corticosteroid therapy for 45 days consecutively
- 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®) *(Effective 10/16/2024)*

- 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

RENEWAL REQUIREMENTS:

- 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®)

- 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
- Beneficiary is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- 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

Renewal Requirements (Xolair®)

- 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)

Prescribers with questions on how to obtain a PA should call 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- Rapid Acting Insulin

- Apidra® SoloStar pen/vial (insulin glulisine)
- Humalog® U-100 cartridge (insulin lispro)- **BRAND ONLY**
- Humalog® U-100 Jr. KwikPen (insulin lispro)- **BRAND ONLY**
- Humalog® U-100 Kwikpen/vial (insulin lispro)- **BRAND ONLY**
- Insulin aspart cartridge/vial/FlexPen (generic for Novolog®)
- Novolog® U-100 cartridge/FlexPen/vial (insulin aspart)-

Non-Preferred- Rapid Acting Insulin

- Admelog® SoloStar pen/vial (insulin lispro)
- Afrezza® inhalation powder (insulin human)
- Fiasp® vial/FlexTouch Pen/Penfill (insulin aspart)
- Humalog® U-200 KwikPen (insulin lispro)
- Humalog® Tempo pens
- Insulin lispro Jr. KwikPen (generic for Humalog®)
- Insulin lispro KwikPen/vial (generic for Humalog®)
- Lyumjev™ pen/vial (insulin lispro-aabc)
- Lyumjev™ Tempo pen

Preferred- Rapid/Intermediate Acting Combinations

- Humalog® Mix KwikPen (insulin lispro/lispro protamine) - **BRAND ONLY**
- Humalog® Mix vial (insulin lispro/lispro protamine)
- Insulin aspart mix pen/vial (generic for Novolog® Mix)
- Novolog® Mix FlexPen (insulin aspart/aspart protamine)
- Novolog® Mix vial (insulin aspart/aspart protamine)

Non-Preferred - Rapid/Intermediate Acting Combinations

- Insulin lispro mix pen (generic for Humalog® Mix)

Preferred - Regular Insulin

- Humulin® R U-100 vial (OTC)
- Humulin® R U-500 KwikPen
- Humulin® R U-500 vial
- Novolin® R U-100 vial (OTC)

Non-Preferred - Regular Insulin

- Novolin® R U-100 FlexPen (OTC)

Preferred -Intermediate Insulin

- Humulin® N U-100 vial (OTC)
- Novolin® N U-100 vial (OTC)

Non-Preferred- Intermediate Insulin

- Humulin® N U-100 KwikPen (OTC)
- Novolin® N U-100 FlexPen (OTC)

Preferred- Regular/Intermediate Acting Combinations

- Humulin® 70/30 KwikPen (OTC)
- Humulin® 70/30 vial (OTC)

Non-Preferred- Regular/Intermediate Acting Combinations

- Novolin® 70/30 vial (OTC)
- Novolin® 70/30 FlexPen (OTC)

Preferred -Long Acting Insulin

- Lantus® SoloStar pen (insulin glargine)
- Lantus® vial (insulin glargine)
- Levemir® FlexTouch (insulin detemir)
- Levemir® vial (insulin detemir)

Non-Preferred-Long Acting Insulin

- Basaglar® KwikPen (insulin glargine)
- Basaglar® Tempo pens
- Insulin glargine Max SoloStar pen (generic for Toujeo®)
- Insulin glargine SoloStar pen (generic for Toujeo®)
- Rezvoglar® pen (insulin glargine-aglr)
- Semglee™ pen/vial (insulin glargine-yfgn)
- Soliqua® injection (insulin glargine/lixisenatide)
- Toujeo® SoloStar pen (insulin glargine)
- Toujeo® Max SoloStar pen (insulin glargine)
- Tresiba® U-100 and U-200 FlexTouch (insulin degludec)
- Tresiba® vial (insulin degludec)
- Xultophy® injection (insulin degludec/liraglutide)

Intranasal Rhinitis Agents

(Effective 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

- Fluticasone propionate nasal spray (Flonase)
- Azelastine nasal spray (Astelin, Astepro)
- Ipratropium nasal spray (Atrovent)

Non-Preferred Agents

- Azelastine/fluticasone nasal spray (Dymista)
- Beclomethasone AQ nasal spray (Beconase AQ)
- Beclomethasone nasal spray (Qnasl)
- Ciclesonide nasal spray (Omnaris, Zetonna)
- Flunisolide nasal spray (Xhance, Ticanase)
- Olopatadine 6% nasal spray (Patanase)
- Olopatadine/Mometasone (Ryaltris)

Non-Preferred agents with criteria

- Mometasone furoate nasal spray (Nasonex)

Approval criteria for Non-Preferred agents with criteria

- Approvable if the beneficiary is between 2 years through 3 years of age

Iptacopan (Fabhalta) 200 mg capsule

(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 recipient 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

Isosorbide Dinitrate/Hydralazine (BiDil)

(Implemented 09/18/2013)

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 require manual review for prior authorization

- BiDil

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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

- Recipient must be ≥ 12 years of age; AND
- Prescriber must be a dermatologist; AND
- Recipient must have a diagnosis of severe recalcitrant nodular acne with many inflammatory nodules measuring a diameter of 5 mm or greater; AND
- Recipient 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 recipient 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 recipients. Female recipients must also sign the Pregnancy Prevention Consent form. If the recipient 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 recipient 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 recipients 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

- Recipient 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
- Recipient is pregnant; OR
- All required information is not provided; OR
- Recipient 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 (Corlanor)

(Implemented 05/04/2015)
(Updated 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

- Corlanor

Additional criteria

Quantity limits apply

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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** (MUPIROCON 2% OINTMENT – STERILE GAUZE – TAPE)
- **LIDOCAINE-PRILOCAINE 2.5%-2.5% CREAM KIT** (LIDOCAIN- 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)
- **ROWASA 4 GM/60 ML ENEMA KIT** (MESALAMINE 4 GM/60 ML ENEMA – CLEANSING WIPES)
- **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.

Drugs that require manual review for prior authorization

- Takhzyro

Approval criteria

- 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 (Joenja®) 70mg tablet

(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:
    o Pregnant
    o Weighs less than 45 kg
    o Requires concomitant strong CYP3A4 inhibitors (e.g., itraconazole)
    o Requires concomitant moderate or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin)
    o Moderate to severe hepatic impairment

• Prescriber must submit **ALL** of the following:
    o Current chart notes with documentation of specific symptoms for this beneficiary and documentation of variant
    o Previous therapies including surgery
    o Current negative pregnancy test for females of reproductive potential
    o Current weight
    o MRI or CT imaging results documenting lesions with descriptions
    o Current labs including LFTs
    o Medical necessity over IVIG and sirolimus
    o Baseline % naïve B cell

• Initial PA for 3 months

RENEWAL REQUIREMENTS:

• Prescriber must submit ALL of the following:
    o Prescriber must submit current chart notes
    o 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

Letermovir (Prevymis)

(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

- Prevymis

Additional criteria

- Age limits apply
- Quantity limits apply

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Leucovorin tablets and vials

(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.

POS DENIAL CRITERIA:

- Recipient 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

Top of the document

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 agent with criteria

- Montelukast tablets, chewable tablets, and granules (generic for Singulair®)

Nonpreferred agents

- Accolate® tablet (zafirlukast)
- Singulair® tablets, chewable tablets, 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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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

Drugs that require manual review for prior authorization

- Inbrija

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 Solutionspharmacy unit at 1-800-424-7976.

APPROVAL CRITERIA:

- Recipient must be ≥ 18 years of age; AND
- Recipient 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
- Recipients 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
- Recipient should have a trial and failure of ketoconazole and mitotane unless contraindicated or recipient cannot tolerate both medications

DENIAL CRITERIA:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient 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 Recipients that develop hypocortisolemia should decrease the dose or discontinue the medication; OR
- Recipient continues to have hypercortisolemia despite maximum recommended dosage of 1200 mg per day; OR
- Recipient 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

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Levothyroxine Solution (Ermeza and Thyquidity)

(Implemented 04/01/2020)

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.

Drugs that do not require prior authorization

- All strengths of generic levothyroxine tablets
- Euthyrox tablets

Drugs that require manual review for prior authorization

- Ermeza
- Thyquidity

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Levothyroxine Vial

(Implemented 04/17/2012)

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 manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Levothyroxine 200 mcg vial
- Levothyroxine 500 mcg vial

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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 5/10/18)
(Updated 7/1/18)

(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 no 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)

Nonpreferred 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

Nonpreferred 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 Lomitapide mesylate (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 Bempedoic Acid (Nexletol/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 (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 (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 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

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 LIMIT:

- 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 (Xdemvy™) 0.25% drops

(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

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 must be ≥1 year of age; 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 be approved or continue with any of the following:
  - documnted hepatic decompensation
  - daily dose >28.5 mg
  - not concurrently ordered ursodeoxycholic acid
  - if continued pruritis or has no decrease in serum bile acid after trial with maximum dose of 380 mcg/kg per day
- 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

Quantity Edits:

3 bottles (90 mL)/ 30 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:

- Recipient must be ≥ 12 years of age and weigh at least 35 kg; AND
- Recipient 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
- Recipient 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; AN
    - 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:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient is pregnant; OR
- Recipient's treatment plan includes concomitant use with valganciclovir or ganciclovir; OR
- Recipient has end state renal disease or severe hepatic impairment; OR
- Prescriber ordered as prophylaxis therapy; OR
- Recipient 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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Mavacetan - 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:

- Recipient must be at least 18 years of age; AND
- Recipient 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
- Recipient 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:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient has a baseline LVEF <55% or Valsalva LVOT peak gradient < 50 mmHg; OR
- Recipient requires moderate to strong CYP2C19 inhibitors or inducers, OR strong CYP3A4 inhibitors, OR moderate to strong CYP3A4 inducers; OR
- Recipient 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

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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 tablets
- Naltrexone 50mg tablets
- Suboxone® Film (BRAND ONLY)
- Zubsolv SL tablets

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 8mg nasal spray
- Naloxone 0.4mg/mL vial
- Naloxone 2mg/2mL syringe
- Naloxone 4mg nasal spray
- Narcan 4mg nasal spray
- Rextovy 4mg nasal spray
- Zimhi 5mg/0.5mL 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

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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Mepron (Atovaquone)

(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 authorization

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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Meropenem-Vaborbactam (Vabomere) Injection

(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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Mesalamine 1000mg Suppository (Canasa)

(Implemented 06/21/2011)

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.

Criteria

Quantity limits apply

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Methoxsalen Capsule (Oxsoralen-Ultra, 8-MOP)

(Implemented 09/23/2014)

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

- Oxsoralen-Ultra
- 8-MOP

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Metreleptin 11.3mg Vial (Myalept)

(Implemented 09/23/2014)

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

- Myalept Vial

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Methotrexate Injection (Otrexup and Reditrex)

(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 prior authorization

- Otrexup
- Reditrex

Additional criteria

Quantity limits apply

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Methotrexate Sodium (Trexall)

(Implemented 8/17/2010)

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.

Drugs that do not require prior authorization

- Methotrexate 2.5mg tablet

Drugs that require manual review for prior authorization

- Trexall 5mg
- Trexall 7.5mg
- Trexall 10mg
- Trexall 15mg

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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

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 (Likmez™) 500mg/5mL suspension

(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:
  o 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.
  o Skin and skin structure infections caused by *Bacteroides* species including the *B. fragilis* group, *Clostridium* species, *Peptococcus* species, *Peptostreptococcus* species, and *Fusobacterium* species.
  o 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.
  o Bacterial septicemia caused by *Bacteroides* species including the *B. fragilis* group and *Clostridium* species.
  o Bone and joint infections, (as adjunctive therapy), caused by *Bacteroides* species including the *B. fragilis* group.
  o Central nervous system (CNS) infections, including meningitis and brain abscess, caused by *Bacteroides* species including the *B. fragilis* group.
  o Lower respiratory tract infections, including pneumonia, empyema, and lung abscess, caused by *Bacteroides* species including the *B. fragilis* group.
  o Endocarditis caused by *Bacteroides* species including the *B. fragilis* group.
- Prescriber must submit **ALL** of the following:
  o Current chart notes
  o Report indicating diagnosis/bacteria requiring treatment
  o Culture and sensitivity if available
  o Medical necessity over other antibiotics available without a PA including metronidazole tablets
  o Dose requested

RENEWAL REQUIREMENTS

- Continuation requires a report that documents continued bacteria positivity

QUANTITY EDITS

No set maximum quantity since based on dose required

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 300mg Tablet (Korlym)

(Implemented 07/23/2012)

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 manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Korlym **Plan Prefers Brand**
- Mifepristone

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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 LIMITS

Limited to 1 capsule every 2 days (Dose is 1 capsule every other day)
Quantity limited to 14 capsules for a 28-day supply

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Miglustat (Opfolda™) 65mg capsule

(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

Miglustat (Zavesca®) Capsule

(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.

Drugs that require manual review for prior authorization

- Zavesca

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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 Agents 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)
- 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 (i.e., amiodarone, carvedilol, macrolides) or BCRP substrates (i.e., statins) – 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:

- Recipient 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 (Amerge)
- Rizatriptan 10mg MLT (Maxalt MLT)
- Rizatriptan 10mg tablet (Maxalt)
- Rizatriptan 5mg MLT (Maxalt MLT)
- Rizatriptan 5mg tablet (Maxalt)
- Sumatriptan succinate tablet (Imitrex)
- Zolmitriptan tablet (Zomig)
- Zolmitriptan ODT (Zomig ZMT)

Preferred agents with criteria

- Sumatriptan 4mg/0.5ml kit refill (Imitrex)
- Sumatriptan 6mg/0.5ml kit refill (Imitrex)
- Sumatriptan 6mg/0.5ml vial (Imitrex)
- Sumatriptan 20mg nasal spray (Imitrex)
- Sumatriptan 5mg nasal spray (Imitrex)

Nonpreferred agents

- Almotriptan malate tablet (Axert)
- Eletriptan HBr tablet (Relpax)
- Frova (frovatriptan) tablet
- Frovatriptan succinate tablet (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 (Treximet)
- Tosymra nasal spray (sumatriptan)
- Zembrace Symtouch pen (sumatriptan)
- Zolmitriptan 2.5 mg and 5 mg nasal spray (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

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® (Erenumab-aooe) autoinjector
- Emgality® 120 mg (galcanezumab) pen and syringe
- Nurtec ODT® (rimegepant)
- Qulipta® (atogepant) tablet

Non-Preferred Agents

- Ajovy® (fremanezumab-vfrm) injection 225mg syringe
- Emgality® (galcanezumab) injection 100 mg pen and syringe

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 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:

- Recipient must be ≥ 18 years of age; AND
- Recipient 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
- Recipient'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:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Prescriber is requesting a dose > 50 mg twice daily; O
- Recipient has moderate or severe hepatic impairment; O
- Recipient 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; O
- Recipient has 2 non-missense variants; O
- Recipient 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 mofetil (Myhibbin™) 200 mg/mL suspension

(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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Nafarelin Nasal Spray (Synarel)

(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.

Approval criteria

- Diagnosis of central precocious puberty (CPP) in the previous three years, OR
- Diagnosis of endometriosis in the previous three years

Denial criteria

Diagnosis of infertility in the previous three years

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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:

o Most recent polysomnogram (PSG) results

- o 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)
- o Current chart notes
- o 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):

- o Most recent polysomnogram (PSG) results
- o Current chart notes
- o Documentation of plan for monitoring compliance of positive airway treatment
- o 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):

- o Most recent polysomnogram (PSG) results with sleep study performed during patient's normal sleep time
- o 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)

- o Current chart notes
- o Baseline Epworth Sleepiness Scale (ESS)
- o 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:
- o Trial and failure of CII stimulant in the last year
- o Trial and failure of a preferred CIV stimulant in the last year

• Prescriber should submit the following for initial request:
- o Most recent polysomnogram (PSG) results
- o 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)
- o Current labs including LFTs
- o Current chart notes
- o Baseline Epworth Sleepiness Scale (ESS) Score for excessive daytime sleepiness associated with narcolepsy
- o 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.

Nedosiran sodium (Rivfloza)
80 mg vial, 128 mg and 160 mg syringe

(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

Neo-Synalar (Neomycin 0.5%, Fluocinolone 0.025%) Cream

(Implemented 07/22/2015)

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

- Neo-Synalar

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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.pharmacy unit at 1-800- 424-7976.

Preferred agents

- Duloxetine (generic for Cymbalta)
- Gabapentin Capsules and Tablets (generic for Neurontin)
- Pregabalin (generic for Lyrica)

Non-preferred agents:

- Cymbalta
- Drizalma sprinkle (duloxetine)
- Gabapentin 250mg/5ml solution (generic for Neurontin)*
- Gabapentin ER tablets (generic for Gralise)
- Gralise tablets (gabapentin ER)
- Horizant tablets (gabapentin ER)
- Lidoderm patch
- Lyrica
- Lyrica CR
- Lyrica solution
- Neurontin capsules, tablets, solution
- 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 (Lampit)

(Effective 9/21/2020)

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.

Drugs that require manual review for prior authorization

- Lampit

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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:

100mg--#60/30 days

150mg--#60/30 days

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Nitisinone Capsule (Orfadin)

(Implemented 09/23/2014)

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

- Orfadin Capsule

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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)

Prescribers with questions on how to obtain a PA should call 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

Rectiv® Rectal Ointment **Plan Prefers Brand**

Nitroglycerin Rectal Ointment

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Noxafil DR Oral Tablet and Noxafil 300mg 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 require manual review for prior authorization

- Noxafil DR Oral Tablet
- Noxafil 300mg Vial

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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.

Drugs that require manual review for prior authorization

Nuzyra®

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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Obeticholic Acid (Ocaliva) Tablets

(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

- Ocaliva 5mg Tablets
- Ocaliva 10mg Tablets

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Octreotide Acetate (Sandostatin LAR Depot)

(Implemented 04/10/2015)

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

- Sandostatin LAR Depot 10 mg
- Sandostatin LAR Depot 20 mg, 30 mg– Brand Preferred if Approved
- Octreotide acetate ER 20 mg, 30 mg

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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:

- Recipient must be ≥ 3 months of age; AND
- Recipient 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
- Recipient has elevated serum bile acid concentration; AND
- Recipient has documented failure of ursodeoxycholic acid (Ursodiol) AND cholestyramine unless there is a documented contraindication; AND
- Recipient 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:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient has PFIC type 2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3); OR
- Recipient has decompensated liver disease; OR
- Recipient 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
- Recipient is not concurrently ordered ursodeoxycholic acid

QUANTITY EDITS:

- 200 mcg pellets--#62 per 31 day
- 600 mcg pellets--#31 per 31 day
- 400 mcg capsules--#155 per 31 day
- 1200 mcg capsules--#155 per 31 days

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Omaveloxolone (Skyclarys™) 50mg capsule

(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

Omeprazole, Amoxicillin, and Clarithromycin combination (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, 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)

Prescribers with questions on how to obtain a PA should call 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 (Optivar®)
- Cromolyn sodium 4% eye drops
- Ketotifen fumarate 0.025% eye drops (Alaway® or Zaditor®)
- Olopatadine HCl 0.1% eye drops (Patanol®)
- Olopatadine HCl 0.2% eye drops (Pataday®)

Non-Preferred agents

- Alcaftadine 0.025% eye drops (Lastacaft®)
- Bepotastine besilate 1.5% eye drops (Bepreve®)
- Cetirizine 0.24% eye drops (Zerviate™)
- Epinastine HCl 0.05% eye drops (Elestat®)
- Loteprednol etabonate 0.2% eye drops (Alrex®)
- Lodoxamide tromethamine 0.1% eye drops (Alomide®)
- Nedocromil sodium 2% eye drops (Alocril®)
- Olopatadine HCl 0.7% eye drops (Pazeo®)
- Olopatadine HCl 0.7% eye drops (Pataday®)

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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
- 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
- Sulfacetamide 10% ophthalmic solution drops
- Tobrex® (tobramycin) 0.3% ointment
- Vigamox® (moxifloxacin) 0.5% ophthalmic solution drops
- Zymaxid® (gatifloxacin) 0.5% ophthalmic solution drops

Ophthalmics -Antibiotic-Steroid Combination Drops

(Implemented 10/11/2011)

(Updated 5/10/17, Effective 7/1/17)

(Updated 7/1/2020)

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 Status:

- Neomycin sulfate /polymyxin B/ dexamethasone ophthalmic ointment
- Neomycin sulfate /polymyxin B/ dexamethasone 0.1% ophthalmic suspension drops
- Sulfacetamide sodium 10% / prednisolone sodium phosphate 0.23% ophthalmic solution drops
- Tobramycin 0.3%/dexamethasone 0.1% ophthalmic suspension drops
- Tobramycin / dexamethasone (TOBRADEX®) 0.3%/ 0.1% ophthalmic ointment

Non-Preferred Status:

- Neomycin 3.5 mg/ polymyxin B sulfates 10K / hydrocortisone 1% ophthalmic suspension drops
- Neomycin sulfate/ polymyxin B sulfates/ bacitracin zinc/ hydrocortisone ophthalmic ointment
- Loteprednol 0.5%/tobramycin 0.3% (ZYLET®) ophthalmic suspension drops
- Maxitrol® (neomycin/polymyxin B/dexamethasone) ophthalmic ointment
- Maxitrol® (neomycin/polymyxin B/dexamethasone) ophthalmic solution drops
- Prednisolone acetate 0.6%/gentamicin sulfate 0.3% (PRED-G®) ophthalmic ointment
- Prednisolone acetate 1%/ gentamicin sulfate 0.3% (PRED-G®) ophthalmic suspension drops
- Sulfacetamide sodium 10%/ prednisolone 0.2% (BLEPHAMIDE® S.O.P.) ophthalmic ointment
- Sulfacetamide sodium 10% / prednisolone 0.2% (BLEPHAMIDE®) ophthalmic suspension drops
- Tobramycin / dexamethasone (TOBRADEX® ST) 0.3%/0.05% ophthalmic suspension drops

Ophthalmics - Anti-inflammatory Drops

(Implemented 01/12/2010)

(Updated and added to PDL 7/1/2020)

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

- Bromfenac 0.09% eye drops (Bromday®)
- Dexamethasone Sodium Phosphate 0.1% eye drops (Decadron®)
- Diclofenac 0.1% eye drops (Voltaren®)
- Fluorometholone 0.1% eye drops (FML Liquifilm®)
- Fluorometholone 0.25% eye drops (FML Forte®)
- Flurbiprofen 0.03% eye drops (Ocufen®)
- Ketorolac 0.5% eye drops (Acular®)
- Prednisolone acetate 1% eye drops (Pred Forte®)
- Prednisolone sodium 1% eye drops (AK-Pred®)

Non- Preferred agents

- Bromfenac 0.07% eye drops (Prolensa®)
- Bromfenac 0.075% eye drops (BromSite®)
- Dexamethasone 0.1% suspension eye drops (Maxidex®)
- Difluprednate 0.05% eye drops (Durezol®)
- Fluorometholone 0.1% eye drops (Flarex®)
- Fluorometholone 0.1% ointment (FML S.O.P.®)
- FML Liquifilm® 0.1% eye drops
- Ketorolac 0.45% eye drops (Acuvail®)
- Ketorolac 0.4% eye drops (Acular LS®)
- Loteprednol etabonate 0.25% eye drops (Eysuvis®)
- Loteprednol etabonate 0.38% gel (Lotemax SM®)
- Loteprednol etabonate 0.5% eye drop/12ps (Lotemax®)
- Loteprednol etabonate 0.5% eye gel drops (Lotemax®)
- Loteprednol etabonate 0.5% ointment (Lotemax®)
- Loteprednol etabonate 1% suspension (Inveltys®)
- Nepafenac 0.1% eye drops (Nevanac®)
- Nepafenac 0.3% eye drops (Ilevro®)
- Prednisolone acetate 0.12% eye drops (Pred Mild®)

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Ophthalmics, Anti-inflammatory (Immunomodulator)

(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)
- 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

Denial criteria for Preferred Agents

- Therapeutic duplication with Lacrisert (hydroxypropyl cellulose)

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

- Recipient must be ≥ 18 years of age; AND
- Recipient 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
- Recipient should be in Parkinson's Disease stages 2 to 4 in the OFF state in the modified Hoehn and Yahr Scale; AND
- Recipient must be on levodopa/carbidopa for at least one year with a stable dose at least 4 weeks prior to starting ONGENTYS; AND
- Recipient must be taking at least 3 doses of levodopa per day; AND
- Recipient must take ONGENTYS in combination with levodopa/carbidopa; AND
- Recipient 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, recipient 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

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient is diagnosed with severe hepatic impairment (Child-Pugh C); OR • Recipient is diagnosed with end stage renal disease; OR
- Recipient has a history of pheochromocytoma, paraganglioma, or other catecholamine secreting neoplasms; OR
- Recipient takes concomitant non-selective monoamine oxidase (MAO) inhibitors; OR
- Recipient is diagnosed with a major psychotic disorder in the last year (i.e., major depressive disorder, bipolar, psychosis, generalized anxiety disorder); OR
- Recipient has < 2 hours a day of OFF time; OR
- Recipient has a diagnosis of atypical parkinsonism or secondary parkinsonism variants; OR
- Recipient 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)

Prescribers with questions on how to obtain a PA should call 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)
- Xtampza ER capsule (oxycodone ER)

Nonpreferred agents with criteria

- Belbuca films (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 (generic for Dolophine)
- Methadone solution
- Methadone Intensol conc
- Morphine sulfate extended-release capsule (generic for Avinza, Kadian)
- Nucynta ER tablet (tapentadol HCl)
- 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)

Nonpreferred 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 nonpreferred agents with criteria

- Fentanyl patch
  - NPO
  - Currently in LTC
  - Cancer diagnosis in the past 12 months
  - No therapeutic duplication with other long-acting opioids
- Morphine sulfate long-acting capsules or oxycodone long-acting tablet
  - Currently in LTC
  - Cancer diagnosis in the past 12 months
  - No therapeutic duplication with other long-acting opioids
- Methadone HCl (Dolophine)
  - Cancer diagnosis in the past 12 months
  - No therapeutic duplication with other long-acting opioids
- Methadone oral solution for Neonatal Abstinence Syndrome
  - Infant's age is ≤ 90 days of age at the time drug claim is submitted
  - Quantity of methadone oral solution dispensed is not more than 10mL for a 30-day supply
  - Incoming claim and the claim in history will not make the total quantity of methadone oral solution more than 10mL for the previous 30-day supply

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

Opioids, Short-Acting

(Implemented 11/12/2008)
(Updated 05/10/2017, Effective 7/1/17)

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 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 tablet 300-15 mg, 300-30 mg, 300-60 mg
- Acetaminophen-codeine elixir or solution120 mg-12 mg/5 ml in 118 ml and 473 ml bottle
- Codeine tablet 15 mg, 30 mg, 60 mg,
- Hydrocodone / acetaminophen tablet 5/325 mg, 7.5/325 mg, 10/325 mg
- Hydrocodone/ acetaminophen oral solution 7.5-325 mg/15 ml
- Hydrocodone/ibuprofen tablet (VICOPROFEN) **7.5/200 mg**
- Hydromorphone tablet 2 mg, 4 mg, 8 mg
- Morphine IR tablet 15 mg, 30 mg,
- Morphine oral solution 10 mg/5 ml, 20 mg/5 ml,
- Morphine concentrated oral solution 100 mg/5 ml
- Meperidine tablet 50 mg
- Meperidine oral solution 50 mg/ 5 ml
- Oxycodone tablet 5 mg, 10 mg, 15 mg, 20 mg, 30 mg
- Oxycodone oral solution 5 mg/ 5 ml
- Oxycodone/ acetaminophen tablet 5 mg-325 mg, 7.5 mg-325mg, 10mg – 325 mg
- Oxycodone/ acetaminophen solution 5-325 mg/ 5 ml
- Tramadol tablet 50 mg
- Tramadol/ acetaminophen tablet 37.5 mg-325 mg

Non-Preferred Status for all strengths unless otherwise noted

- Acetaminophen-codeine elixir or solution 120 mg-12 mg/5 ml unit dose cups, and 300 mg-30 mg/12.5 ml unit dose cups
- Acetaminophen with codeine (CAPITAL® and CODEINE) oral suspension 120 mg-12 mg/ 5 ml
- Benzhydrocodone/acetaminophen (APADAZ®) 4.08mg-325mg, 6.12mg-325mg. and 8.16mg-325mg
- Butalbital/caffeine/APAP w/codeine 50 mg-325 mg-30 mg, and 50 mg-300 mg-30 mg
- Butalbital/caffeine/APAP w/codeine capsules (FIORICET)
- Butalbital/caffeine/ASA w/codeine capsules (FIORINAL)
- Butalbital compound w/codeine

- Butorphanol 10 mg/ml nasal spray
- Carisoprodol Compound w/Codeine
- Dihydrocodeine/APAP/caffeine 320.5 mg- 30 mg
- Dilaudid® tablet and oral solution
- Hydrocodone / acetaminophen tablet, 5-300 mg,7.5-300 mg, 10-300 mg, 2.5-325 mg,
- Hydrocodone/APAP Oral Solution ***Unit Dose Cups*** 7.5-325 mg/15 ml, 5-163 mg/7.5 ml, 10-325 mg/ 15 ml, 2.5-108 mg/ 5 ml, 5-217 mg/ 10 ml,
- Hydrocodone/APAP (ZAMICET®) 10 mg-325 mg/15 ml oral solution
- Hydrocodone-ibuprofen tablet (VICOPRFEN) **10 mg-200 mg, 5 mg-200 mg**
- Hydrocodone/ibuprofen (REPREXAIN™) 2.5mg-200mg, 5mg-200mg, 7.5mg-200mg, 10mg-200mg tablet
- Hydromorphone 1 mg/1 ml oral solution
- Hydromorphone 3 mg rectal suppository
- Levorphanol tablets
- Meperidine tablet 100 mg
- Oxycodone (OXAYDO®) tablets 5mg, 7.5mg
- Oxycodone capsule 5 mg
- Oxycodone concentrated oral solution 20 mg/mlOxycodone 10 mg/0.5 ml oral syringe
- Oxycodone 5 mg/5 ml solution unit dose cups
- Oxycodone/ APAP 2.5 mg-325 mg,
- Oxycodone/APAP (PRIMLEV™) 5 mg-300 mg, 7.5 mg-300 mg, 10 mg-300 mg)
- Oxycodone/APAP (PROLATE™) 5 mg-300 mg, 7.5 mg-300 mg, 10 mg-300 mg)
- Oxycodone/aspirin
- Oxycodone/Ibuprofen tablet 5 mg-400 mg
- Oxymorphone (OPANA®) tablets
- Pentazocine/naloxone tablet
- Roxicodone® tablet
- Seglentis (Tramadol/Celecoxib)
- Tapentadol (NUCYNTA®) tablet and oral solution
- Tramadol 25 mg, 75 mg, 100 mg tablets

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 (Metaproterenol syrup 10 mg/5 ml, 10 mg, 20 mg tablet; Terbutaline 2.5 mg, 5 mg tablet, and Terbutaline vials)

(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

- Metaproterenol Syrup 10mg/5ml
- Metaproterenol 10mg Tablet
- Metaproterenol 20mg Tablet
- Terbutaline 2.5mg Tablet
- Terbutaline 5mg Tablet
- Terbutaline Vials

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Oseltamivir Suspension (Tamiflu)

(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

- ≤ 12 years of age, AND
- At least 1 year of age

Additional criteria

- Quantity Limits apply

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Osilodrostat (Isturisa®)

Prescribers with questions on how to obtain a PA should call 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

- Recipient ≥ 18 years of age; **AND**
- Diagnosis of Cushing's disease 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**
- 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

- Recipient should have a trial and failure of ketoconazole and mitotane unless contraindicated or recipient cannot tolerate both medications; **AND**
- Current labs should indicate the recipient does not have hypokalemia or hypomagnesemia; **AND**
- Recipients with risk factors for QT prolongation should have more frequent ECG monitoring

Denial Criteria:

- Recipient does not meet the approval criteria; **OR**
- Dose requested is > 30 mg twice daily; **OR**
- Recipient has not trialed ketoconazole and mitotane **OR** had a contraindication or intolerance to both medications; **OR**
- Recipient is showing symptoms of adrenal insufficiency

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 Osteoporosis Drugs

- Alendronate sodium 5mg daily dose (Fosamax®)
- Alendronate sodium 10mg daily dose (Fosamax®)
- Alendronate sodium 35mg weekly dose (Fosamax®)
- Alendronate sodium 40mg weekly dose (Fosamax®)
- Alendronate sodium 70mg weekly dose (Fosamax®)

Non-Preferred **WITH** Criteria Osteoporosis Drugs

- Prolia® injection
- Evista® (raloxifene) tablets

Non-Preferred **NO** Criteria Osteoporosis Drugs

- Actonel® (Risedronate) tablet
- Atelvia® (Risedronate DR) tablet
- Binosto® effervescent (Alendronate) tablet
- Boniva ® (Ibandronate) tablet
- Boniva® (Ibandronate) injection
- Calcitonin-Salmon (Miacalcin® and Fortical®)
- Evenity® injection
- Fosamax® Plus D tablet
- Fosamax® oral solution
- Forteo® injection (Teriparatide)
- Teriparatide injection
- Tymlos® injection

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:

- 1 Prolia® claim is found in Medicaid drug history in the previous 12months.
- 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 1 injection per 175 days willbe 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

At least 4 or more claims for raloxifene in the past 186 days

Additional criteria

- Forteo® quantity limits apply

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Oteseconazole (Vivjoa™) 150mg capsule

(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

- Recipient 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
- Recipient must have permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy, or post-menopausal)
- Recipient 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 recipients with HbA1c>9%, prescriber must provide efforts taken to achieve better glycemic control
- Recipient 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 recipients 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, 01/18/2011)
(Updated 10/01/16, 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

- Ciprodex® Otic suspension (ciprofloxacin and dexamethasone) **BRAND NAME**
- Ciprofloxacin/dexamethasone suspension (generic for Ciprodex®)
- Neomycin/polymyxin/HC Otic solution/suspension (generic for Cortisporin®)
- Acetic acid 2% Otic solution
- 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)

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)

Nonpreferred 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 (Rhofade) Topical Cream

Prescribers with questions on how to obtain a PA should call 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

- Rhofade Topical Cream

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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
- 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
- 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

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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Palforzia (peanut powder)

(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:

- Recipient must be ≥ 4 years of age and ≤ 17 years of age to initiate treatment; AND
- Recipient must have a confirmed diagnosis of a peanut allergy; AND
- Prescriber must be an Allergy and Immunology specialist; AND
- Prescriber, clinic, pharmacy, and recipient must be enrolled in the Risk Evaluation and
- Mitigation Strategy (REMS) program and remain compliant with program requirements; AND
- Prescriber must attest that the recipient has been counseled to continue a peanut-avoiding diet as this medication is for accidental exposure to peanuts; AND
- Recipient 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).
- PAs 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:

- Recipient does not meet the FDA approved indication OR have a diagnosis supported in the
- official Compendia; OR
- Recipient 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.
- Recipient has suspected eosinophilic esophagitis and/or other eosinophilic gastrointestinal
- disease; OR
- Recipient cannot tolerate doses up to and including the 3 mg dose during Initial Dose
- Escalation; OR
- Recipient had a severe or life-threatening anaphylaxis within the previous 60 days

Palovarotene (Sohonos™) 1mg, 1.5mg, 2.5mg, 5mg, and 10mg capsule

(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.

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

Nonpreferred agents

- Pancreaze
- Pertzye
- Viokace

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Papaverine 30mg/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 (Signifor) Ampule

(Implemented 09/18/2013)

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 require manual review for prior authorization

- Signifor

Additional Criteria

- Quantity Limits Apply

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Patiromer (Veltassa) Powder for Oral Suspension

(Implemented 04/26/2016)

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.

Drugs that require manual review for prior authorization

- Veltassa Powder for Oral Suspension

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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:

- Recipient must be ≥ 18 years of age; AND
- Recipient must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) OR a diagnosis consistent with FDA indications; AND
- Recipient 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 recipient must be provided antibiotics if vaccines were administered less than 2 weeks before starting therapy; AND
- Prescriber, pharmacy, and recipient must be enrolled in the REMS program; AND
- Recipient currently taking eculizumab (Soliris®) or ravulizumab (Ultomiris®) must follow the required dose initiation per the package insert; AND
- Recipients taking eculizumab (Soliris®) or ravulizumab (Ultomiris®) must have been stable for at least 3 months; AND
- Female recipients of reproductive potential should use contraception and have a negative pregnancy test prior to starting therapy; AND
- Recipient'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:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient has not been vaccinated according to package insert/REMS requirements; OR
- Recipient has an unresolved serious infection caused by encapsulated bacteria; OR including *Streptococcus pneumoniae* and *Neisseria meningitidis*
- Recipient is pregnant or breastfeeding

QUANTITY EDITS

10 vials/ 30 days

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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 ofepinephrine;
- 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 EDIT:

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)

Prescribers with questions on how to obtain a PA should call 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 allowed between different strengths of Somavert

Additional criteria

Quantity limits apply

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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® (penicillamine) capsules—**BRAND NAME ONLY**
- Depen® (penicillamine) tablets—**BRAND NAME ONLY**
- Potassium citrate tablets (generic for Urocit-K®)
- Thiola® tablets (tiopronin)—**BRAND NAME ONLY**
- Thiola® EC tablets (tiopronin)—**BRAND NAME ONLY**

Non- Preferred Agents:

- Penicillamine capsules (generic for Cuprimine®)
- Penicillamine tablets (generic for Depen®)
- Tiopronin tablets (generic for Thiola®)
- Tiopronin DR tablets (generic for Thiola® EC)
- Urocit-K® ER tablets (potassium citrate)

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Phenoxybenzamine (Dibenzyline)

(Implemented 05/04/2015)

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.

Drug that requires manual review for prior authorization

- Dibenzyline

Link to Memorandum

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® (ferric citrate) tablet
- Fosrenol® (lanthanum carbonate) chewable tablet
- Lanthanum Carbonate chewable tablet (generic for Fosrenol®)
- Phoslyra® (calcium acetate) 667 mg/5 ml oral solution
- Renvela® (sevelamer carbonate) Powder Pack
- Renvela® (sevelamer carbonate) tablet
- Sevelamer HCl tablets (generic for Renagel®)
- Velphoro® (sucroferric oxyhydroxide) chewable tablet
- Xphozah® (tenapanor) tablet

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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:

- Recipient must be ≥18 years of age; AND
- Recipient 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:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient has a history of glaucoma or ocular hypertension; OR
- Recipient 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

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Pirfenidone (Esbriet) tablet/capsule

(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® (leuprolide)42 mg
- Eligard® (leuprolide) 7.5 mg, 22.5 mg-3 month, 30 mg-4 month, and 45 mg-6 month
- Lupron® (leuprolide) 1 mg
- Lupron Depot® (leuprolide) 7.5 mg, 22.5 mg-3 month, 30 mg-4 month, 45mg-6 month, and Lupron 2 week Kit
- Trelstar® (triptorelin) 3.75 mg, 11.25 mg, 22.5 mg

Endometriosis or Uterine Leiomyoma

Preferred Agents

- Lupaneta® (leuprolide inj and norethindrone tablets) 3.75mg for monthly administration up to 6 months
- Lupron Depot® (leuprolide) 3.75mg and 11.25mg-3 month

Nonpreferred Agents

- None

POINT-OF-SALE APPROVAL CRITERIA

- Billed diagnosis of endometriosis or uterine leiomyoma (fibroids), AND
  o <12 billed claims of 3.75mg leuprolide injection (which would include Lupaneta®) in the previous 3 year Medicaid history, OR
  o <4 billed claims of 11.25mg 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® (leuprolide) 3.75mg, 7.5mg, and 11.25mg – 3 month

Nonpreferred Agents

- None

POINT-OF-SALE APPROVAL CRITERIA

- 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® (leuprolide) 45mg
- Lupron Depot-Ped® (leuprolide) 7.5mg, 11.25mg, 15mg, 11.25 3-month kit, 30mg 3-month kit, and the 45mg 6-month kit
- Synarel® (nafarelin) spray

Nonpreferred Agents

- Triptodur® (triptorelin) 22.5mg 6-month

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 5/10/18)
(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

- Aspirin/dipyridamole (generic for Aggrenox®)
- BRILINTA® (ticagrelor) tablet
- Clopidogrel (generic for Plavix®)
- Dipyridamole
- Prasugrel (generic for Effient)

NONPREFERRED AGENTS

- EFFIENT®
- PLAVIX®

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Podofilox (Condylox 0.5% topical solution and gel)

(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 OR

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 (Noxafil) Suspension

(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
- Organ transplant procedure
- Graft vs. host disease
- 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 30days. 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 (Noxafil DR 100mg Oral Tablet and Noxafil 300mg 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 require manual review for prior authorization

- Noxafil DR 100mg Tablet
- Noxafil 300mg Vial

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Potassium Chloride Capsules, Packets, and Tablets

(Updated 04/14/2017)

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 do not require prior authorization

- Potassium chloride 8 mEq extended-release capsule [Micro-K]
- Potassium chloride 10 mEq extended-release capsule [Micro-K]
- Potassium chloride 8 mEq extended release-tablet [Klor-Con 8 mEq tablet]
- Potassium chloride 10 mEq extended-release tablet [Klor-Con M10]
- Potassium chloride 20 mEq extended-release tablet [Klor-Con M20]

Drugs that require manual review for prior authorization

- Potassium chloride 20 mEq powder packet
  ]

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Potassium Chloride Oral Liquid and Effervescent Tablets

(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

- Generic prednisolone sodium phosphate 15mg/5ml (same as Orapred ® Solution) is available without a prior authorization
- 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 (Rayos DR)

Prescribers with questions on how to obtain a PA should call 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

- Rayos DR 1mg
- Rayos DR 2mg
- Rayos DR 5mg

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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 Limits

- 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 capsules (generic for Prilosec® (Rx only))
- Pantoprazole sodium tablets (generic for Protonix®)

Nonpreferred agents

- Aciphex® tablets (rabeprazole)
- Dexilant® capsules
- 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 capsules (generic for Prevacid®)
- Lansoprazole ODT (generic for Prevacid® Solutabs)
- Omeprazole/sodium bicarbonate (generic for Zegerid®)
- Prevacid®
- Prevacid® Solutab
- Prilosec® Suspension
- Protonix® tablets
- Rabeprazole sodium (generic for Aciphex®)
- Vimovo®
- Zegerid® capsules/packets

Nonpreferred agents with criteria

- Nexium Packets (Suspension) -**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 recipients age 15 months or older
- Approve treatment beyond 93 days for recipients 15 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 recipients 15 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 nonpreferred agents with criteria

- Nexium Packets
  - Recipient ≤ 4 years of age

- Protonix® suspension
  - Recipient < 7 years of age **OR**
  - History of NPO within the past 365 days

Denial criteria

- Nexium packets
  - Recipient Age > 4
- Protonix Suspension
  - No documented history of NPO (Appendix A) within past 365 days
  - Recipient Age ≥ 7

- All Proton Pump Inhibitors

  > 93 days of PPI therapy in the past 365 days for recipients 15 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 with No Criteria

- Remodulin vials (treprostinil)- **BRAND ONLY**
- Veletri vials (epoprostenol)- **BRAND ONLY**

Preferred PAH Agents with PA Criteria

- Ambrisentan (generic for Letairis)
- Sildenafil tablets (generic for Revatio) see sildenafil
- Sildenafil vials
- Tadalafil tablets (generic for Adcirca, Alyq) see tadalafil
- Tracleer tablets (bosentan) – **BRAND ONLY**

Non-Preferred PAH agents

- Adcirca tablets (tadalafil)
- Adempas tablets (riociguat)
- Bosentan tablets (generic for Tracleer®)
- Bosentan suspension (Bosentan suspension)
- Epoprostenol vials (generic for Veletri)
- Epoprostenol vials (generic for Flolan)
- Flolan vials (epoprostenol)
- Letairis tablets (ambrisentan)
- Liqrev suspension (sildenafil)
- Opsumit tablets (macitentan)
- Opsynvi tablets (macitentan/tadalafil)
- Orenitram tablets (treprostinil)
- Revatio (sildenafil) Suspension
- Revatio tablets
- Sildenafil suspension (generic for Revatio)
- Tadliq suspension (tadalafil)
- Tracleer suspension (bosentan)
- Treprostinil vials
- Tyvaso vials and Tyvaso DPI (treprostinil)
- Uptravi injection and tablets(selexipag)
- Ventavis (iloprost)
- Winrevair vial (sotatercept-csrk) see Winrevair

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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Ruxolitinib (Opzelura®) VITILIGO

(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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Spesolimab (Spevigo®) PUSTULAR PSORIASIS

(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 PUSTULAR PSORIASIS:

- 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
- Prescriber 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 prescriber to submit updated notes with documentation of a positive response to therapy

Pyridostigmine Timespan (Mestinon Timespan)

(Implemented 04/08/2014)

Prescribers may request an override by calling the Prime Help Desk at 1-800-424-7895 (toll-free).

Approval criteria

- >/= 90 days of Pyridostigmine ER therapy in the past 120 days

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Pyrimethamine (Daraprim)

(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 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

- Daraprim

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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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Raloxifene (Evista)

(Implemented 08/21/2010)
(Updated 09/30/2015)

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 this product may be faxed to the Prime Therapeutics State Government Solutions pharmacy unit at 1-800-424-7976.

The clinical point-of-sale approval criteria have been revised to the following:

- 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

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Ranolazine (Aspruzyo Sprinkle)

(Implemented 7/4/2022)

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.

Drug that requires a manual review for prior authorization

- ASPRUZYO SPRINKLE

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.

Denial 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 100mg for infants weighing ≥5kg [≥11lb]). Providers should bill with procedure code 90380 or 90381.
  - ACIP recommends 1 dose of nirsevimab (200mg, administered as two 100mg 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 (Rezdiffra™) 60 mg, 80 mg, and 100 mg tablet

(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:

- Recipient must be ≥ 18 years of age; AND
- Recipient 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:

- Recipient 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
- Recipient has a fever and/or bloody stools

QUANTITY EDITS:

#12/ 23 days

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Rifaximin 550mg Tablets (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

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Risdiplam (Evrysdi) solution

(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 recipients 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

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Roflumilast Tablets (Daliresp)

(Updated 1/1/2020)

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.

Non-Preferred Agents for COPD that Require Manual Review

- Daliresp
- Roflumilast (generic for Daliresp)

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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
- Recipient has a documented diagnosis of moderate to severe plaque psoriasis
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient 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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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
Metrogel 1% Topical
Mirvaso 0.33% Gel
Noritate 1% Cream

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 [MetroCream 0.75%]
- Metronidazole 0.75% Topical Gel [Metrogel 0.75%]
- Metronidazole 0.75% Topical Lotion [MetroLotion 0.75%]

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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)

Prescribers with questions on how to obtain a PA should call 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 requires manual review for prior authorization

- Kuvan
- Javygtor

Top of the document

Satralizumab (Enspryng)

(Implemented 10/21/2020)
(Updated 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:

- Prescribed by a specialist experienced with NMOSD
  - Recipient is diagnosed with neuromyelitis optica spectrum disorder (NMOSD) and is anti-aquaporin-4 (AQP4) antibody positive and confirmed with the following: o Test indicating recipient is seropositive for AQP4-IgG antibodies
  - Recipient 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)
- Recipient 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
- Recipient must have history of at least one documented relapse (including first attack) in the last 12 months
- Recipient must have an Expanded Disability Status Scale (EDSS) score ≤ 6.5
- Recipient is not prescribed medication for the treatment of multiple sclerosis (i.e., interferon, dimethyl fumarate, fingolimod, glatiramer, etc.)
- Recipient 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)
- Prescriber 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)

Top of the document

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
- Restoril
- 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
- Quviviq (daridorexant)
- Ramelteon (generic for Rozerem)
- Silenor
- 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 (Livdelzi®) capsule

(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 (Wegovy®) 0.25 mg, 0.5 mg, 1 mg, 1.7 mg, & 2.4 mg injection

(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)

Serostim

(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 manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Serostim

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Setmelanotide (Imcivree®) 10mg/mL solution

(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/m^2 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/1.73m²)
- 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

Sildenafil tablets (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

Sinecatechins (Veregen ointment 15%)

(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

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Sirolimus (Hyftor™) 0.2% gel

(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:

- Recipient 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
- Recipient is diagnosed with tuberous sclerosis with facial angiofibromas **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient must have at least 3 angiofibromas measuring ≥2 mm in diameter
- Recipient 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
- Recipient 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 5mg, 10mg, 20mg tablets (generic for Lioresal®)
- Chlorzoxazone 500 mg tablet (generic for Parafon®)
- Cyclobenzaprine tablets (generic for Flexeril®)
- Metaxalone tablet (generic for Skelaxin®)
- Methocarbamol tablets (generic for Robaxin®)
- Tizanidine HCl tablet (generic for Zanaflex®)

Nonpreferred agents

- Amrix® ER capsule (cyclobenzaprine)
- Baclofen Suspension (generic for Fleqsuvy®)
- Baclofen Suspension (generic for Ozobax®)
- Baclofen 15mg tablets
- Carisoprodol tablets (generic Soma®)
- Carisoprodol/Aspirin tablets (generic for Soma® Compound)
- Carisoprodol/Aspirin/Codeine tablets (generic for Soma Compound w/ Codeine)
- Chlorzoxazone 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 (baclofen suspension)
- Lyvispah (baclofen granules)
- Lorzone® tablet (generic for chlorzoxazone)
- 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® Capsule)
- Zanaflex® (tizanidine)

QUANTITY EDITS:

- Methocarbamol 500mg and 750mg, up to 8 tablets/24 hours; #248/31 days' supply

Top of the document

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

Top of the document

Sodium Zirconium Cyclosilicate (Lokelma)

(Implemented 01/01/2019)

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

- Lokelma 5gm Powder Pack
- Lokelma 10gm Powder Pack

Additional Criteria

- Quantity Limits Apply

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Sotalol (Sotylize) Solution

(Implemented 07/22/2015)

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

- Sotylize

Top of the document

Sotatercept (Winrevair™) injection

(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 (Filspari™) 200mg and 400mg tablet

(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

Top of the document

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 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 800-160/20ml U.D. 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)

(Implemented 12/10/2013)

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.

Drugs that require manual review for prior authorization

- Astagraf XL

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Tafenoquine (Krintafel) tablets

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.

Drugs that require manual review for prior authorization

- Vyndaqel
- Vyndamax

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 (Vtama) Cream

(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
- Recipient has a documented diagnosis of moderate to severe plaque psoriasis
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient 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)

Prescribers with questions on how to obtain a PA should call 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 (etanercept)
- HUMIRA (adalimumab)
- OTEZLA (apremilast)

Non-Preferred Agents

- ABRILADA (adalimumab-afzb)
- ACTEMRA (tocilizumab)
- ADALIMUMAB-AACF (generic for Idacio)
- ADALIMUMAB-AATY (generic for Yuflyma)
- ADALIMUMAB-ADAZ (generic for Hyrimoz)
- ADALIMUMAB-ADBM (generic for Cyltezo)
- ADALIMUMAB-FKJP (generic for Hulio)
- ADALIMUMAB-RYVK (generic for Simlandi)
- AMJEVITA (adalimumab-atto)
- ARCALYST (rilonacept)
- BIMZELX (bimekizumab-bkzx)
- CIBINQO (abrocitinib)
- CIMZIA (certolizumab)
- COSENTYX (secukinumab)
- CYLTEZO (adalimumab-adbm)
- EBGLYSS (lebrikizumab-lbkz)
- ENSPRYNG (satralizumab-mwge)
- ENTYVIO PEN (vedolizumab)
- HADLIMA (adalimumab-bwwd)
- HULIO (adalimumab-fkjp)
- HYRIMOZ (adalimumab-adaz)
- IDACIO (adalimumab-aacf)
- ILARIS (canakinumab)
- ILUMYA (tildrakizumab-asmm)
- KEVZARA (sarilumab)
- KINERET (anakinra)
- LITFULO (ritlecitinib)
- OLUMIANT (baricitinib)
- OMVOH (mirikizumab-mrkz)
- ORENCIA CLICKJECT AND SYRINGE (abatacept)
- RINVOQ (upadacitinib)
- SILIQ (brodalumab)
- SIMLANDI (adalimumab-ryvk)
- SIMPONI (golimumab)

- SKYRIZI (risankizumab-rzaa)
- SOTYKTU (deucravacitinib)
- SPEVIGO (spesolimab-sbzo)
- STELARA (ustekinumab)
- TALTZ (ixekizumab)
- TREMFYA (guselkumab)
- TYENNE (tocilizumab-aazg)
- VELSIPITY (etrasimod)
- XELJANZ, XELJANZ XR (tofacitinib)
- YUFLYMA (adalimumab-aaty)
- YUSIMRY (adalimumab-aqvh)
- ZYMFENTRA (infliximab-dyyb)

Agents Covered Under Medical Claims Only- Please refer to AFMC for PA criteria

- AVSOLA (infliximab-axxq)
- ENTYVIO VIAL (vedolizumab)
- INFLECTRA (infliximab-dyyb)
- REMICADE (infliximab)
- RENFLEXIS (infliximab-abda)
- UPLIZNA (inebilizumab- cdon)

REFER TO INDIVIDUAL PRODUCT'S PACKAGE INSERT FOR FDA APPROVED INDICATIONS

APPROVAL CRITERIA FOR PLAQUE PSORIASIS

- Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist treating plaque psoriasis
- Recipient has a documented diagnosis of moderate to severe plaque psoriasis
- Recipient 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®
- Recipient 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
- Recipient must have tried and failed phototherapy or have a contraindication
- Recipient 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)
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies
    - Current psoriasis description with BSA and PASI score
- 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 prescriber to submit updated notes with documentation of a positive response to

therapy

APPROVAL CRITERIA FOR PSORIATIC ARTHRITIS AND RHEUMATOID ARTHRITIS

- Prescribed by or in consultation with a rheumatologist or other specialist treating psoriatic arthritis
- Recipient has a documented diagnosis of psoriatic arthritis
- Recipient 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
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies
    - Current labs as baseline (e.g., Erythrocyte Sedimentation Rate, C-Reactive Protein level)
- 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 prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ULCERATIVE COLITIS

- Prescribed by or in consultation with a gastroenterologist
- Recipient 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
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient 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)
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies
    - Current labs including inflammatory markers (i.e., fecal calprotectin, endoscopic Mayo subscore)
- Recipient 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.

APPROVAL CRITERIA FOR CROHN'S DISEASE

- Prescribed by or in consultation with a gastroenterologist
- Recipient 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.
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is prescribed a dose that meets the package insert requirements for indication, age, and weight or supported in MicroMedex®
- Recipient 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
- Prescriber 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)
- Recipient 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.

APPROVAL CRITERIA FOR JUVENILE IDIOPATHIC ARTHRITIS OR DEFICIENCY OF IL-1 RECEPTOR ANTAGONIST

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient has a documented diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (JIA) or deficiency of IL-1 receptor antagonist (DIRA)
- Recipient 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
- Prescriber must submit the following:
    - Current chart notes
    - Documentation of previous therapies with description of current symptoms
    - Current labs including CBCs and inflammatory markers
- 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 prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ANKYLOSING SPONDYLITIS OR NONRADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient has a documented diagnosis of either ankylosing spondylitis or nonradiographic axial
- spondyloarthritis
- Recipient 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)
- Prescriber 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 prescriber to submit updated notes with documentation of a positive response to therapy

For complete Atopic Dermatitis criteria, please see Immunomodulators, Atopic Dermatitis

APPROVAL CRITERIA FOR ATOPIC DERMATITIS

- 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 any other monoclonal antibodies or cytokine & CAM antagonists
- Beneficiary must have a trial and failure of both topical and systemic medications 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 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 change in 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

APPROVAL CRITERIA FOR CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES

- Prescribed by or in consultation with a specialist in treating CAPS
- Recipient must have a diagnosis of cryopyrin-associated periodic syndromes (CAPS) or neonatal-onset multisystem inflammatory disease (NOMID)
- Recipient 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®
- Prescriber must submit the following:
  - Current chart notes
  - Confirmation of the diagnosis with genetic test results if available
  - Baseline symptoms
  - 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 prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR GIANT CELL ARTERITIS

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient has a confirmed diagnosis of giant cell arteritis based on clinical symptoms and ONE of the following:
  - Temporal artery biopsy
  - Ultrasound of vessels
- Recipient 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®
- Prescriber 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

APPROVAL CRITERIA FOR SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DIEASE

- Prescribed by or in consultation with a rheumatologist, pulmonologist, or other specialist
- Recipient 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
- Recipient 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
- Prescriber 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 prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR RECURRENT PERICARDITIS

- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient 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®
- Recipient should not receive this medication if not diagnosed with an inflammatory phenotype.
- Recipient 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
- Prescriber 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

APPROVAL CRITERIA FOR UVEITIS

- Prescribed by or in consultation with a rheumatologist, ophthalmologist, or other specialist for treating uveitis
- Recipient must be diagnosed with non-infectious intermediate, posterior, or panuveitis
- Recipient 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)
- Prescriber 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 prescriber 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

- Prescribed by or in consultation with a rheumatologist or other rare disease specialist for treating

TRAPS

- Recipient must be diagnosed with TNF Receptor Associated Periodic Syndrome (TRAPS) after infectious or neoplastic causes of recurrent fevers are excluded
- Recipient 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
- Prescriber 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 prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR FAMILIAL MEDITERRANEAN FEVER

- Prescribed by or in consultation with a rheumatologist or other rare disease specialist for treating FMF
- Recipient must be diagnosed with Familial Mediterranean Fever (FMF)
- Recipient 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)
- Prescriber 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 prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR STILL'S DISEASE

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient must be diagnosed with active Still's Disease (either Adult-Onset Still's Disease (AOSD) or Systemic Juvenile Idiopathic Arthritis (SJIA))
- Recipient 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

- Prescriber must submit the following:
  - Current chart notes
  - Documentation of symptoms and criteria used for diagnosis
  - Previous therapies tried
  - Current weight for dose determination
- 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 prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ALOPECIA AREATA

- Prescribed by or in consultation with a dermatologist
- Recipient has a documented diagnosis of alopecia areata with >50% scalp hair loss or refractory disease
- Recipient 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)
- Recipient 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®
- Recipient 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
- Prescriber 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 prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR POLYMYALGIA RHEUMATICA

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient 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)
- Prescriber must submit the following:
  - Current chart notes

- Documentation of symptoms
- Current labs including ESR and CRP
- Medical necessity over corticosteroids at maximum tolerated doses

APPROVAL CRITERIA FOR HIDRADENITIS SUPPURATIVA

- 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.
- Recipient 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
- Recipient with diagnosis of Hurley Stage II:
  - Recipient 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 recipient 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 recipient's comorbidities)
  - Recipients who are refractory after at least two 3-month therapies or have progressed to Stage III during treatment may benefit from biologics
    - Adalimumab; OR
    - Secukinumab; OR
    - Infliximab (2nd line after adalimumab)
- Recipient with diagnosis of Hurley Stage III may begin a biologic without a trial from the list above
- Prescriber 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
- Renewal requires prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR ENTHESITIS-RELATED ARTHRITIS

- Prescribed by or in consultation with a rheumatologist or other specialist
- Recipient has a documented diagnosis of enthesitis-related arthritis
- Recipient 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
- 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 prescriber to submit updated notes with documentation of a positive response to therapy

APPROVAL CRITERIA FOR GOUT FLARES

- 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).
- Prescriber 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 prescriber to submit updated notes with documentation of continued gout flare. Ilaris® requires at least 12 weeks between doses.

OTEZLA (Apremilast) is manual review for Behçet's Disease. For criteria for this indication please see: Apremilast (Otezla)

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.

Drugs that require manual review for prior authorization

- Hetlioz Capsule
- Hetlioz Suspension

APPROVAL CRITERIA

- Recipient with Non-24 diagnosis must be ≥ 18 years of age, and recipient with SMS diagnosis must be ≥ 3 years of age; AND
- Recipient 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
    - Recipient must have tried and failed melatonin and other sleep aids
  - Sighted patient
    - Recipient must have tried and failed melatonin and other sleep aids; AND
    - Recipient 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:

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient requires the use of strong CYP1A2 inhibitors or strong CYP3A4 inducers; OR
- Recipient 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.

Drug
Tazorac

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 potency category.

Approval criteria (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 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 Vial (Gattex)

(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 manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.

Drugs that require manual review for prior authorization

- Gattex

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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 Agent with Criteria

- Testosterone cypionate 100mg/ml injection
- Testosterone cypionate 200mg/ml injection
- Testosterone enanthate 200mg/ml injection
- Testosterone gel pump (**GENERIC ONLY** 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)

Criteria for Preferred Agents with Criteria

- Male
- Diagnosis of one of the following diagnoses in the previous 2 years:
  - Hypospadias
  - Klinefelter Syndrome
  - Kallmann Syndrome
  - Panhypopituitarism
  - Prader-Willi Syndrome

Denial criteria

- Female
- Diagnosis of one of the following diagnoses in the previous 2 years:
    - Decreased libido
    - Impotence
    - Any other sexual dysfunction diagnoses

Exceptions (Request through Manual Review Process)

Approve for women with diagnosis of breast cancer or hormone-responsive tumor in history

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) Approval Criteria:

- Recipient 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
- Recipient 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

- Recipient 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

- Recipient must be ≥ 18 years of age; AND
- Dose requirements; AND
    - Begin with 25 mg once daily
    - Max of 100 mg once daily
- Recipient must be prescribed interferon-based therapies.

Severe Aplastic Anemia

- Recipient 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:

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient has a diagnosis of myelodysplastic syndrome; OR
- Hepatitis C recipient is not being treated for HCV infection or the recipient has been prescribed a direct-acting antiviral agent instead of interferon; OR
- Recipient platelet count is ≥ 50,000/µL at time of PA request; OR
- Recipient 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 recipient 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 TABLETS (avatrombopag maleate)
- MULPLETA TABLETS (lusutrombopag)
- PROMACTA SUSPENSION (eltrombopag olamine)
- TAVALISSE TABLETS (fostamatinib disodium)

Quantity Limits for Promacta

50mg #62/31 days
All other strengths #31/31 days

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Thyroid, pork (Adthyza Thyroid) 15 mg, 30 mg, 60 mg, 90 mg, 120 mg tablet

(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

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 (Elimite™)
- Natroba 0.9%™ (spinosad suspension) **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.

Approval Criteria for POS:

- Diagnosis in Medicaid medical history in previous 3 years of cyclic heavy menstrual bleeding; AND
- Recipient'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)
- Recipient'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 fortransderm scopolamine

Additional criteria

Quantity limits apply

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Trientine HCl (Syprine) Capsule

(Implemented 09/18/2013)

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 require manual review for prior authorization

- Syprine

Additional Criteria

- Quantity Limits Apply

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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:

- Recipient has a confirmed diagnosis of long-chain fatty acid oxidation disorder OR a diagnosis consistent with FDA indication; AND
- Recipient 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:

- Recipient does not meet the FDA approved indication OR have a diagnosis supported in the official Compendia; OR
- Recipient has pancreatic insufficiency; OR
- Recipient requires concomitant pancreatic lipase inhibitors (e.g. orlistat); OR
- Recipient is receiving another medium-chain triglyceride product; OR
- Recipient has a feeding tube manufactured of polyvinyl chloride (PVC).

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Trofinetide (Daybue™) 200mg/mL solution

(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:
    o Abnormal muscle tone/dystonia
    o Abnormal respiration pattern
    o Feeding difficulties
    o Intellectual disability (i.e., I.Q. score < 70)
    o Loss of mobility or gait abnormalities
    o Partial or complete loss of acquired hand skills
    o Partial or complete loss of speech
    o Seizures
    o 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:
    o Moderate to severe renal impairment
    o Intolerable diarrhea
    o No improvement in clinical presentation compared to baseline
    o Dose requested is not consistent with weight based dose recommendation
• Prescriber must submit **ALL** of the following:
    o Current chart notes with description of specific symptoms present in this beneficiary
    o Documentation of the MECP2 mutation (if available)
    o Attestation of a clinical diagnosis of RTT in the absence of a MECP2 mutation
    o Current weight
    o Current dose requested
    o Current labs to determine renal function
    o Treatment plan for severe diarrhea and weight loss
    o 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:
    o Current chart notes with documentation of current clinical presentation
    o 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® (carglumic acid) tablets—**BRAND NAME**
- Pheburane® (sodium phenylbutyrate) pellets

Non-preferred Agents

- Buphenyl® (sodium phenylbutyrate) powder
- Buphenyl® (sodium phenylbutyrate) tablet
- Carglumic Acid (generic for Carbaglu®) tablets—**GENERIC**
- Olpruva™ (sodium phenylbutyrate) pellets
- Ravicti® (glycerol phenylbutyrate) liquid
- 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 1.2m2
    - 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® pellets or Buphenyl® tablets/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® tablets
      - Acute treatment for NAGS – 100-250mg/kg
      - Chronic treatment for NAGS – 10-100mg/kg
      - Acute treatment for PA or MMA – 150mg/kg/day for ≤15kg OR 3.3g/m²/day for >15kg
      - If diagnosed with PA or MMA, provide number days treated while hospitalized. Patient should have a maximum of 7 days total.
    - Olpruva™ pellets (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

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 within the past 365 days.

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Vamorolone (Agamree) 40 mg/mL suspension

(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 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

RENEWAL REQUIREMENTS:

- 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: 3 bottles per 30 days

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:

- Recipient must be ≥ 18 years of age; AND
- Recipient 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
- Recipient must have previously been hospitalized for heart failure in the last 6 months or required outpatient IV diuretics in the last 3 months; AND
- Recipient must remain on standard of care therapy; AND
- Recipient of reproductive potential should use contraception and have a negative pregnancy test; AND
- Recipient 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 o
    - Pro-BNP confirms heart failure diagnosis; AND
    - Negative pregnancy test results for recipients of reproductive potential

Denial Criteria:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient is pregnant; OR
- Recipient is taking another soluble guanylate cyclase (sGC) stimulator (i.e., Adempas); OR
- Recipient taking a PDE-5 inhibitor is not recommended to take with this product; OR
- Recipient has severe hepatic impairment (Child-Pugh C) or severe renal impairment (eGFR)

QUANTITY EDITS
#31/ 31 days for each strength

Top of the document

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)**
- **TETRABENAZINE tablet (generic for Xenazine®)**

NON-PREFERRED AGENTS

- **XENAZINE tablet (tetrabenazine)**

APPROVAL 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/1.73m^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

Vonoprazan (Voquezna) tablet, Dual Pak, Triple Pak

(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 (Amvuttra) Syringe

(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
- Recipient meets the minimum age recommended in the manufacturer's package insert for this FDA approved indication
- Recipient is diagnosed with polyneuropathy due to hereditary transthyretin-mediated (hATTR) amyloidosis OR a diagnosis consistent with any updated FDA approved indications
- Recipients 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
- Recipient 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 (Zilbrysq) 16.6 mg, 23 mg, 32.4 mg syringe

(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

Zuranolone (Zurzuvae) 20 mg, 25 mg, 30 mg capsule

(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, B4150-B4156	Enteral formula
B4160-B4162	Enteral formula for pediatrics
96.07	Nasogastric tube insertion
97.01	Nasogastric tube placement
43.11	PEG
46.32	PEJ tube

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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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