

# *Arkansas* Medicaid

## Prescription Drug Program Prior Authorization Criteria

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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 Magellan Medicaid Administration (MMA) Help Desk at 1-800-424-7895 (toll-free) and choose PDL option 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 the Magellan Pharmacy Unit at 1-800-424-7895 (toll-free). The appropriate number is indicated with the associated drug.

Please refer to the Arkansas Medicaid Pharmacy Webpage at <https://arkansas.magellanrx.com/provider/documents> for a complete list of drugs.

The Arkansas Medicaid Preferred Drug List may be found at this link. <https://arkansas.magellanrx.com/provider/docs/rxinfo/PDL.pdf>

## Abemaciclib Tablet (Verzenio)

*(Implemented 03/01/2018)*

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

### Drugs that require a manual review for prior authorization

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- Verzenio Tablet

### Additional criteria

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- Age limits apply
- Quantity limits apply

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## Acalabrutinib Capsule (Calquence)

*(Implemented 03/01/2018)*

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

### Drugs that require a manual review for prior authorization

- Calquence 100mg Capsule

### Additional criteria

- Age limits apply
- Quantity limits apply

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## Abiraterone Acetate Tablet (Zytiga)

*(Implemented 12/10/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Zytiga

### Additional criteria

Quantity limits apply

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## Acitretin Capsule (Soriatane)

*(Implemented 03/26/2008)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## Acyclovir Orally Disintegrating Delayed Release Tablet (Sitavig)

*(Implemented 09/23/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Sitavig

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## Adagrasib (Krazati™) 200mg tablet

(Implemented 5/10/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) and has received at least one prior systemic therapy **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary must have tried and failed at least one prior systemic therapy
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - Requires concomitant use with strong CYP3A inducers
  - Requires concomitant use with strong CYP3A4 inhibitors and has not reached steady state adagrasib concentrations
  - Requires concomitant use with other products that may prolong the QTc interval. If concomitant use cannot be avoided, monitor electrocardiogram and electrolytes
  - Cannot tolerate the minimum dose of 600 mg once daily
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Current labs including CBCs and LFTs
  - Baseline ECG if at risk for QT prolongation or diagnosed with congestive heart failure, bradyarrhythmias, or electrolyte abnormalities
  - Test results verifying the KRAS G12C mutation in tumor or plasma specimens
  - Documentation of previous therapies tried including an immune checkpoint inhibitor (anti-PD-1/PD-L1) (e.g., pembrolizumab, atezolizumab) and/or platinum-based chemotherapy (e.g., cisplatin, carboplatin)

### **RENEWAL REQUIREMENT:**

- Prescriber must submit current chart notes and labs
- Prescriber must submit response to therapy (approval requires the lack of disease progression and lack of unacceptable toxicity)
- Beneficiary continues to meet approval criteria

### **QUANTITY EDITS:**

#180/30 days

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## **Afatinib Dimaleate Tablet (Gilotrif)**

*(Implemented 12/10/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Gilotrif

### Additional criteria

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Quantity limits apply

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## **Alagesic Liquid Oral Solution 50-325-40/15ml**

*(Implemented 01/18/2011)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- NPO ([Appendix A](#)) within past 365 days.

### Age Edit

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- Recipients must be 12 years of age or greater

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## **Alectinib (Alecensa) Capsule**

*(Implemented 07/13/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Alecensa

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## Allergan Extracts

### (Short Ragweed Pollen Allergan Extract) and (Timothy Grass Pollen Allergen Extract)

*(Implemented 09/23/2014)*

*(Updated 07/17/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Ragwitek
- Grastek
- Odactra

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## **Alpelisib (Piqray®)**

*(Implemented 10/16/2019)*

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

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis; AND
- Must be  $\geq 18$  years of age; AND
- If woman, provide documentation that postmenopausal; AND
- Provide documentation that beneficiary has HR positive and HER2negative, PIK3CAmutated, advanced or metastatic breast cancer; AND
- Beneficiary has relapsed after previous treatment with documented evidence of progression; AND • Provide CBCs, BMPs, HbA1c, LFTs; AND
- Provide documentation of previous or current endocrine-based therapy—requires current fulvestrant use; AND
- Provide documentation that patient was advised to start antidiarrheal treatment and educated on the symptoms of hyperglycemia and educated about signs of severe cutaneous reactions; AND
- Beneficiary has either measurable disease or at least one predominantly lytic bone lesion present; AND
- ECOG score  $\leq 2$ ; AND
- Initial approval for 1 month due to significant adverse reaction potential

### **DENIAL CRITERIA:**

- Beneficiary does not meet approval criteria; OR
- History of or current diagnosis of severe cutaneous reactions including Stevens Johnson Syndrome, Erythema Multiforme or Toxic Epidermal Necrolysis; OR
- Beneficiary has inflammatory breast cancer→; OR
- Beneficiary has diabetes mellitus Type 1 or uncontrolled Type 2; OR
- Beneficiary has Child-Pugh score B or C; OR
- Beneficiary has history of acute pancreatitis within 1 year of screening or past history of chronic pancreatitis; OR
- Beneficiary is pregnant or breastfeeding; OR
- Beneficiary taking strong CYP3A4 inducers

### **QUANTITY EDITS:**

- 200mg/day pack #28/28 days
- 250mg/day pack #56/28 days
- 300mg/day pack #56/28 days

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## **Alpelisib (Vioice®)**

(Implemented 7/20/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 2$  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  $\geq 18$  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

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## Alpha-1 Proteinase Inhibitors

(Implemented 10/1/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq$ 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  $\leq$  11 $\mu$ M/L or  $\leq$  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 Magellan 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 Magellan Medicaid Administration 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)
- Namenda® tablet (memantine)
- Namzatic® 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 cavitory 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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

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### Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

- 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 (SELF INJECTED EPINEPHRINE)**

*(Updated 7/1/2023)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### **PREFERRED AGENTS**

- EpiPen®--BRAND ONLY
- EpiPen Jr®--BRAND ONLY

### **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 (generic for EpiPen Jr® and EpiPen®)
- 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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)
- EPANED (enalapril solution)
- LOTREL
- MOEXIPRIL (generic for UNIVASC)
- MOEXIPRIL/HCTZ (generic for UNIRETIC)
- NORLIQVA (amlodipine suspension)
- PERINDOPRIL (generic for ACEON)
- QBRELIS (lisinopril solution)
- TARKA
- TRANDOLAPRIL (generic for MAVIK)
- TRANDOLAPRIL/VERAPAMIL (generic for TARKA)
- ZESTORETIC

### **NON-PREFERRED WITH CRITERIA STATUS**

CAPTROPIL (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)

### **PREFERRED AGENTS WITH CRITERIA:**

- ENTRESTO (valsartan/sacubitril)
  - 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
- CANDESARTAN (generic for ATACAND)
- CANDESARTAN/HCTZ (generic for ATACAND 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)
- TELMISARTAN (generic for MICARDIS)
- TELMISARTAN/AMLODIPINE (generic for TWYNSTA)
- TELMISARTAN/HCTZ (generic for MICARDIS HCT)

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## Antibiotics, Long-acting

*(Implemented 09/21/2009 and 8/17/2010)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 short-acting antibiotics are available without a prior authorization.

### Drugs that require manual review for prior authorization

- Amoxicillin ER 775mg (Moxatag ER)
- Ciprofloxacin ER 500mg, 1000mg (Cipro XR, Proquin XR)
- Metronidazole ER 750mg (Flagyl ER)

[Link to Memorandum: Clarithromycin XL, Flagyl ER 750 mg](#)

[Link to Memorandum:](#) Removal of manual review for Clarithromycin XL

[Link to Memorandum: Ciprofloxacin ER, Proquin, Moxatag](#)

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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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### PREFERRED AGENTS

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

### Approval criteria

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

### Additional criteria

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- 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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 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® Powder Packet (vigabatrin) **BRAND ONLY**
- Sabril® tablet (vigabatrin) **BRAND ONLY**
- Tegretol® suspension (carbamazepine) **BRAND ONLY**
- Topiramate tablet (generic for Topamax®)
- Trileptal® suspension (oxcarbazepine) **BRAND ONLY**
- Valproic acid capsule (generic for Depakene®)
- Valproic acid solution (generic for Depakene®)
- Zonisamide capsule (generic for Zonegran®)

## **NONPREFERRED ANTICONVULSANT AGENTS**

- Aptiom® (eslicarbazepine acetate)
- Banzel® suspension (rufinamide)
- Banzel® tablet (rufinamide)
- Briviact® solution (brivaracetam)
- Briviact® tablet (brivaracetam)
- 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)<sup>\*\*\*</sup> (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)<sup>\*\*\*</sup> (Link to [Fenfluramine Solution \(Fintepla\)](#))
- Fycompa® suspension (perampanel)
- Fycompa® tablet (perampanel)
- Gabapentin solution (generic for Neurontin®)<sup>\*\*</sup>
- Gabitril® tablet (tiagabine)
- Keppra® solution (levetiracetam)
- Keppra® tablet (levetiracetam)
- Keppra XR® tablet (levetiracetam)
- Lamictal® dispersible tablet (lamotrigine)
- Lamictal® dose pack (lamotrigine)
- Lamictal® ODT dose pack (lamotrigine)
- Lamictal® ODT tablet (lamotrigine)
- Lamictal® tablet (lamotrigine)
- Lamictal® XR tablet (lamotrigine ER)
- Lamictal® XR dose pack (lamotrigine)
- Lamotrigine dispersible tablet (generic for Lamictal®)
- Lamotrigine dose pack (generic for Lamictal®)

**NONPREFERRED ANTICONVULSANT AGENTS (CONTINUED)**

- 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 suspension (generic for Trileptal®)
- Oxtellar XR® tablet (oxcarbazepine)
- 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®)
- 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 powder pack (generic for Sabril®)
- Vigabatrin tablet (generic for Sabril®)
- Vimpat® solution (lacosamide)
- Vimpat® tablet (lacosamide)
- Vimpat® tablet dose pack (lacosamide)
- Xcopri® tablet (cenobamate)
- Xcopri® titration pack (cenobamate)
- Zarontin® capsule (ethosuximide)
- Zarontin® solution (ethosuximide)

## **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**

- None

### **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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents with criteria

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- 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 (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

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- 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)
- Citalopram solution (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)

### Approval criteria for preferred agents with criteria

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Drug daily dose ≤ maximum daily dose ([Table 1](#))

### Approval criteria for preferred agents resulting from a therapeutic duplication

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- 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)

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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

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- 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  $\geq 90$  days' supply in the previous 186 days for the same drug, strength, and daily dose

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

<b>Drug</b>	<b>Minimal daily therapeutic dose</b>	<b>Maximum daily dose</b>
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.

<b>Table 1.2 – Selective Serotonin (norepinephrine) Reuptake Inhibitors (combinations)SSRI, SSNRI, or SSRI Combinations</b>
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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976**

### Preferred agents: Alpha Glucosidase Inhibitors

- Acarbose (generic for Precose<sup>®</sup>)

### Non-Preferred agents: Alpha Glucosidase Inhibitors

- Glyset<sup>®</sup> (miglitol)
- Miglitol (generic for Glyset<sup>®</sup>)
- Precose<sup>®</sup> (acarbose)

### Preferred agents: Amylin Analogues

- None

### Non-Preferred agents: Amylin Analogues

- Symlin<sup>®</sup> (pramlintide)

### Preferred agents: DPP-4 Inhibitors (manual review)

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

### Non-Preferred agents: DPP-4 Inhibitors

- Alogliptin (generic for Nesina<sup>®</sup>)
- Alogliptin/metformin (generic for Kazano<sup>®</sup>)
- Alogliptin/pioglitazone (generic for Oseni<sup>®</sup>)
- Glyxambi<sup>®</sup> (linagliptin/empagliflozin)
- Janumet<sup>®</sup> XR (sitagliptin/metformin extended release)
- Jentadueto<sup>®</sup> and Jentadueto XR<sup>®</sup> (linagliptin/metformin)
- Kazano<sup>®</sup> (alogliptin/metformin)
- Kombiglyze<sup>®</sup> XR (saxagliptin/metformin ER)
- Nesina<sup>®</sup> (alogliptin)
- Onglyza<sup>®</sup> (saxagliptin)
- Oseni<sup>®</sup> (alogliptin/pioglitazone)
- Qtern<sup>®</sup> (saxagliptin/dapagliflozin)
- Saxagliptin/metformin ER (generic for Kombiglyze<sup>®</sup> XR)
- Steglujan<sup>®</sup> (sitagliptin/ertugliflozin)
- Trijardy<sup>®</sup> XR (linagliptin/empagliflozin/metformin ER)

### Preferred agents- GLP-1 Agonists

- Bydureon<sup>®</sup> pen/vial (exenatide-ER)- off market
- Byetta<sup>®</sup> pen (exenatide)
- Victoza<sup>®</sup> pen (liraglutide)

### **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<sup>™</sup> injection (lixisenatide)
- Bydureon<sup>®</sup> BCise (exenatide ER)
- Mounjaro<sup>®</sup> injection (tirzepatide)
- Ozempic<sup>®</sup> injection (semaglutide)
- Rybelsus<sup>®</sup> tablet (semaglutide)
- Soliqua<sup>®</sup> injection (lixisenatide/insulin glargine)
- Trulicity<sup>®</sup> pen (dulaglutide)
- Xultophy<sup>®</sup> injection (insulin degludec/liraglutide)

### Insulins – Please see [Insulins](#)

### Preferred agents - Meglitinides

- Nateglinide (generic for Starlix<sup>®</sup>)
- Repaglinide (generic for Prandin<sup>®</sup>)

### Non-Preferred agents - Meglitinides

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

### Preferred agents - Metformins

- Metformin 500mg (generic for Glucophage<sup>®</sup>)
- Metformin 850mg (generic for Glucophage<sup>®</sup>)
- Metformin 1000mg (generic for Glucophage<sup>®</sup>)
- Metformin ER 500mg (generic for Glucophage XR<sup>®</sup>)
- Metformin ER 750mg (generic for Glucophage XR<sup>®</sup>)

### Non-Preferred agents - Metformins

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

### Preferred agents – SGLT-2 Inhibitors

- Farxiga<sup>®</sup> (dapagliflozin)
- Jardiance<sup>®</sup> (empagliflozin)
- Synjardy<sup>®</sup> (empagliflozin/metformin)
- Xigduo<sup>®</sup> ER (dapagliflozin/metformin ER)

### **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<sup>®</sup> 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

- Brenzavvy<sup>®</sup> (bexagliflozin)
- Inpefa<sup>®</sup> (sotagliflozin)
- Invokamet<sup>®</sup> (canagliflozin/metformin)
- Invokamet<sup>®</sup> XR (canagliflozin/metformin ER)
- Invokana<sup>®</sup> (canagliflozin)
- Segluromet<sup>™</sup> (ertugliflozin/metformin)
- Steglatro<sup>™</sup> (ertugliflozin)
- Synjardy<sup>®</sup> XR (empagliflozin/metformin ER)

### Preferred agents-Sulfonylureas

- Glimepiride (generic for Amaryl<sup>®</sup>)
- Glimepiride/pioglitazone (generic for Duetact<sup>®</sup>)
- Glipizide (generic for Glucotrol<sup>®</sup>)
- Glipizide ER (generic for Glucotrol XL<sup>®</sup>)
- Glipizide/Metformin (generic for Metaglip<sup>®</sup>)
- Glyburide (generic for Diabeta<sup>®</sup>)

- Glyburide micronized (generic for Micronase<sup>®</sup>, Glynase<sup>®</sup>)
- Glyburide/Metformin (generic for Glucovance<sup>®</sup>)

#### Non-Preferred Agents-Sulfonylureas

- Amaryl<sup>®</sup> (glimepiride)
- Duetact<sup>®</sup>
- Glucotrol<sup>®</sup> /Glucotrol XL<sup>®</sup> (glipizide)
- Glynase<sup>®</sup> (glyburide micronized)

#### Preferred agents-Thiazolidinediones

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

#### Non- Preferred agents-Thiazolidinediones

- ActoPlus Met<sup>®</sup>
- Actos<sup>®</sup> (pioglitazone)
- Avandia<sup>®</sup> (rosiglitazone)
- Duetact<sup>®</sup>

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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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents with criteria

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- 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

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- Aprepitant (Emend)
- Dolasetron (Anzemet)
- Granisetron (Kytril, Sancuso)
- Netupitant-Palonosetron HCl (Akynzeo)
- Palonosetron HCl (Aloxi)
- 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

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No therapeutic duplication with other 5-HT3 receptor antagonists

### Additional criteria

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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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred Topical Antifungal Agents

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- 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

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- Butenafine 1% cream (Mentax®)
- Ciclopirox 0.77% cream, 1% shampoo (Ciclodan, Loprox)
- Clotrimazole-Betamethasone Rx lotion
- Econazole 1% cream, foam
- Ketoconazole 2% cream, foam (Extina® Foam)
- 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

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- 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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

### Nonpreferred agents

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- 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- 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

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- Ketorolac tablet (Toradol)

### Nonpreferred agents

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- Diclofenac epolamine (Flector)
- Diclofenac epolamine (Licart)
- Diclofenac potassium (Cambia, 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)
- Piroxicam (Feldene)
- Salsalate (Disalcid)
- Sulindac (Clinoril)
- Tolmetin sodium (Tolectin)

#### Nonpreferred agents with criteria

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

#### Approval criteria for nonpreferred agents with criteria

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- Diclofenac Sodium 3% Gel (Solaraze)  
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

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- 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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[Link to PDL Memorandum: NSAIDS](#)

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## Antiparkinson's Agents

(Effective 1/1/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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)
- 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](#)
- Kynmobi (apomorphine) [See Criteria for Kynmobi](#)
- Nourianz (istradefylline) [See Criteria 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)

**Prescribers with questions on how to obtain a PA should call the Magellan 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

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- 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)

### Non-preferred Agents

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- Rykindo ER® (risperidone)
- Uzedy 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 Uzedey™ 50 mg, 75 mg, and 125 mg claim in the last 45 days; Uzedey™ 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 Uzedey™ 50 mg, 75 mg, and 125 mg claim in the last 45 days; Uzedey™ 100 mg, 150 mg, 200 mg and 250 mg claim in the last 90 days

**Uzedey™ 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
- Requires the medical necessity over preferred options

**Criterion 1**

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

**Criterion 2**

- Uzedey™ 50 mg, 75 mg, and 125 mg claim in the last 45 days; Uzedey™ 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 – Preferred Agents for ALL Ages

(Implemented 10/1/2019)

(Updated 7/1/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### **Preferred ORAL Antipsychotic Agents with Criteria (ALL AGES)**

- **First Generation Antipsychotic Agents- Preferred**
  - Chlorpromazine tablets
  - Fluphenazine tablets
  - Haloperidol Lactate Concentrate Solution\*\*
  - Haloperidol tablets
  - Loxapine capsules
  - Perphenazine tablets
  - Thioridazine tablets
  
- **Second Generation Antipsychotic Agents- Preferred\***
  - Aripiprazole tablets (generic for Abilify®)
  - Clozapine tablets (generic for Clozaril®)
  - Lurasidone (generic for Latuda) \*\*\*
  - Olanzapine ODT\*\* (generic for Zyprexa Zydis®)
  - Olanzapine tablets (generic for Zyprexa®)
  - Olanzapine/fluoxetine capsules (generic for Symbyax®)\*\*\*\*
  - Paliperidone tablets (generic for Invega®)
  - Quetiapine tablets (generic for Seroquel®)
  - Risperidone ODT\*\* (generic for Risperdal®)
  - Risperidone solution\*\* (generic for Risperdal®)
  - Risperidone tablets (generic for Risperdal®)
  - Ziprasidone (generic for Geodon®)

**\* Brand Names are listed for reference unless specifically denoted as “BRAND ONLY” Preferred**

**\*\* ODT and Solutions are Preferred ONLY for Ages < 7 v/o or patients with a diagnosis of NPO in history**

**\*\*\*Claims for Lurasidone for recipients ≥18 years of age will process at POS without a PA if the recipient’s Medicaid profile indicates paid claims of ≥ 2 preferred agents in the last 24 months.**

**\*\*\*\*Please see Second Generation Antidepressant criteria**

## **Antipsychotics, Oral – Non-Preferred Agents for ALL Ages**

*(Implemented 10/1/2019)*

*(Updated 7/1/2022)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976**

### **Non-Preferred ORAL Antipsychotic Agents (ALL AGES)**

- **First Generation Antipsychotic Agents-Non-Preferred**
  - Chlorpromazine oral concentrate
  - Fluphenazine Elixir/Solution
  - Molindone tablets
  - Perphenazine/Amitriptyline tablets
  - Pimozide tablets
  - Thiothixene capsules
  - Trifluoperazine tablets
  
- **Second Generation Antipsychotic Agents – Non-Preferred**
  - Abilify Mycite® tablets
  - Abilify® tablets/discmelt/solution
  - Aripiprazole ODT and Solution (generic for Abilify)
  - Caplyta® (lumateperone)
  - Clozapine ODT tablets (generic for Fazaclo®)
  - Fanapt® tablets (iloperidone)
  - Geodon® capsules
  - Invega® tablets
  - Latuda (lurasidone)
  - Lybalvi® tablets (olanzapine/samidorphan)
  - Nuplazid® tablets/capsules (pimavanserin)
  - Quetiapine EXTENDED RELEASE (Seroquel® XR)
  - Rexulti® tablets (brexpiprazole)
  - Risperdal tablets/solution/ODT
  - Saphris® Sublingual (asenapine)
  - Secuado® transdermal (asenapine)
  - Seroquel IR/XR tablets
  - Symbyax capsules
  - Versacloz® Suspension
  - Vraylar® Capsules (cariprazine)
  - Zyprexa® tablets/Zydis

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## Antipsychotics, Oral –Criteria for Adults

(Implemented 10/1/2019)

(Updated 1/23/2020)

(Updated 2/23/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 1-800-424-7976.**

### 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

### POS EDITS for QUETIAPINE ONLY:

- One of the following criteria must be met:  
(*Recipients <18 years of age will not be included in this POS edit*):
  - **Criterion 1:** Recipient has a billed diagnosis in the past two years for one of the following:
    - Schizoaffective disorder
    - Schizophrenia
    - Bipolar I disorder
    - Bipolar II disorder
    - Unspecified bipolar and related disorder
    - Unspecified schizophrenia spectrum and other psychotic disorders
    - Delusional disorder
    - Major depressive disorder, recurrent, severe with psychotic symptoms
    - Major depressive disorder, single episode, severe with psychotic features
  - **Criterion 2:** Recipient has a paid pharmacy claim in their Medicaid drug history for quetiapine in the last 120 days
- If the recipient does not meet one of the POS criteria, a prior authorization request must be submitted including the following:
  - Current chart notes
  - Previous medication therapies
  - Medical necessity for the off-label use (If the request is for sedation, provide the medical necessity over other medications that can be used for sleep such as melatonin, trazodone, and alpha blockers.)

### POS EDITS for LURASIDONE ONLY:

- Claims for Lurasidone for recipients  $\geq 18$  years of age will process at POS without a PA if the recipient's Medicaid profile indicates paid claims of  $\geq 2$  preferred agents in the last 24 months

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## Antipsychotics, Oral – Adult Dosing Charts

<b>ATYPICAL ANTIPSYCHOTIC MAXIMUM THERAPEUTIC DOSING AND QUANTITIES FOR ADULTS (≥ 18 YEARS OLD)</b>			
<b>Aripiprazole (e.g. Abilify®) Tablet Medicaid Max Daily Dose = 30mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

<b>Asenapine (e.g. Saphris®) SL Tablet Medicaid Max Daily Dose = 20mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

**Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria**

<b>Brexpiprazole (e.g. Rexulti ®) Tablet Medicaid Max Daily dose = 4mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

<b>Cariprazine (e.g. Vraylar ®) Capsule Medicaid Max Daily Dose = 6mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

<b>Clozapine (e.g. Clozaril ®) Tablet Medicaid Max Daily Dose = 900mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

**Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria**

<b>Iloperidone (e.g. Fanapt ®) Tablet Medicaid Max Daily Dose = 24mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

<b>Lurasidone (e.g. Latuda ®) Tablet Medicaid Max Daily Dose = 80mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

<b>Olanzapine (e.g. Zyprexa ®) Tablet Medicaid Max Daily Dose = 20mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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 ®) 20mg Tablet & ODT	20 mg	1	31

**Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria**

<b>Paliperidone ER (e.g. Invega ®) Tablet Medicaid Max Daily dose = 12mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

<b>Quetiapine (e.g. Seroquel®) Tablet Medicaid Max Daily Dose = 800mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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®) 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

<b>Quetiapine ER (e.g. Seroquel XR®) Tablet Medicaid Max Daily Dose = 800mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

<b>Risperidone (e.g. Risperdal®) Tablet Medicaid Max Daily Dose = 16mg</b>			
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**Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria**

<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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	12 4
Risperidone (e.g. Risperdal®) 1mg/ml Oral Solution (30ml)	4 mg	4 ml	12 0

<b>Ziprasidone (e.g. Geodon®) Capsule Medicaid Max Daily Dose = 160mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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**

<b>Chlorpromazine (e.g. Thorazine®) Tablet Medicaid Max Daily Dose = 800mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

<b>Fluphenazine (e.g. Prolixin®) Tablet Medicaid Max Daily Dose = 40mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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<b>Haloperidol (e.g. Haldol®) Tablet Medicaid Max Daily Dose = 40mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

<b>Loxapine (e.g. Loxitane®) Capsule Medicaid Max Daily Dose = 250mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAXIMUM CUMULATIVE QTY</b>
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

Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

<b>Perphenazine (e.g. Trilafon®) Tablet Medicaid Max Daily Dose = 64mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

  

<b>Perphenazine-Amitriptyline (e.g. Etrafon®) Tablet Medicaid Max Daily Dose = 16MG/100MG</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

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

<b>Thioridazine (e.g. Mellaril®) Tablet Medicaid Max Daily Dose = 800mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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<b>Thiothixene (e.g. Navane®) Capsule Medicaid Max Daily Dose = 60mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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

<b>Trifluoperazine (e.g. Stelazine®) Tablet Medicaid Max Daily Dose = 40mg</b>			
<b>DRUG NAME</b>	<b>MEDICAID MAX DAILY DOSE BY STRENGTH</b>	<b>MEDICAID MAX DAILY QUANTITY EDIT</b>	<b>MEDICAID MONTHLY MAX CUMULATIVE QTY</b>
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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### 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 requires >= 90 days of Seroquel XR therapy in the past 120 days. Immediate-release quetiapine (Seroquel) is covered via existing criteria.

### Additional dose criteria

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#### Atypical antipsychotics

- Requested dose must be an approved dose for age range ([Table 2](#))
- Requested maximum daily dose must be approved for age range ([Table 2.2](#)).

Denial criteria

## Antipsychotics

- Claims with a therapeutic duplication on the same date of service
- Requests for Loxapine, Thioridazine, Thiothixene, Fanapt®, or Saphris®, Rexulti ® for patients <18 years of age
- 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

Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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® Zydys®	5mg	QD	1 tab	1 tab	1 tab	1 tab
Zyprexa® Zydys®	10mg	QD		1 tab	1 tab	1 tab
Zyprexa® Zydys®	15mg	QD			1 tab	1 tab
Zyprexa® Zydys®	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)

[Link to Memorandum](#)

[Link to Memorandum](#) (Initial Antipsychotic criteria)

[Link to Memorandum](#) (Requirements of informed consent and metabolic monitoring)

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## Apalutamide (Erleada)

(Updated 4/18/2018)

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

### **APPROVAL CRITERIA:**

- Beneficiary is  $\geq$  18 years of age;
- Beneficiary has high risk non-metastatic castration-resistant prostate cancer demonstrated during continuous ADT, defined as 3 PSA rises, at least 1 week apart, with the last PSA greater than ( $>$ ) 2 nanogram per milliliter (ng/mL);
- Beneficiary has histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation or small cell features with high risk for development of metastases, defined as prostate-specific antigen doubling time (PSADT) less than or equal to ( $\leq$ ) 10 months. PSADT is calculated using at least 3 prostate-specific antigen (PSA) values obtained during continuous ADT (androgen deprivation therapy);
- Beneficiary must be receiving gonadotropin-releasing hormone (GnRH) analog concurrently, OR the beneficiary has had a bilateral orchiectomy. If the beneficiary's Medicaid profile does not provide documentation of either of these, the prescriber must submit the documentation;
- Beneficiary must maintain castrate levels of testosterone of  $<$  50 ng/dL within 4 weeks of the PA request for ERLEADA™;
- Patients who received a first generation anti-androgen (for example, bicalutamide, flutamide, nilutamide) must have at least a 4-week washout prior to PA request AND must show continuing disease (PSA) progression (an increase in PSA) after washout;
- At least 4 weeks must have elapsed from the use of 5-alpha reductase inhibitors (finasteride or dutasteride), estrogens, and any other anti-cancer therapy prior to request to start ERLEADA™;
- At least 4 weeks must have elapsed from major surgery or radiation therapy prior to request to start ERLEADA™;
- Beneficiary has Eastern Cooperative Oncology Group Performance Status 0 or 1;
- Beneficiary must be currently receiving bone loss prevention treatment with bone-sparing agents must be on stable doses for at least 4 weeks prior to PA request for ERLEADA™.
- PA approval will be month-to-month due to high incidence of adverse reactions requiring dose interruption or modification

### **DENIAL CRITERIA:**

- Presence of confirmed distant metastases, including central nervous system and vertebral or meningeal involvement;
- Symptomatic local or regional disease requiring medical intervention;
- Prior treatment with second generation anti-androgens; • Prior treatment with CYP17 inhibitors;
- Prior treatment with radiopharmaceutical agents, or any other investigational agent for nonmetastatic castration-resistant prostate cancer;
- Prior chemotherapy for prostate cancer except if administered in the adjuvant/neoadjuvant setting;
- History of seizure or condition that may pre-dispose to seizure;

### **Quantity edit:**

- Daily dose not to exceed 240 mg once daily;
- ERLEADA™ 60mg is available as a bottle of 120 tablets. However, due to the high incidence of adverse events requiring dose reduction, the approved quantity will be entered at the time of each PA approval in the event of a dose reduction.

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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 Magellan 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**

- NUVIGIL<sup>®</sup> (armodafinil) **(BRAND ONLY)**
- XYREM<sup>®</sup> SOLUTION (sodium oxybate) **(BRAND ONLY)**

### **Non-preferred agents**

- Armodafinil tablet (generic for NUVIGIL<sup>®</sup>)
- LUMRYZ ER<sup>®</sup> SUSPENSION (sodium oxybate) – when rebate eligible
- Modafinil tablet (generic for PROVIGIL<sup>®</sup>)
- PROVIGIL<sup>®</sup> TABLET (modafinil)
- Sodium oxybate solution (generic for XYREM<sup>®</sup>)
- SUNOSI<sup>®</sup> TABLET (solriamfetol)
- WAKIX<sup>®</sup> TABLET (pitolisant)
- XYWAV<sup>®</sup> 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  $\geq 7$  years and  $< 19$  years must have a trial of a CII stimulant in the last year
- Beneficiary  $\geq 19$  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 2naps (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  $\geq 19$  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  $\geq 7$  years and  $< 19$  years require a documented trial and failure of CII in the last year with documentation of the medical necessity over the preferred medications.

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## Aromatase Inhibitors (Arimidex and Femara)

*(Implemented 09/24/2008)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Drugs that require prior authorization

- Anastrozole oral tablet [Arimidex]
- Letrozole oral tablet [Femara]

### Approval criteria

Medical history for female breast cancer in the past 3 years

### Denial criteria

- Diagnosis of Infertility in Medicaid History

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## Apomorphine (Kynmobi)

(Implemented 10/21/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq$  18 years of age; AND
- Recipient must have a diagnosis of Parkinson's disease with acute, intermittent "OFF" episodes OR a diagnosis consistent with FDA indications; AND
- Recipient must be compliant on current therapy of levodopa/carbidopa (immediate or CR) at maximally tolerated doses for at least 4 weeks before adding KYNMOBI; AND
- At baseline, recipient must experience at least one well defined "OFF" episode per day with a total daily "OFF" time duration of  $\geq$  2 hours during the waking day, based on patient self-assessment; AND
- Recipient is Hoehn and Yahr Stage III or less in the "ON" state; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current vital signs including blood pressure and heart rate and documentation that recipient has been evaluated for potential hypotension/orthostatic hypotension AND
  - Current labs including CBC, BMP and LFTs; AND
  - Documentation that the recipient has an antiemetic (e.g. trimethobenzamide) beginning 3 days prior to initial dose; AND
  - Medical necessity of adding this medication over increasing the current levodopa/carbidopa dosage or adding another PD medication that does not require a PA; AND
  - Baseline Unified Parkinson's Disease Rating Scale (UPDRS) Part III Motor Examination score.

### **Denial Criteria:**

- Recipient does not meet the FDA approved indication OR have a diagnosis supported in the official Compendia; OR
- Recipient requires concomitant use of 5HT3 antagonists (i.e., ondansetron, granisetron, dolasetron, palonosetron, alosetron), dopamine antagonists (excluding quetiapine or clozapine) or dopamine depleting agents due to risk for profound hypotension or loss of consciousness; OR
- Recipient has a documented history of hypotension; OR
- Recipient has drug or alcohol dependency issues noted in the past 12 months; OR
- Recipient has major psychiatric disorder including, but not limited to, dementia, bipolar disorder, psychosis OR suicidal ideation/attempt in the last year; OR
- Recipient has  $\leq$  2 hours per day of "OFF" time; OR
- Recipient has Hoehn and Yahr stage  $>$  3 in an "ON" state; OR
- Recipient cannot tolerate the 10 mg dose; OR
- Recipient reports significant daytime sleepiness or episodes of falling asleep during activities that require active participation.

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## **Apremilast (Otezla)**

*(Implemented 7/1/2021)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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:

- Recipient must be  $\geq 18$  of age; AND
- Recipient must have a diagnosis of Behçet's Disease OR a diagnosis consistent with FDA indications; AND
- Recipient with oral ulcers has tried and failed topical corticosteroids (i.e., triamcinolone acetonide cream 0.1% in Orabase); AND
- Recipient has tried and failed at least 3 months of treatment with colchicine or immunosuppressant; AND
- Prescriber must submit current chart notes; AND
- Disease manifestation besides oral ulcers will be reviewed on a case-by-case basis; AND
- Initial PA approved for 3 months

### Denial Criteria for Behçet's Disease:

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia

### QUANTITY EDITS:

- #62/31 days

## **Asciminib (Scemblix)**

(Implemented 1/19/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) with one of the following:
  - Recipients without the T315I mutation must previously have been treated with two or more tyrosine kinase inhibitors (TKIs) (e.g., imatinib, nilotinib, dasatinib, radotinib or ponatinib); OR
  - Recipients with the T315I mutation must have a trial and failure of ponatinib unless the development of the T315I mutation was determined after the ponatinib trial; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs including CBC, serum lipase, and amylase levels; AND
  - Genetic test results with confirmation of the Philadelphia chromosome and/or the BCRABL gene; AND
  - Test results for the T315I mutation, if applicable; AND
  - Previous therapy; AND
  - Current blood pressure; AND
- Initial PA will be approved for 1 month to determine tolerability

### **DENIAL CRITERIA:**

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient without the T315I mutation must be able to tolerate the minimum dose of 40 mg daily (or 20 mg twice daily); Recipient with the T315I mutation must be able to tolerate the minimum dose of 160 mg twice daily; OR
- Recipient has uncontrolled hypertension; OR
- Recipient has baseline platelets <50 X 10<sup>9</sup> /L; OR
- Recipient has recent history of pancreatitis; OR
- Recipient is pregnant

### **QUANTITY EDITS:**

- 20 mg--#60/ 30 days
- 40 mg--#60/ 30 days
- PA required for quantity override on patients with T315I mutation

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## Asfotase Alfa (Strensiq) Injection

*(Implemented 07/13/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 (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 OPZELURA

- Beneficiary must be  $\geq 12$  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):
  - Baseline impacted body surface area (BSA)  $\geq 10\%$
  - Baseline Eczema Area and Severity Index (EASI) total score of  $\geq 16$
  - Baseline weekly averaged peak pruritis Numeric Rating Scale (NRS)  $\geq 7$
  - Baseline Investigator's Global Assessment (IGA) score  $\geq 3$
  - Baseline Scoring Atopic Dermatitis (SCORAD) score  $\geq 25$
- 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

Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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- 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)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Preferred agents with criteria

- ADDERALL XR CAPSULE (**BRAND ONLY**)
- AMPHETAMINE/DEXTROAMPHETAMINE SALTS TABLETS (generic for ADDERALL IR)
- ATOMOXETINE CAPSULE (generic for STRATTERA)
- CLONIDINE IR TABLETS (generic for CATAPRES)
- CLONIDINE ER TABLET (generic for KAPVAY ER)
- CONCERTA (**BRAND ONLY**)
- DAYTRANA PATCH (**BRAND ONLY**)
- DEXMETHYLPHENIDATE ER CAPSULE (generic for FOCALIN XR)
- DEXMETHYLPHENIDATE IR TABLET (generic for FOCALIN)
- DEXTROAMPHETAMINE TABLET 5 mg and 10 mg TABS (generic for ZENZEDI)
- FOCALIN TABLETS
- FOCALIN XR CAPSULES
- GUANFACINE IR TABLETS (generic for TENEX)
- GUANFACINE ER TABLETS (generic for INTUNIVE ER)
- METHYLPHENIDATE TABS (generic for METHYLIN, RITALIN IR)
- VYVANSE CHEW TABLETS (**BRAND ONLY**)
- VYVANSE CAPSULES (**BRAND ONLY**)

### Nonpreferred agents

- ADHANSIA XR CAPSULE
- ADZENYS ER SUSPENSION
- ADZENYS XR-ODT
- AMPHETAMINE SUSPENSION (generic for ADZENYS ER)
- AMPHETAMINE/ DEXTROAMPHETAMINE SALTS ER CAPSULE – **GENERIC FOR ADDERALL XR ONLY**
- 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)
- DYANAVAL XR SUSPENSION
- DYANAVAL 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 CONCERTA ONLY**)
- 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
- 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:

Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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- ≤ 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

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Quantity limits apply

[Link to Memorandum](#)

[Link to Memorandum](#)

[Link to Memorandum: CII Stimulant for Adults](#)

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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: Manually Reviewed agents for adults: > 19 years of age**

- ADDERALL XR CAPSULE (**BRAND ONLY**)
- AMPHETAMINE/DEXTROAMPHETAMINE SALTS TABLETS (generic for ADDERALL IR)
- ATOMOXETINE CAPSULE (generic for STRATERRA)
- CLONIDINE IR TABLETS (generic for CATAPRES)
- CLONIDINE ER TABLET (generic for KAPVAY ER)
- CONCERTA TABS (**BRAND ONLY**)
- DAYTRANA PATCH (**BRAND ONLY**)
- DEXMETHYLPHENIDATE ER CAPSULE (generic for FOCALIN XR)
- DESMETHYLPHENIDATE IR TABLET (generic for FOCALIN)
- DEXTROAMPHETAMINE TABLET (generic for ZENZEDI)
- FOCALIN TABLETS
- FOCALIN XR CAPSULE
- GUANFACINE IR TABLETS (generic for TENEX)
- GUANFACINE ER TABLETS (generic for INTUNIVE ER)
- METHYLPHENIDATE TABLET (generic for METHYLIN, RITALIN IR)
- VYVANSE CHEW TABLETS (**BRAND ONLY**)
- VYVANSE CAPSULES (**BRAND ONLY**)

### **Non- Preferred Agents**

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- ADHANSIA XR CAPSULE
- ADZENYS ER SUSPENSION
- ADZENYS XR-ODT
- AMPHETAMINE SUSPENSION (generic for ADZENYS ER SUSPENSION)
- AMPHETAMINE/ DEXTROAMPHETAMINE SALTS ER CAPSULE – **GENERIC FOR ADDERALL XR ONLY**
- 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)
- 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 CONCERTA ONLY**)
- 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
- 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  $\geq 19$  years of age  
<https://ar.magellanrx.com/documents/268611/269351/Adult%20Use%20of%20a%20C-II%20Stimulant%20Statement%20of%20Medical%20Necessity/d9a327df-d05c-665e-b17b-593f58e8c95e>
- 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

## Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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- 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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

## Avapritinib (Ayvakit)

(Implemented 4/15/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq$  18 years of age; AND
- Recipient is diagnosed with unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations or diagnosis consistent with FDA indication; AND
- Prescriber should provide the following:
  - Current chart notes
  - Current labs including CBC with differential, comprehensive metabolic panel (CMP) and LFTs
  - Documentation of measurable lesion

### Denial Criteria:

- Recipient cannot tolerate the minimum dose of 100mg daily; OR
- Recipient must take moderate or strong CYP3A inhibitors or inducers; OR
- Recipient has severe intracranial hemorrhage; OR
- Reduce dose or discontinue for severe central nervous system effects; OR
- Recipient is pregnant or breastfeeding; OR
- Recipient has platelet count  $<$  90,000/mL; OR
- Recipient has severe renal impairment (CrCl= 3 times ULN and any AST)

### QUANTITY EDITS:

#30/30 days for each strength

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## **Axitinib Tablet (Inlyta)**

*(Implemented 07/09/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Inlyta tablet

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## **Azacitidine (Onureg)**

(Implemented 1/20/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 55$  years of age; AND
- Recipient must have the diagnosis of acute myeloid leukemia and either achieved first complete remission OR complete remission with incomplete blood count recovery after intensive induction chemotherapy and are not able to complete intensive curative therapy OR a diagnosis consistent with FDA indication; AND
- Recipient should not be substituting ONUREG for IV or subcutaneous azacitidine at the same doses; AND
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies and response; AND
  - Current labs including CBC with differential and LFTs (delay therapy cycle if ANC  $< 0.5$  Gi/L) AND
  - Required dosage since dose adjustments are required for neutropenia, thrombocytopenia, and gastrointestinal toxicity; AND
- Recipient must not be a candidate for hematopoietic stem cell transplant; AND
- Recipient must be prescribed an antiemetic for use during the first 2 cycles; AND
- PA's approved month-to-month until stable due to significant thrombocytopenia and neutropenia risks

### **Denial Criteria**

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient has not received recent intensive induction chemotherapy; OR
- Recipient is pregnant or breastfeeding; OR
- Recipient cannot tolerate the minimum dose of 200 mg per day with a reduced treatment duration of 7 days; OR
- Recipient has a diagnosis of myelodysplastic syndrome; OR
- Recipient has moderate to severe hepatic impairment (total bilirubin  $>1.5$  to  $3 \times$  ULN); OR
- Recipient had a prior bone marrow or stem cell transplantation

### **Quantity Edits**

#14/ 28 days

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## **Azithromycin (Azithromycin Powder Packets and ZMAX)**

*(Implemented 04/12/2011)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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
- ZMAX 2gm/60ml suspension

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## Baloxavir marboxil (Xofluza)

(Implemented 1/16/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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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## Balsalazide Disodium Tablet (Giazo)

*(Implemented 07/09/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Giazo

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## **Becaplermin (Regranex)**

*(Implemented 01/12/2005)*

*(Updated 09/29/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Approval criteria

- Submitted diagnosis of diabetes, type I or type II, with neurological manifestations in the previous 365 days, AND
- Submitted diagnosis of skin ulcer (neuropathic ulcer) in past 180 days

### Denial criteria

- > one claim in past 30 days

### Additional criteria

Quantity limits apply

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## **Bedaquiline Fumarate Tablet (Sirturo)**

*(Implemented 12/10/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age (for subcutaneous injection); AND
- 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 FDA indications; AND
- Recipient with SLE must have:
  - Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score of  $\geq 8$ ; AND
  - Positive autoantibody test (anti-nuclear antibody (ANA) and/or anti-double-stranded DNA (anti-dsDNA)); AND
- Recipient with LN must have:
  - Clinical diagnosis of SLE; AND
  - Biopsy confirmed active lupus nephritis
- Recipient must take concomitant standard therapy which could include corticosteroids (e.g., prednisone), antimalarials (e.g., hydroxychloroquine), NSAIDs, and immunosuppressive (e.g., azathioprine, methotrexate, mycophenolate); AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - 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; AND
  - Current blood pressure; AND
  - Medical necessity over supported immunosuppressive therapy alone for SLE patients (i.e., mycophenolate mofetil or azathioprine).

### Denial Criteria

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient has progressive multifocal leukoencephalopathy (PML); OR
- Recipient has a SELENA-SLEDAI score of  $< 8$  and does not have a positive autoantibody test; OR
- Recipient has been 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; OR
- Recipient is pregnant; OR
- Recipient is not taking concomitant standard therapy.

QUANTITY EDITS:

4 syringes/ 28 days

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## Belumosudil (Rezurock)

(Implemented 10/20/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 12$  years of age; AND
- Recipient must be diagnosed with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy OR a diagnosis consistent with FDA indication; AND
- Recipient of reproductive potential should use effective contraception; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Documentation of previous therapies tried with response; AND
  - Current labs including CBC with differential, LFTs, and CMP; AND
  - Negative pregnancy test for female recipient 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 demonstrates disease progression; OR
- Recipient develops hepatotoxicity while on the medication with either Grade 4 AST or ALT (20X ULN) or Grade 3-4 bilirubin (3X ULN)
- Recipient has the following labs values at baseline (provide if available):
  - Platelets  $< 50 \times 10^9 /L$
  - ANC  $< 1.5 \times 10^9 /L$
  - AST or ALT  $> 3X$  ULN
  - Total bilirubin  $> 1.5X$  ULN
  - eGFR  $< 30$  mL/min/1.73m<sup>2</sup>
  - FEV1  $\leq 39\%$  (patients with pulmonary manifestations)

### QUANTITY EDITS:

#30/ 30 days

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## **Bempedoic Acid (Nexletol/Nexlizet)**

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age; AND
- Recipient must have a diagnosis of heterozygous familial hypercholesterolemia or atherosclerotic cardiovascular disease OR a diagnosis consistent with FDA indications; AND
- Provider must submit the following:
  - Current chart notes
  - Chart notes during trials of statins AND
  - ezetimibe AND
  - Current labs including lipids and LFTs as well as labs corresponding with previous trials of statins AND ezetimibe taken concomitantly; AND
  - Uric acid levels for patients with a gout diagnosis; AND
  - Medical necessity over the use of medications outlined in current treatment guidelines; AND
- Compliance on previous lipid therapy is required unless contraindicated (see definition).
- Recipient's Medicaid claims history will be consulted, and a pharmacy printout may be requested to ensure compliance; AND
- Recipient must be prescribed concomitant statin therapy unless contraindicated or patient demonstrated statin intolerance (see definition); AND
- Recipient should have an LDL-C  $\geq 70$ mg/dL and/or non-HDL-C  $\geq 100$ mg/dL after trials of moderate-high intensity statins and ezetimibe per current treatment guidelines unless the recipient has a contraindication; AND
- Provider must submit diet plan for lowering cholesterol; AND
- If recipient smokes, provider should submit a smoking cessation plan or documentation that the recipient has been counseled on smoking cessation; AND
- Initial approval for 2 months

### Denial Criteria

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient has a ruptured tendon; OR
- Provider orders concomitant statin therapy with simvastatin dose  $> 20$  mg or pravastatin dose  $> 40$  mg; OR
- Recipient has end-stage renal disease (ESRD) receiving dialysis OR severe hepatic impairment (Child-Pugh C); OR
- Recipient is taking PCSK9 inhibitors; OR
- Recipient does not have baseline lipids meeting approval criteria; OR
- Recipient has not compliantly trialed concomitant therapy of statins with ezetimibe per treatment guidelines (For patients that do not have a contraindication or intolerance to statins).

### QUANTITY EDITS:

#31/ 31 days

[Link to Memorandum](#)

## **Belzutifan (Welireg)**

*(Implemented on 10/20/2021)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age; AND
- Recipient must be diagnosed with von Hippel-Lindau (VHL) disease and require therapy for renal cell carcinoma, central nervous system hemangioblastoma, or pancreatic neuroendocrine tumor but does not require immediate surgery OR a diagnosis consistent with FDA indications; AND
- Recipient of reproductive potential should use effective non-hormonal contraception; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Previous therapies tried; AND
  - Documentation of diagnosis (i.e., MRI results, fundoscopy report, abdominal US/MRI results, or blood & urinary catecholamine metabolites) with tumor size; AND
  - Current labs; AND
  - Baseline oxygen saturation; AND
  - Pregnancy test results of female recipient of reproductive potential
- Initial PA approved for 1 month

### Denial Criteria:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient is pregnant; OR
- Recipient with a hemoglobin  $<9$  g/dL should have medication withheld (If possible, resume at reduced dose if Hb increases to  $\geq 9$  g/dL.) and permanently discontinue depending on the severity of anemia; OR
- Recipient with decreased oxygen saturation (pulse oximeter  $<88\%$ ) should have medication withheld (If possible, resume at same or reduced dose depending on severity.) and permanently discontinue for life-threatening or recurrent symptomatic hypoxia; OR
- Recipient has severe renal or hepatic impairment; OR
- Recipient requires immediate need for tumor surgery

### QUANTITY EDITS:

#90/ 30 days

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## Benign Prostatic Hypertrophy (BPH) Drugs

(Implemented 01/12/2012)

(Updated to PDL on 10/1/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### **Preferred Agents:**

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

### **Non-Preferred Agents:**

- Avodart<sup>®</sup> capsule (dutasteride)
- Cardura<sup>®</sup> tablet (doxazosin)
- Cardura<sup>®</sup> XL tablet (doxazosin)
- Cialis<sup>®</sup> tablet (tadalafil)‡
- Dutasteride/Tamsulosin capsule (generic for Jalyn<sup>®</sup>)
- Entadfi<sup>®</sup> (finasteride/tadalafil) capsule
- Flomax<sup>®</sup> capsule (tamsulosin)
- Jalyn<sup>®</sup> capsule (dutasteride/tamsulosin)
- Proscar<sup>®</sup> tablet (finasteride)
- Rapaflo<sup>®</sup> capsule (silodosin)
- Silodosin capsule (generic for Rapaflo<sup>®</sup>)
- Tadalafil tablet (generic for Cialis<sup>®</sup>)‡

\*\*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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.**

### Approval Criteria

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- 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 22.5 mg Capsule requires a Manual PA (see Temazepam 22.5 mg)
- Alprazolam XR [Xanax XR] additional approval criteria:
  - $\geq 18$  years of age, AND
  - $\geq 90$  days of Alprazolam XR therapy in the past 120 days
- Alprazolam oral-disintegrating tablet [Niravam]
  - $\geq 18$  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 12 months:
    - 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 Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Approval criteria

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

### Additional criteria

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Quantity limits apply

### Exemption criteria

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Midazolam 2 mg/ml Syrup

- Claims for 30 ml or less will pay at point-of-sale for anyage.

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## Berotralstat (Orladeyo)

(Implementation Date 4/21/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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
  - 17 $\alpha$ -alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
  - Antifibrinolytic agents (e.g.  $\epsilon$ -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

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## Beta Adrenergic Blocking Agents

(Implemented 10/17/2007)

(Updated 1/1/2019)

(Updated 1/1/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- Acebutolol (generic for Sectral)
- Atenolol (generic for Tenormin)
- Atenolol/Chlorthalidone (generic for Tenoretic)
- Bisoprolol fumarate (generic for Zebeta)
- Bisoprolol/HCTZ (generic for Ziac)
- Bystolic -**BRAND NAME ONLY**
- Carvedilol tablet (generic for Coreg)
- Labetalol HCl (generic for Normodyne)
- Metoprolol succinate extended-release (generic for Toprol XL)
- Metoprolol tartrate (generic for Lopressor)
- Propranolol HCl immediate-release (generic for Inderal)
- Sotalol tablets (generic for Betapace)

### Nonpreferred agents

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- Betapace
- Betaxolone (generic for Kerlone)
- Carvedilol phosphate CR capsule (Coreg CR)
- Coreg
- Coreg CR
- Corgard
- Hemangeol (propranolol) suspension
- Inderal LA (propranolol ER)
- Kapsargo (metoprolol) sprinkle
- Metoprolol/HCTZ (generic for Lopressor HCT)
- Nadolol (generic for Corgard)
- Nadolol/Bendroflumethiazide (generic for Corzide)
- Nebivolol HCl (generic for Bystolic)
- Pindolol (generic for Viskin)
- 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

Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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- 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 Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- Diagnosis of Homocystinuria in the previous 2 years.

### Additional criteria

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Quantity limits apply

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## **Bexarotene Gel (Targretin)**

*(Implemented 10/01/2004)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Targretin

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## **Binimetinib (Mektovi 15mg Tablets)**

*(Implemented 01/01/2019)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Mektovi 15mg Tablets

### Additional Criteria

- Quantity Limits Apply

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## **Bosutinib (Bosulif 100mg and 500mg Tablets)**

*(Implemented 03/19/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Bosulif

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## Bowel Prep Agents and Kits

(Implementation Date 10/11/2011)

(Updated 01/01/2019)

(Updated 7/1/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration 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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## Brigatinib (Alunbrig) Tablet

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Alunbrig 30mg and 90mg Tablet

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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 Magellan 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 Magellan Medicaid Administration 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  $\geq 40$  years of age; **AND**
- No Therapeutic Duplication (TD) with overlapping days' supply between drugs in the same drug classification.

### Additional criteria

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- 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 Magellan 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 Magellan Medicaid Administration 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 Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Preferred Agents with Criteria

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

### Non- Preferred Agents

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- 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

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- 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

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- 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 Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Preferred Agents with Criteria

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- Anoro Ellipta<sup>®</sup> (umeclidinium-vilanterol)
- Bevespi Aerosphere<sup>®</sup> (formoterol/glycopyrrolate)
- Stiolto Respimat<sup>®</sup> (tiotropium/olodaterol)

### Non-Preferred Agents

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- Duaklir Pressair<sup>®</sup> (aclidinium/formoterol)

### Approval criteria for preferred agents with criteria

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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<sup>®</sup>, Bevespi<sup>®</sup> or Stiolto<sup>®</sup> 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)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Preferred ICS/LABA agents with criteria

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

### Approval Criteria for Symbicort<sup>®</sup> and Dulera<sup>®</sup> and Advair HFA/Diskus<sup>®</sup>

- **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<sup>®</sup>
    - Advair HFA<sup>®</sup>
    - Dulera<sup>®</sup>
    - Symbicort<sup>®</sup>
- **Criterion 3:**
  - Age: ≥ 4 Years of Age AND
  - Asthma diagnosis in the past two years
- **Criterion 4:**
  - Age ≥ 4 Years of years old **AND**
  - One of the following criteria below:
    - ≥ Three inhaled corticosteroid claims in the last 120 days, OR
    - ≥ Three oral steroid claims in the last 120 days, OR
    - Combination for ≥ three claims (as defined below) in the last 120 days:
      - One Inhaled Corticosteroid + 2 Oral Steroids
      - Two Inhaled Corticosteroids + 1 Oral Steroids

### Non-Preferred agents

- AirDuo Digihaler<sup>®</sup> (fluticasone/salmeterol)
- AirDuo RespiClick<sup>®</sup> (fluticasone/salmeterol)
- Breo Ellipta<sup>®</sup> (fluticasone furoate/vilanterol)
- Breyna<sup>®</sup> (budesonide/formoterol)
- Budesonide/formoterol (generic for Symbicort<sup>®</sup>)—GENERIC ONLY
- Fluticasone/salmeterol (generic for Advair<sup>®</sup> Diskus)—GENERIC ONLY
- Fluticasone/salmeterol HFA (generic for Advair<sup>®</sup> HFA)—GENERIC ONLY
- Fluticasone/salmeterol (generic for AirDuo<sup>®</sup> RespiClick)
- Fluticasone/vilanterol (generic for Breo Ellipta<sup>®</sup>)
- Wixela Inhub<sup>®</sup> (fluticasone/salmeterol)

### Quantity Limits

- Symbicort<sup>®</sup>--#2 inhalers per month for 120 actuation size  
If the recipient needs > 8 puffs per day, a PA can be submitted to approve an additional inhaler.
- Dulera<sup>®</sup>--#2 inhalers per month
- Advair Diskus<sup>®</sup> and Advair HFA<sup>®</sup>- 1 inhaler per month 9

(\*\*NOTE\*\* Advair Diskus<sup>®</sup> and Advair HFA<sup>®</sup> 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 Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- None at this time

### Non-Preferred agents

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- Breztri<sup>®</sup> Inhaler (budesonide/glycopyrrolate/formoterol)
- Trelegy Ellipta<sup>®</sup> (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 Magellan 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

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- Submitted Diagnosis of Ulcerative Colitis in the past 2 years

### Additional criteria

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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 Magellan 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

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

### Additional criteria

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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 Magellan 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 m<sup>2</sup> 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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## Butalbital Products

(Implemented 01/18/2011)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- 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 12 months:
  - 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq 1$  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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq 1$  severe or life-threatening laryngeal attack per month or  $\geq 4$  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.
  - 17 $\alpha$ -alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
  - Antifibrinolytic agents (e.g.  $\epsilon$ -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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq 1$  severe or life-threatening laryngeal attack per month or  $\geq 4$  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.
  - $17\alpha$ -alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
  - Antifibrinolytic agents (e.g.  $\epsilon$ -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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## **Cabozantinib (Cometriq) Capsule**

*(Implemented 07/09/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Cometriq

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## **Cabozantinib (Cabometyx) Tablet**

*(Implemented 05/23/2017)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Cabometyx 20mg, 40mg, and 60mg Tablet

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## Capmatinib (Tabrecta™)

(Effective 7/15/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 has been diagnosed with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test **OR** diagnosis consistent with FDA indications; **AND**
- Prescriber should submit the following:
  - Current chart notes with previous therapies tried; **AND**
  - Current labs including LFTs and CBCs; **AND**
  - Documentation of MET exon 14 skipping mutation; **AND**
- Recipient must have a negative status for epidermal growth factor receptor (EGFR) wild-type and anaplastic lymphoma kinase (ALK) gene mutations; **AND**
- If Tabrecta™ must be co-administered with a P-gp substrate (e.g. digoxin) or BCRP substrate (e.g. rosuvastatin), prescriber should submit a plan for dosage decreases of the substrates; **AND**
- Initial PA may be approved for 3 months.

### Denial Criteria

- Recipient is unable to tolerate the minimum dose of 200 mg twice daily, **OR**
- Recipient has EGFR mutations or ALK-positive rearrangement, **OR**
- Recipient has Interstitial Lung Disease/Pneumonitis, **OR**
- Recipient has Grade 4 increase in AST and/or ALT without elevated bilirubin **OR** ALT and/or AST >3X ULN with bilirubin >2X ULN **OR** Grade 4 increase in bilirubin without elevated AST and/or ALT, **OR**
- Recipient is pregnant or breastfeeding, **OR**
- Recipient requires coadministration with a moderate or strong CYP3A inducer (e.g. bosentan, rifampin or phenytoin), **OR**
- Recipient has disease progression on this medication

### Quantity Edits

- 150 mg tablet — #120/30 days
- 200 mg tablet — #120/30 days

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## Caplacizumab-yhdp (Cablivi)

(Implemented 10/16/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 ≥ 100X10<sup>9</sup> /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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.**

<b>Drug</b>	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 Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- $\geq$  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

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

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## Calcium Channel Blockers

*(Implemented 07/12/2005)*

*(Updated 07/20/2015)*

*(Updated 1/1/2021)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration 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)
- 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 ( $\geq 2$  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)  $> 5 \times$  upper limit of normal (ULN); ALT or AST  $> 3 \times$  ULN and total bilirubin  $> 2 \times$  ULN or international normalized ratio (INR)  $> 1.5$ ; ALT or AST  $> 3 \times$  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 Magellan 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 Magellan Medicaid Administration 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

### Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

- 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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## Carbidopa (Lodosyn)

*(Implemented 01/12/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- At least 1 paid Medicaid claim for Sinemet (carbidopa/levodopa) in the previous 60 days, OR
- At least 1 paid Medicaid claim for Stalevo in the previous 60 days.

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## **Carbidopa/Levodopa Enteral Infusion Suspension (Duopa)**

*(Implemented 07/22/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Duopa Enteral Infusion

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## Carbidopa-Levodopa-Entacapone (Stalevo)

*(Implemented 01/12/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- No therapeutic duplication with Comtan.

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## **Carglumic Acid (Carbaglu)**

*(Implemented 01/19/22)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 have a diagnosis of hyperammonemia due to N-acetylglutamate Synthase (NAGS) deficiency, Propionic Acidemia (PA), or Methylmalonic Acidemia (MMA) OR a diagnosis consistent with FDA approved indication; AND
- Recipient must remain on standard of care therapy for acute, severe hyperammonemia, and CARBAGLU can be used alone in chronic NAGS; AND
- Prescriber must order a dose consistent with diagnosis and kidney function; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs including plasma ammonia levels and eGFR; AND
  - Current weight; AND
  - Current BMI for recipients with PA or MMA weighing more than 15 kg; AND
  - Daily dose requested; AND
  - Documentation of adjunctive standard of care therapy for acute hyperammonemia; AND
  - Number of days treated while hospitalized for PA or MMA (max of 7 days total)

### **DENIAL CRITERIA:**

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Prescriber requests therapy for PA or MMA for longer than 7 days total which includes doses received during hospitalization; OR
- Prescriber requests dose outside of guidance from package insert

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## **Cedazuridine/Decitabine (Inqovi)**

*(Implemented 10/21/2020)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age; AND
- Recipient has a documented diagnosis of myelodysplastic syndrome (MDS) OR a diagnosis consistent with FDA indications; AND
- Prescriber must submit the following
  - Current chart notes; AND
  - Current labs including CBC with differential, BMP, and LFTs; AND
  - Female recipients of childbearing potential must have a negative pregnancy test prior to beginning Inqovi® OR have documentation of contraception usage; AND
  - Documentation of prior therapies with response; AND
  - Medical necessity over IV decitabine; AND
- Recipient has an absolute neutrophil count (ANC)  $> 1,000/\mu\text{L}$  and platelets  $> 50,000/\mu\text{L}$ ; AND
- Recipient has Total or direct bilirubin  $\leq 2 \times$  upper limit of normal (ULN); AST/SGOT and ALT/SGPT  $\leq 2.5 \times$  ULN; AND
- Recipient has serum creatinine  $\leq 1.5 \times$  ULN or calculated creatinine clearance or glomerular filtration rate  $> 50 \text{ mL/min/1.73 m}^2$ ; AND
- Prior authorizations will be approved for only one (1) month at a time

### **Denial Criteria:**

- Recipient does not meet the FDA approved indication OR have a diagnosis supported in the official Compendia; OR
- Recipient is pregnant; OR
- Recipient does not meet lab approval criteria; OR
- Recipient is taking concomitant IV decitabine; OR
- Recipient had cytotoxic chemotherapy or prior azacitidine or decitabine within 4 weeks of first dose; OR
- Recipient has rapidly progressive or highly proliferative disease (total white blood cell count of  $> 15 \times 10^9 /\text{L}$ ) or other criteria that render the subject at high risk of requiring intensive cytotoxic chemotherapy within the next 3 months; OR
- Recipient has a life-threatening illness or severe organ system dysfunction, such as uncontrolled congestive heart failure or chronic obstructive pulmonary disease, or other reasons including laboratory abnormalities, which could compromise the recipient's safety, interfere with absorption or metabolism.

### **QUANTITY EDITS:**

#5 tablets/ 28 days

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## **Cenegerm-in-bkbj (Oxervate)**

*(Implemented 04/20/2022)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### **APPROVAL CRITERIA:**

- Recipient must be  $\geq 2$  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

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## Cephalosporins

(Implemented 4/1/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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

### Non-Preferred agents

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

*(Implemented 09/23/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Zykadia

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## Chlorpheniramine ER 12mg

*(Implemented 04/08/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- $\geq$  90 days of Chlorpheniramine ER therapy in the past 120 days

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## **Cholic Acid (Cholbam)**

*(Updated 05/20/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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**

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- 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 Magellan 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 Magellan Medicaid Administration pharmacy unit at 1-800-424-7976.**

### PREFERRED AGENTS

- Amitiza® (Lubiprostone capsule) **BRAND ONLY**
- Linzess (linaclotide)
- Movantik (naloxegol)

### NONPREFERRED AGENTS

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

### Approval criteria for Amitiza

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#### Criterion 1:

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

#### Criterion 2:

- Recipient must be  $\geq 18$  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
- 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; 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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## **Cidofovir Injection (Vistide)**

*(Implemented 04/17/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Vistide

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.**

### Approval criteria

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**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 diagnoses 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 diagnoses 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 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 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 Magellan 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 Magellan Medicaid Administration 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## **Cobimetinib (Cotellic) Tablets**

*(Implemented 04/26/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Cotellic tablets 20mg

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## Colony Stimulating Factors

*(Reviewed 5/10/18)*

*(Effective 7/1/18)*

*(Effective 7/1/2021)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### PREFERRED AGENTS

- NEUPOGEN (filgrastim) vial and syringe
- NYVEPRIA (pegfilgrastim-apgf)

### NONPREFERRED AGENTS

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

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## Corticosteroids, Oral Inhaled (ICS)

(Implemented 08/11/2009)

(Updated 2/22/18)

(Effective 4/1/18)

(Updated 1/15/2020)

(Updated 1/1/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- Asmanex<sup>®</sup> Twisthaler (mometasone furoate)
- Flovent Diskus<sup>®</sup>
- Flovent<sup>®</sup> HFA Inhaler (fluticasone propionate HFA inhaler) – **BRAND ONLY**
- Pulmicort Flexhaler<sup>®</sup>

### Preferred Agents with Criteria

- Budesonide ampules for nebulizer (generic for Pulmicort Respules<sup>®</sup>)

### Non-Preferred Agents

- Airsupra<sup>®</sup> (budesonide/albuterol)
- Alvesco<sup>®</sup> (ciclesonide)
- Armonair Digihaler<sup>®</sup> (fluticasone propionate)
- Arnuity Ellipta<sup>®</sup> (fluticasone furoate)
- Asmanex HFA<sup>®</sup> (mometasone furoate)
- Fluticasone HFA (generic for Flovent HFA<sup>®</sup>)
- Pulmicort Respules<sup>®</sup> (budesonide)
- QVAR Redihaler<sup>®</sup> (beclomethasone dipropionate)

### Approval criteria for 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 Eosinophilic Esophagitis
  - Age < 10 years—maximum dose is 2 mg/day
  - Age ≥ 10 years—maximum dose is 4 mg/day

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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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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, 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%  
Fluocinolone 0.01% solution, 90 ml  
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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 time of discharge with specific taper directions; **AND**
- PA will be approved at the time of discharge for the amount needed for completion of the taper. Recipients cannot fill Acthar as a pharmacy benefit and use during hospitalization.

**PA Form can be found at:**

[https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx\\_PA\\_Request\\_Form\\_Acthar.pdf](https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx_PA_Request_Form_Acthar.pdf)

### 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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## Crizotinib Capsule (Xalkori)

*(Implemented 04/17/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

Xalkori

### Information required for the manual review process

Detection of ALK-positive NSCLC using an FDA-approved test, indicated for this use

### Additional criteria

Quantity limits apply

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## **Crofelemer Delayed Release Tablet (Fulyzaq)**

*(Implemented 07/09/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Fulyzaq

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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 Magellan 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 Magellan Medicaid Administration (MMA) 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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## **Cyclosporine 0.05% Eye Solution (Cequa)**

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Cequa Ophthalmic Solution

## Cyproheptadine 4mg/10ml U.D. Cup

*(Implemented 04/08/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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Currently LTC

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Cystaran Ophthalmic Drop
- Cystadrops Ophthalmic Drop

### Additional criteria

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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

### Additional criteria

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## **Dalfampridine Extended-Release Tablet (Ampyra ER)**

*(Implemented 09/28/2010)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Ampyra ER 10mg tablet

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## Dabrafenib (Tafinlar) Capsules and Suspension

*(Implemented 09/18/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Tafinlar

### Additional Criteria

- Quantity Limits Apply

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## Dacomitinib (Vizimpro)

(Implemented 1/16/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Vizimpro

### Approval Criteria

- Beneficiary is > 18 years old
- Beneficiary has diagnosis metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test
- Female beneficiary is not pregnant or breastfeeding
- Beneficiary has at least 12-month disease free interval between previous systemic therapy and recurrence of disease
- Provider must submit baseline lab documentation to show beneficiary has adequate renal, hematologic, and liver function
- ECOG score is 0-2
- PA approval one month

### Denial Criteria

- No diagnosis of NSCLC with approved mutation
- Disease progression;
- Interstitial Lung Disease (ILD)
- Use of PPIs concomitantly
- CrCl < 30 mL/min
- ECOG 3 or 4
- History of brain mets or leptomeningeal mets
- Concomitant use of CYP2D6 substrates

### QUANTITY LIMITS:

Max of 1 tablet daily and 30 tablets/30 days

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## Darolutamide (Nubeqa®)

(Implemented 10/16/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 have a diagnosis of non-metastatic castration-resistant prostate cancer OR metastatic hormone-sensitive prostate cancer in combination with docetaxel OR a diagnosis consistent with FDA indication
- Beneficiary should not be approved or continue on this therapy with any of the following:
  - History of any of the following in the last 6 months: stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, CHF NUHA class III or IV
  - Currently taking P-gp and strong or moderate CYP3A4 inducers (e.g., rifampicin) due to decreased Nubeqa® levels
  - Cannot tolerate the minimum dose of 300 mg twice daily
- Beneficiary must receive a gonadotropin-releasing hormone analog concurrently or have had a bilateral orchiectomy
- Beneficiary must have a castrate level of testosterone
- Provider must submit ALL of the following:
  - Current chart notes
  - Documentation of previous therapy
  - Current labs including CBCs, LFTs, renal function, testosterone level, and PSA
  - Attestation of counseling for sexually active patients that are not surgically sterile to use condoms
- PA's may be approved for 3 months at a time

### **QUANTITY EDITS:**

#120 per 30 days

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## Dasatinib (Sprycel)

*(Implemented 01/13/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Sprycel

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## Deferasirox Tablet (Jadenu)

*(Implemented 04/13/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq$  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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq 18$  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 m<sup>2</sup>
- 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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## Deutetrabenazine and Deutetrabenazine Extended-Release (Austedo and Austedo XR) Tablet

(Implemented 11/22/2017)

(Updated 11/27/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Austedo 6mg Tablet
- Austedo 9mg Tablet
- Austedo 12mg Tablet
- Austedo XR 6mg Tablet
- Austedo XR 12 mg Tablet
- Austedo XR 24mg Tablet

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis; AND
- Beneficiary must be 18 years of age or older; AND
- Prescriber must submit chart notes with documentation on the impact of TD or chorea symptoms with activities of daily living; AND
- Beneficiary must either have a diagnosis of moderate to severe tardive dyskinesia or chorea associated with Huntington's Disease. If has tardive dyskinesia, beneficiary must meet the following DSM-5 criteria:
  - Involuntary athetoid or choreiform movements; AND
  - History of treatment with dopamine receptor blocking agent (DRBA) (e.g. antipsychotics or metoclopramide); AND
  - Symptom duration lasting longer than 4 to 8 weeks; AND
- Beneficiary with chorea associated with Huntington's Disease must not be suicidal or have untreated or inadequately treated depression; AND
- Austedo® must be prescribed by a neurologist or psychiatrist; or prescriber has consulted with a neurologist or psychiatrist if symptoms are due to antipsychotic usage or Huntington's disease. Austedo® may also be prescribed by gastroenterology if symptoms are due to metoclopramide usage.; AND
- Prescriber must submit the completed Medicaid "Ingrezza® / Austedo® Statement of Medical Necessity" form with the initial request as part of the manual review; Form can be found at:  
[https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx\\_SMN\\_Form\\_Ingrezza\\_Austedo.pdf](https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx_SMN_Form_Ingrezza_Austedo.pdf)
- For treating Tardive Dyskinesia, prescriber must submit a baseline Abnormal Involuntary Movement Scale (AIMS) form as part of the manual PA review; AND
- Female beneficiary must not be pregnant or breastfeeding; AND
- If beneficiary has taken benztropine, or any other agent for EPS symptoms, provider must submit data documenting the response to the agent; AND

Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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- Beneficiary must not have congenital long QT Syndrome (LQTS) or cardiac arrhythmias associated with a prolonged QT interval and prescriber must provide attestation; AND

- If beneficiary takes a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) OR the beneficiary is a poor CYP2D6 metabolizer, maximum daily dose is reduced to 36mg; AND
- Beneficiary must not have hepatic impairment and prescriber must provide attestation; AND
- Beneficiary must not be taking monoamine oxidase inhibitors (MAOIs), any other VMAT2 inhibitor or reserpine; AND
- Provider must provide the Austedo® tapering plan with each PA request until beneficiary reaches a stable, maintenance dose; AND
- The initial Austedo® PA will be approved for two (2) months to allow time for titration. Austedo® 6mg 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.

**DENIAL CRITERIA:**

- Beneficiary is < 18 years of age; OR
- Beneficiary is not compliant on prescribed dose after previous approval; OR
- Prescriber requests dose > 48mg/ day; OR
- Prescriber requests a dose > 36mg/ day for beneficiaries taking a strong CYP2D6 inhibitor or is a poor CYP2D6 metabolizer; OR
- Beneficiary does not have an improvement from baseline AIMS score or a positive clinical response to therapy on renewal request; OR
- Beneficiary with a diagnosis of chorea associated with Huntington's Disease is suicidal or has untreated or inadequately treated depression; OR
- Beneficiary is pregnant or breastfeeding; OR
- Beneficiary has congenital long QT Syndrome or cardiac arrhythmias associated with prolonged QT interval; OR
- Beneficiary has documented hepatic impairment OR
- Beneficiary develops Neuroleptic Malignant Syndrome OR
- Beneficiary takes reserpine, MAOIs or any other VMAT2 inhibitor OR
- Beneficiary does not meet approval criteria.

**QUANTITY EDITS:**

6mg tablets = #60 per 30 days  
9mg tablets = #120 per 30 days  
12mg tablets = #120 per 30 days  
6mg XR tablets = #30 per 30 days  
12mg XR tablets = #30 per 30 days  
24mg XR tablets = #60 per 30 days

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## **Dexchlorpheniramine maleate (Ryclora™)**

*(Implemented 1/16/2019)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq 2$  years of age and  $\leq 6$  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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## Duvelisib (Copiktra) Capsule

(Memo 2/14/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Copiktra 15 mg capsule
- Copiktra 25 mg capsule

### APPROVAL CRITERIA require all of the following:

- Age > 18 years old;
- Beneficiary has diagnosis of chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), OR follicular lymphoma (FL), AND has relapsed or has refractory disease, AND has had at least two prior CLL/SLL therapies or two prior FL systemic therapies;
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2;
- Must meet the following laboratory parameters:
  - Serum aspartate transaminase (AST/SGOT) or alanine transaminase (ALT/SGPT)  $\leq 3$  x upper limit of normal (ULN)
  - Total bilirubin  $\leq 1.5$  x ULN
  - Serum creatinine  $\leq 2.0$  x ULN
  - Hemoglobin  $\geq 8.0$  g/dL with or without transfusion support
  - Platelet count  $\geq 10,000$   $\mu$ L with or without transfusion support
- Female beneficiary of childbearing potential must have a current negative pregnancy test at the time of PA request;
- Female beneficiary is not lactating;
- Prescriber has prescribed Trimethoprim-sulfamethoxazole (TMP-SMX), or other appropriate agent, as prophylaxis for jiroveci pneumonia (PJP), formerly known as Pneumocystis carinii pneumonia (PCP);
- Prescriber has prescribed prophylactic antiviral treatment for prevention of cytomegalovirus (CMV) infection or reactivation;
- Initial PA will be approved for 1 month

### DENIAL CRITERIA, any one of the following:

- Disease progression;
- Beneficiary is unable to tolerate a minimum dose of 15 mg twice daily;
- Beneficiary does not have a diagnosis of CLL, SLL, or FL;
- Beneficiary has not received 2 previous treatments for CLL, SLL, or FL;
- Beneficiary has Richter syndrome (RS), also called Richter transformation;
- Beneficiary has prolymphocytic leukemia;

- Beneficiary has uncontrolled autoimmune hemolytic anemia (AIHA) or idiopathic thrombocytopenia purpura (ITP) that is uncontrolled or requiring > 20 mg once daily (QD) of prednisone (or equivalent) to maintain hemoglobin > 8.0 g/dL or platelets > 10,000  $\mu$ L without transfusion support;
- Beneficiary has diagnosis of FL grade 3b;
- Beneficiary has a history of tuberculosis treatment within the preceding two years;
- Beneficiary is pregnant, planning to become pregnant, or breastfeeding;
- Beneficiary does not meet laboratory requirements listed under approval criteria;
- Beneficiary has an ECOG score >2;
- Prior allogenic transplant
- Prior treatment with PI3K or BTK inhibitors
- Ongoing treatment with chronic immunosuppressants (i.e. cyclosporine, prednisone > 20 mg daily, etc.)
- Patient has or has a history of or current HIV, Hepatitis B or C, or history of alcohol abuse or liver disease;
- QTc > 480 msec;
- Beneficiary is unable to receive prophylactic treatment for jiroveci pneumonia (PJP), formerly known as Pneumocystis carinii pneumonia (PCP);

**QUANTITY LIMIT:**

- Strength of capsule will be entered at the time of PA approval;
- Quantity limit of both strengths not to exceed 2 per day and 56 capsules per 28-day supply;

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## **Dexamethasone Dose Pak (DexPak and Zema-Pak)**

*(Implemented 10/11/2011)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Dexamethasone 1.5mg Tablet

### Drugs that require manual review for prior authorization

- Dexpak
- Zema-Pak

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Nuedexta capsule

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## Dichlorphenamide (Keveyis)

*(Implemented 02/16/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## **Digoxin Tablet 187.5mcg and 62.5mcg Tablet (Lanoxin)**

*(Implemented 07/13/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Lanoxin 187.5mcg
- Lanoxin 62.5mcg

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## **Dihydroergotamine Mesylate Nasal Spray (Migranal)**

*(Implemented 07/09/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Migranal Nasal Spray

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## Disopyramide CR (Norpace CR)

*(Implemented 04/08/2014)*

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

### Approval criteria

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- $\geq$  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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.**

### Approval criteria

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Diagnosis of cystic fibrosis in medical history

### Additional criteria

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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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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

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## Doxycycline/Minocycline

*(Implemented 06/19/2008)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 mg tablet (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 5mg Chewable Tablet (Aldex AN)

*(Implemented 09/28/2010)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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Patients  $\leq$  6 years of age that cannot swallow a solid oral dosage form.

### Additional criteria

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Quantity limits apply

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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**

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- 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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976**

### Approval criteria

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#### 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 as single 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

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- 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

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

[Link to Memorandum](#)

## **Elacestrant (Orserdu™) 86mg and 345mg tablet**

*(Implemented 5/10/2023)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 estrogen receptor (ER)+/ human epidermal growth factor receptor (HER2)-, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary must be a postmenopausal female or an adult male
- Beneficiary should not be approved with any of the following:
  - Not diagnosed with ER+/HER2- breast cancer
  - Does not have the ESR1 mutation
  - Cannot tolerate the minimum dose of 172 mg once daily
  - Pregnancy
  - Requires concomitant strong or moderate CYP3A4 inducers or inhibitors
  - Severe hepatic impairment
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous therapies tried with response
  - Test results documenting ESR1 mutation
  - Current labs including lipid panel (must be monitored periodically)

### **RENEWAL REQUIREMENTS:**

- Beneficiary continues to meet approval criteria
- Beneficiary does not demonstrate disease progression or unacceptable toxicity
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including lipid panel

### **QUANTITY EDITS:**

86 mg tablets--#93/31 days

345 mg tablets--#31/31 days

## **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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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)

#### Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

- 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  $\leq$  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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Eliglustat (Cerdelga) Capsule

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## **Enasidenib Mesylate (Idhifa) Tablet**

*(Implemented 11/22/2017)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Idhifa 50mg Film Coated Tablet
- Idhifa 100mg Film Coated Tablet

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## Encorafenib (Braftovi) Capsule

*(Implemented 01/01/2019)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Braftovi 50mg Capsule
- Braftovi 75mg Capsule

### Additional Criteria

- Quantity Limits Apply

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## Entacapone (Comtan)

*(Implemented 01/12/2012)*

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

### Approval criteria

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- At least 1 paid Medicaid claim for Sinemet (carbidopa/levodopa) in the past 60 days, AND
- No therapeutic duplication with Stalevo.

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## Entecavir (Baraclude)

*(Implemented 09/24/2008)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- 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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## Entrectinib (Rozyltrek™) capsules

(Implemented 10/16/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case; AND
- Must be  $\geq 18$  years of age for NSCLC diagnosis and  $\geq 12$  years of age for Solid Tumors diagnosis; AND
- Beneficiary must have a diagnosis of either ROS1-Positive Non-Small Cell Lung Cancer OR neurotrophic receptor tyrosine kinase (NTRK) Gene Fusion-Positive Solid Tumors (sarcoma, lung cancer, salivary gland tumor, secretory breast cancer, thyroid cancer and colorectal cancer); AND
- Beneficiaries with diagnosis of NTRK Gene Fusion-Positive Solid Tumors must have one of the following:
  - have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion without a known acquired resistance mutation,
  - are metastatic or where surgical resection is likely to result in severe morbidity,
  - have either progressed following treatment or have no satisfactory alternative therapy.
- Provider must submit histologically or cytologically confirmed diagnosis of NTRK1, NTRK2, NTRK3, ROS1
- ALK molecular alteration by using tests such as, next generation sequencing (NGS) or fluorescence in situ hybridization (FISH); AND
- ECOG  $\leq 2$ ; AND
- Provider must submit current chart notes and documentation of previous treatment (if applicable); AND
- Provide current body surface area (BSA) for pediatric patients to adequately verify dosing; AND
- Provide current labs including: AND
  - Liver Function Tests (LFTs) (monitor every 2 weeks for first month, then monthly)
  - Baseline serum uric acid levels (monitor periodically)
  - Complete Blood Count (CBC) with differential
  - Basic Metabolic Panel (BMP)
- Provide ECG baseline with documentation of QTcF and baseline LVEF; AND
- Provider must attest to counseling sexually active patients (male and female) that are not surgically sterile to use condoms or other forms of birth control; AND
- Initial PA approve 1 month to monitor for adverse reactions

**DENIAL CRITERIA:**

- Beneficiary does not meet approval criteria
- Beneficiary has symptomatic CHF, myocardial infarction, unstable angina, or coronary artery bypass graft within 3 months; OR
- LVEF  $\leq$  50%; OR
- Beneficiary has risk factors for torsade de pointes; OR
- Beneficiary has known interstitial lung disease, interstitial fibrosis or history of tyrosine kinase inhibitor-induced pneumonitis; OR
- Beneficiary has a diagnosis of torsade de pointes, polymorphic ventricular tachycardia or signs/symptoms of serious arrhythmia; OR
- Beneficiary is pregnant or breastfeeding; OR
- Beneficiary has hepatotoxicity with ALT or AST  $>3$  X ULN with concurrent total bilirubin  $>1.5$  X ULN (in absence of cholestasis or hemolysis); OR
- Beneficiary has Grade 4 central nervous system effects; OR
- Beneficiary requires moderate or strong CYP3A inhibitors. If requires coadministration, reduce Rozlytrek™ dose and provide documentation of monitoring adverse reactions; OR
- Beneficiary requires moderate or strong CYP3A4 inducers as Rozlytrek™ plasma concentrations are decreased; OR
- Beneficiary requires another medication that can prolong QT/QTc intervals

**QUANTITY EDITS:**

100mg capsules -- #30 per 30 days

200mg capsules -- #90 per 30 days

## Enzalutamide - (Xtandi)

*(Implemented 12/19/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Xtandi

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## Eosinophilic Esophagitis

(Implemented 7/20/2022)

(Updated 7/19/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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.

### **Manual Review APPROVAL CRITERIA for Dupixent (dupilumab):**

- Beneficiary must be ≥ 12 years of age and at least 40 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

## Erlotinib (Tarceva®)

(Implemented 7/17/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Tarceva

#### Approval Criteria

- Manual review on a case-by-case basis;
- ≥18 years old
- Must have a diagnosis consistent with the FDA approved indications listed above
- For NSCLC patient—documentation on the presence of EGFR exon 19 deletions or exon 21 substitution mutations using an FDA-approved test
- Pregnancy test results if applicable
- ECOG ≤ 2
- Documentation of smoking status
- Provide the following labs:
  - CBC
  - Renal function and serum electrolytes
  - Liver function tests
  - INR if taking warfarin
  - Clinical trial required leukocytes ≥ 3,000/μL
    - absolute neutrophil count ≥ 1,500/ μL ▪ platelets ≥ 100,000/ μL
    - total bilirubin ≤ 1.5 X institutional upper limit of normal
    - AST(SGOT)/ALT(SGPT) ≤ 3 X institutional upper limit of normal, unless the liver is involved with tumor, in which case the AST/ALT must be ≤ 5 X institutional upper limit of normal
    - creatinine clearance ≥ 50 mL/min/1.73 m<sup>2</sup>, as measured by 24hour collection OR
    - creatinine ≤ 1.5 X institutional upper limit of normal
- For NSCLC patient—documentation of disease progression following course of standard chemotherapy or participants unwilling/unable to undergo chemo
- For pancreatic cancer patient—documentation of combination of gemcitabine with TARCEVA®
- For pancreatic cancer patient--prior adjuvant chemotherapy is allowed provided that patients did not receive gemcitabine and the chemotherapy was completed > six months prior to initiation of therapy

#### Denial Criteria

- NSCLS patient has EGFR mutations different than the approved indication
- Denied if NSCLC patient continues to take a platinum-based chemotherapy
- Pregnancy
- Discontinue or deny if have any of the following:
  - Gastrointestinal perforations
  - Bullous and exfoliative skin disorders

- Ocular disorders such as corneal perforation, ulceration or severe keratitis
- Diagnosis of Interstitial Lung Disease (ILD)
- Denied if pancreatic cancer patient is not taking gemcitabine
- Denied if patient has brain metastases
- Denied if pancreatic cancer patient had prior systemic treatment for metastatic disease

**QUANTITY EDITS:**

- 25mg tablets #60/ 30 days
- 100mg tablets #30/ 30 days
- 150mg tablets #30/ 30 days

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## Erdfafitinib (Balversa™)

(Implemented 7/17/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Balversa

#### Approval Criteria

- Manual review on a case-by-case basis
- ≥18 years old
- Metastatic or surgically unresectable urothelial cancer with presence of FGFR alteration documented by FDA-approved companion diagnostic with disease progression on prior chemotherapy
- Chart notes
- Provide the following:
- Current labs including
  - CBC
  - Serum phosphate level
  - Pregnancy tests results if applicable
  - Baseline ophthalmological examination
- ECOG ≤2
- Currently erdafitinib is considered category 2A in the treatment of urothelial cancer per the NCCN guidelines--Provide the medical necessity of erdafitinib over other agents indicated as category 1 in the NCCN guidelines

#### Denial Criteria

- Doesn't meet the above approval diagnosis
- Pregnancy
- Hold if received chemotherapy or definitive radiotherapy within the last 2 week
- Must withhold BALVERSA™ if serum phosphate is ≥7 mg/dL until returns to < 5.5mg/dL or baseline. Has persistent phosphate level greater than upper limit of normal (ULN) during screening (within 14 days of treatment and prior to Cycle 1 Day 1) and despite medical management
- Grade 4 Central Serous Retinopathy/Retinal Pigment Epithelial Detachment (CSR/RPED) and withhold
- Caution use with CYP2C9 or CYP3A4 inhibitors or inducers

#### QUANTITY EDITS:

- 3mg tablet; #84 per 28 days
- 4mg tablet; #56 per 28 days
- 5mg tablet; #28 per 28 days

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## Esketamine solution (Spravato)

(Implemented 5/1/2020)

(Updated 5/10/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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:

Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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Initial PA (weeks 1-4)—2 kits/week Renewal

PA (week 5 and after)—1 kit/week

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## Erythropoiesis stimulating agents

*(Implemented 03/26/2008)*

*(Re-review 5/10/18)*

*(Effective 7/1/18)*

*(Updated 4/15/2020)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### PREFERRED AGENTS with Criteria

- EPOGEN® (epoetin alfa) vial
- PROCRIPT® (epoetin alfa) vial

### NON-PREFERRED AGENTS

- ARANESP® (darbepoetin alfa in polysorbat) vial and syringe
- MIRCERA® (methoxy peg-epoetin beta) syringe
- RETACRIT® (epoetin alfa) vials

### Approval Criteria for PREFERRED AGENTS with Criteria

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

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## Estrogen-replacement Agents

(Implemented 07/11/2008)

(Updated 10/31/2015)

(Updated 4/1/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- CLIMARA<sup>®</sup> PRO PATCH (estradiol/levonorgestrel)
- ESTRADIOL oral tablet (generic for Estrace<sup>®</sup>)
- ESTRADIOL once weekly transdermal (generic for Climara<sup>®</sup>)
- ESTRADIOL twice weekly transdermal (generic for Alora<sup>®</sup>, Vivelle-Dot<sup>®</sup>, Minivelle<sup>®</sup> Dotti<sup>®</sup>, Lyllana<sup>®</sup>)
- PREMARIN<sup>®</sup> tablet (conjugated estrogen)
- PREMPRO<sup>®</sup> tablet (conjugated estrogen/medroxyprogesterone)

### Nonpreferred agents

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- ACTIVELLA<sup>®</sup> tablet (estradiol/norethindrone acetate)
- ALORA<sup>®</sup> patch (estradiol)
- AMABELZ<sup>®</sup> tablet (estradiol/norethindrone acetate)
- BIJUVA<sup>®</sup> capsule (estradiol/progesterone)
- CLIMARA<sup>®</sup> patch (estradiol)
- COMBIPATCH<sup>®</sup> patch (estradiol/norethindrone acetate)
- DIVIGEL<sup>®</sup> topical gel (estradiol)
- DOTTI<sup>®</sup> patch (estradiol)
- DUAVEE<sup>®</sup> tablet (estrogens, conjugated/Bazedoxifene)
- ELESTRIN<sup>®</sup> gel (estradiol)
- ESTRACE<sup>®</sup> tablet (estradiol)
- ESTRADIOL vaginal tablet (generic for Vagifem<sup>®</sup>, Yuvaferm<sup>®</sup>)
- ESTRING<sup>®</sup> vaginal ring (estradiol)
- EVAMIST<sup>®</sup> spray (estradiol)
- FEMHRT<sup>®</sup> tablet (ethinyl estradiol/norethindrone)
- FEMRING<sup>®</sup> vaginal ring (estradiol acetate)
- FYAVOLV<sup>®</sup> tablet (ethinyl estradiol/norethindrone)
- JINTELI<sup>®</sup> tablet (ethinyl estradiol/norethindrone)
- LOPREEZA<sup>®</sup> tablet (estradiol/norethindrone acetate)
- LYLLANA<sup>®</sup> patch (estradiol)
- MENEST<sup>®</sup> tablet (estrogens, esterified)
- MENOSTAR<sup>®</sup> patch (estradiol)
- MIMVEY<sup>®</sup> tablet (estradiol/norethindrone acetate)
- MINIVELLE<sup>®</sup> patch (estradiol)
- VAGIFEM<sup>®</sup> vaginal tablet (estradiol)

- VIVELLE-DOT® patch (estradiol)
- YUVAFEM® vaginal tablet (estradiol)

#### Nonpreferred agents with criteria

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- 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

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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 (Afinitor)

*(Implemented 07/23/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Afinitor

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## Everolimus Tablet (Zortress)

(Implemented 04/10/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) 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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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<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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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

## **Fedratinib (Inrebic®)**

*(Implemented 10/16/2019)*

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

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis; AND
- Must be ≥ 18 years of age; AND
- Beneficiary has a diagnosis of intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF); AND
- Provide the following baseline labs:
  - Thiamine (Vitamin B1)
  - CBC with platelets
  - Creatinine and BUN
  - Hepatic panel
  - Amylase and lipase; AND
- Beneficiary must have thiamine deficiencies corrected prior to initiating Inrebic®; AND
- Beneficiary has an enlarged spleen, palpable at least 5 cm below costal margin; AND
- ECOG score ≤ 2; AND
- Beneficiary must have at least 2 hydroxyurea drug claims in Medicaid drug history. If no hydroxyurea drug claims in Medicaid drug history, provider must submit documentation to substantiate that beneficiary had an inadequate response to or was intolerant to hydroxyurea; AND
- Provider must submit the medical necessity over the use of Jakafi (ruxolitinb); AND
- Beneficiary must taper off ruxolitinib prior to initiating Inrebic®; AND
- Provider must reduce Inrebic® dose to 200mg once daily if beneficiary has severe renal impairment (CrCl 15mL/min to 29mL/min) ; AND
- Initial PA will be for the specific strength required for dose; approval time will be for 1 month

**DENIAL CRITERIA:**

- Beneficiary does not meet approval criteria; OR
- Beneficiary has a platelet count < 50 x 10<sup>9</sup> /L; OR
- Beneficiary has thiamine deficiency; OR
- Beneficiary has signs of Wernicke's encephalopathy (ataxia, mental status changes and ophthalmoplegia); OR
- Beneficiary has had a splenectomy; OR
- Beneficiary has previous history of chronic liver disease; OR
- Beneficiary does not show a positive response by spleen size reduction or symptom improvement after 6 months of therapy; OR
- Continued use of strong and moderate CYP3A4 inducers; OR
- Continued use with dual CYP3A4 and CYP2C19 inhibitors; OR
- Beneficiary unable to tolerate 200mg daily dose

**QUANTITY EDITS:**

#120 per 30 days

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## Fenfluramine Solution (Fintepla)

(Implemented 10/21/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 2$  and  $\leq 18$  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 hemiclonic seizures, 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
  - 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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## Fentanyl Buccal Tablet (Fentora and Onsolis)

(Implemented 04/27/2005)

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

### Approval criteria

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- $\geq 18$  years of age, AND
- Opioid Tolerance of a ceiling dose for  $\geq$  seven days during the past 30 days of one of the following: Fentanyl patch, Hydromorphone LA, Morphine LA, or Oxycodone LA AND
- Cancer with malignancies as determined by:
  - Diagnosis in past two years

### Denial criteria

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- $< 18$  years of age, OR
- Remaining estimated days supply of fentanyl buccal tablet in history is  $> 25\%$
- Therapeutic duplication with Abstral
- Therapeutic duplication with of Actiq
- Therapeutic duplication with other strengths of Fentora
- Therapeutic duplication with other strengths of Onsolis

### Additional criteria

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Quantity limits apply

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## Fentanyl Nasal Spray (Lazanda)

*(Implemented 09/23/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Lazanda 100mcg Nasal Spray
- Lazanda 400mcg Nasal Spray

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## Fentanyl 100mcg Sublingual Tablet (Abstral)

(Implemented 01/31/2011)

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

### Approval criteria

---

- $\geq 18$  years of age, AND
- Opioid Tolerance of a ceiling dose for  $\geq$  seven days during the past 30 days of one of the following: Fentanyl patch, Hydromorphone LA, Morphine LA, or Oxycodone LA AND
- Cancer with malignancies as determined by:
  - Diagnosis in past two years

### Denial criteria

---

- $< 18$  years of age, OR
- Remaining estimated days supply of fentanyl buccal tablet in history is  $> 25\%$
- Therapeutic duplication with other strengths of Abstral
- Therapeutic duplication with Actiq
- Therapeutic duplication with Fentora
- Therapeutic duplication with Onsolis

### Additional criteria

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Quantity limits apply

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## Fentanyl Sublingual Spray(Subsys)

(Implemented 01/31/2011)

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

### Approval criteria

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- $\geq 18$  years of age, AND
- Opioid Tolerance of a ceiling dose for  $\geq$  seven days during the past 30 days of one of the following: Fentanyl patch, Hydromorphone LA, Morphine LA, or Oxycodone LA AND
- Cancer with malignancies as determined by:
  - Diagnosis in past two years

### Denial criteria

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- $< 18$  years of age, OR
- Remaining estimated days supply of fentanyl sublingual spray in history is  $> 25\%$
- Therapeutic duplication with Abstral
- Therapeutic duplication with Actiq
- Therapeutic duplication with Fentora
- Therapeutic duplication with Onsolis

### Additional criteria

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Quantity limits apply

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## Fentanyl citrate oral transmucosal (Actiq)

(Implemented 04/27/2005)

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

### Approval criteria

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- $\geq$  16 years of age, AND
- Opioid tolerance of a ceiling dose for  $\geq$  seven days during the past 30 days of one of the following: Fentanyl patch, Hydromorphone LA, Morphine LA, or Oxycodone LA  
AND
- Cancer with malignancies as determined by:
  - Diagnosis in past two years

### Denial criteria

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- $<$  16 years of age, OR
- Remaining estimated days supply of fentanyl citrate transmucosal in history is  $>$  25%
- Therapeutic duplication with other strengths of Actiq
- Therapeutic duplication with Fentora
- Therapeutic duplication with Onsolis
- Therapeutic duplication with Abstral

### Additional criteria

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Quantity limits apply

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## Fezolinetant (Veozah™) 45mg tablet

(Effective 7/19/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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/1.73m<sup>2</sup>)
  - 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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/1.73m<sup>2</sup> and diabetic retinopathy OR
  - UACR of ≥ 300 mg/g and eGFR 25-75 mL/min/1.73m<sup>2</sup>
- 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/1.73m<sup>2</sup> 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

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## **Fidaxomicin (Difacid)**

*(Implemented 01/12/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- $\geq$  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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## Fluorouracil Solution/Cream (Efudex) (Tolak)

(Implemented 06/21/2011)

(Updated 01/17/2017)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing 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
- No therapeutic duplication with Ingenol Gel [Picato]

### 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
- No therapeutic duplication with Ingenol Gel [Picato]

### 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
- No therapeutic duplication with Ingenol Gel [Picato]

### **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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Fluorouracil 0.5% Cream (Carac)

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## Futibatinib (Lytgobi®) 4 mg tablet

(Implemented 1/18/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient must have failed prior platinum-based therapy (e.g., gemcitabine/cisplatin, FOLFOX, FOLFIRI)
- Recipient should not be approved or continue on this therapy with any of the following:
  - Pregnancy
  - Diagnosed with retinal pigment epithelial detachment (RPED)
  - Uncontrolled hyperphosphatemia with continued phosphate >7 mg/dL on lowest dose
  - Does not tolerate the minimum dose of 12 mg daily
  - Require concomitant dual P-gp and strong CYP3A inhibitors or inducers (e.g., itraconazole and rifampin)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Test results confirming the presence of FGFR2 gene fusion or other rearrangements
  - Documentation of the previous therapies
  - Current labs including CBC and serum phosphate
  - Baseline comprehensive ophthalmological exam (repeat every 2 months for first 6 months then every 3 months)
  - Attestation that patients of reproductive potential are using contraception
- Initial approval for 1 month, PA renewals may be 3 months if patient tolerates potential toxicities

### RENEWAL REQUIREMENTS:

- Prescriber must submit current chart notes and labs
- Prescriber must submit response to therapy (approval requires the lack of disease progression and lack of unacceptable toxicity)
- Recipient continues to meet approval criteria

### QUANTITY EDITS:

#155/31 days

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## Gabapentin Quantity Edits

(Effective 7/15/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

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

### APPROVAL CRITERIA:

- For Neurontin (gabapentin), limit to 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

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## **Ganaxolone (Ztalmy)**

*(Effective 10/19/2022)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### **APPROVAL CRITERIA:**

- Recipient must be  $\geq 2$  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  $\leq 28$  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)

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## **Gefitinib (Iressa®)**

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

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis; AND
- Must be  $\geq 18$  years of age; AND
- Beneficiary has diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations; AND
- Verify if beneficiary takes strong CYP3A4 inducers since requires higher dose (e.g., rifampicin, phenytoin or tricyclic antidepressant); AND
- Verify if beneficiary requires proton pump inhibitors due to decrease plasma concentration of Iressa®; AND
- Beneficiary should not be pregnant or breastfeeding; AND
- ECOG score  $\leq 2$ ; AND
- Provide beneficiary's current chart notes; AND
- Provide beneficiary's current labs including CBC and LFTs; AND
- Initial PA duration decided on a case-by-case basis

### **DENIAL CRITERIA:**

- Beneficiary does not meet approval criteria; OR
- Beneficiary has EGFR mutation other than exon 19 deletions or exon 21 (L858R) substitution mutations; OR
- Beneficiary is pregnant and/or breastfeeding; OR
- Beneficiary has confirmed diagnosis of interstitial lung disease; OR
- Beneficiary has confirmed gastrointestinal perforation; OR
- Beneficiary has severe hepatic impairment; OR
- Beneficiary has persistent ulcerative keratitis; OR
- Beneficiary has concomitant proton pump inhibitor usage; OR
- Beneficiary has severe bullous blistering or exfoliating conditions or has a history of toxic epidermal necrolysis, Stevens Johnson syndrome or erythema multiforme

### **QUANTITY EDITS:**

#30 per 30 days

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## Gilteritinib – (Xospata)

(Implemented 4/17/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Xospata

#### **APPROVAL CRITERIA:**

- Age  $\geq$  18 years old
- Will require manual review PA on a case-by-case basis
- Patient has a relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test.
- ECOG score 0-2\*
- AST/ALT  $\leq$  2.5 ULN\*
- SCr  $\leq$  1.5 ULN\*
- eGFR  $>$  50ml/min \*
- Refractory to  $\geq$ 1 cycle of induction chemo or relapsed after achieving remission w/ prior therapy\*
- Provide complete blood count (CBC), basic metabolic panel (BMP) and liver function tests (LFT); hypokalemia and/or hypomagnesemia has been corrected
- Provide initial creatinine phosphokinase (NOTE—should be drawn weekly for the first month, every other week for 2nd month and once monthly thereafter).
- Baseline ECG results (NOTE—repeat on days 8 and 15 of cycle 1, and prior to the start of the next two subsequent cycles.)
- Approval one month at a time due to significant adverse reactions

#### **DENIAL CRITERIA:**

- Age  $<$  18 years old
- Currently pregnant
- Heart failure class 3 or 4 unless LVEF  $\geq$ 45%\*
- Consistent prolonged QTc interval  $>$ 500 msec (dose adjustment may be needed) \*
- Had hematopoietic stem cell transplant (HSCT) within 2 months OR significant GVHD occurring due to transplant OR any grade 2 or higher non-hematological toxicity related to transplant within the past 30 days\*
- Has active CNS leukemia\*
- Drug interaction with combined P-gp and Strong CYP3A Inducers—Avoid concomitant use due to decrease in Xospata® efficacy
- Drug interaction with Strong CYP3A Inhibitors—caution concomitant use due to increased Xospata® exposure
- Diagnosis of Posterior Reversible Encephalopathy Syndrome

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## Glasdegib (Daurismo™)

(Implemented 4/17/2019)

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

### **APPROVAL CRITERIA:**

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- Will require manual review PA on a case-by-case basis
- Age ≥ 75 years old (PI study for ≥ 55 years)
- Must be newly diagnosed with acute myeloid leukemia (AML)
- Must use in combination with low-dose cytarabine
- Must have comorbidities that preclude the use of intensive induction chemo such as severe cardiac disease (LVEF <45%), ECOG =2 (but could have ECOG if met other criteria), or baseline serum creatinine >1.3mg/dL. \*
- Must also receive low-dose cytarabine on days 1 to 10 of each 28-day cycle
- Provide the following labs
  - Complete blood counts—initially and then weekly for first month
  - Electrolytes—initially, weekly for first month, then monthly
  - Renal function—initially, weekly for first month, then monthly
  - Hepatic function—initially and then weekly for first month
  - Serum creatine kinase prior to starting DAURISMO™ as baseline
- Initial ECG report—must be repeated one week later after starting DAURISMO™ and then monthly for next two months
- Bone marrow blast count ≥ 20%\*
- Approve PA for one month at a time due

### **DENIAL CRITERIA:**

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- If does not meet approval criteria above
- QTc interval prolongation with life-threatening arrhythmia
- Platelets less than 10 Gi/L for more than 42 days in the absence of disease
- Neutrophil count less than 0.5 Gi/L for more than 42 days in the absence of disease
- Grade 4 nonhematologic toxicity
- Drug interaction with Strong CYP3A Inducers—avoid use due to decreased effect of Daurismo™ (i.e. Rifampin)
- Drug interaction with other QTc prolonging drugs –avoid use as increased probability for QTc prolongation
- Drug interaction with Strong CYP3A4 Inhibitors—caution use due to increase Daurismo™ level (i.e. Ketoconazole)
- AML M3 Acute Promyelocytic Leukemia (APL) or patients with a t(9:22) cytogenetic translocation.\*
- Patients with known active uncontrolled central nervous system (CNS) leukemia. \*

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## Glaucoma Agents

(Implemented 7/1/17)

(Updated 7/1/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### **Preferred Status only for strengths and package sizes noted:**

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

### **Non-Preferred Status. all package sizes unless otherwise noted:**

- Alphagan P<sup>®</sup> (brimonidine) 0.1% drops
- Apraclonidine 0.5%, 1% solution drops
- Betaxolol 0.25% and 0.5% solution 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<sup>®</sup>)
- Brinzolamide (AZOPT<sup>®</sup>) suspension drops 1%
- Cosopt<sup>®</sup> PF (dorzolamide 2% /timolol) drops
- Dorzolamide 2% /timolol 0.5% (generic for Cosopt<sup>®</sup> PF) solution drops
- Echothiophate (PHOSPHOLINE IODIDE) kit
- Istalol<sup>®</sup> (timolol maleate) 0.5% drops
- Iyuzeh<sup>®</sup> (latanoprost) 0.005% drops
- Metipranolol 0.3% solution drops
- Pilocarpine 1%, 2%, 4% solution drops
- Simbrinza<sup>®</sup> (Brimonidine 1%/ brinzolamide 0.2%) suspension drops, 8ml
- Tafluprost (generic for Zioptan<sup>®</sup>) drops 0.0015%
- Timolol maleate (generic for Istalol<sup>®</sup>) 0.5% drops
- Timolol gel forming solution 0.25%, 0.5% (generic for Timoptic-XE<sup>®</sup>)
- Timolol preservative free ocudose 0.25%, 0.5% (generic for Timoptic Ocudose<sup>®</sup>)
- Timoptic-XE 0.25%, 0.5% gel
- Timoptic 0.25%, 0.5% Ocudose
- Travoprost 0.004% (generic for Travatan Z<sup>®</sup>)

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- Vyzulta® (latanoprostene bunod) 0.024% 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

### Additional criteria

- Age limits apply
- Quantity limits apply

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## **Glycerol Phenylbutyrate Liquid(Ravicti)**

*(Implemented 07/09/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Ravicti

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## **Glycophos 20ml Vial**

*(Implemented 09/18/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Glycophos 20ml vial

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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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## **Glycopyrronium cloths (Qbrexza)**

*(Implemented 1/16/2019)*

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

### **APPROVAL CRITERIA**

- Age edit  $\geq 9$  years; AND
- The ICD-10 code for Primary focal hyperhidrosis, axilla (L74.510) is in Medicaid medical diagnosis history in the previous 365 days; AND
- Must have documentation of a trial or intolerance to an aluminum based antiperspirant such as Drysol, Certain Dri,, Xerac AC, and Hypercare ;

### **DENIAL CRITERIA**

- Absence of approval criteria;
- Denial if either of these 2 codes are found in Medicaid medical diagnosis history regardless of if the diagnosis of Primary focal hyperhidrosis, axilla is found in Medicaid medical diagnosis history
  - Diagnosis in Medicaid medical diagnosis history for Secondary focal hyperhidrosis or Frey's Syndrome (L74.52); OR
  - Diagnosis in Medicaid medical diagnosis history for Generalized hyperhidrosis, night sweats, excessive sweating, (R61)

### **QUANTITY LIMITS:**

- 1 per day; 30 cloths /30 days; standard refill allowance;

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## Growth Hormone

(Implemented 01/24/2007)

(Updated 10/01/2016)

(Updated 1/1/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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)
- SAIZEN® (somatropin)
- SKYTROFA® (lonapegsomatropin-tcgd)
- SOGROYA® (somapacitan-beco)
- ZOMACTON® (somatropin)
- ZORBTIVE® (somatropin)

### **Criteria for Preferred Growth Hormones:**

In children, we may need to question continuation when growth velocity is  $\leq 2.5$  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

**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 IGFBP-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

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- 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 ( $\geq 5$  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 ( $\geq 5$  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

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- 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 dosepack
- Vosevi® (sofosbuvir, velpatasvir, and voxilaprevir tablet, film coated) tablet

Link to Hepatitis C prior authorization form—Portable Document Format (.pdf):

<https://arkansas.magellanrx.com/provider/docs/rxinfo/HepCTreatmntForm.pdf>.

[Link to Memorandum](#)

[Link to Updated Criteria](#)

## 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- Atorvastatin calcium (generic for Lipitor<sup>®</sup>)
- Lovastatin (generic for Mevacor<sup>®</sup>)
- Pravastatin sodium (generic for Pravachol<sup>®</sup>)
- Rosuvastatin (generic for Crestor<sup>®</sup>)
- Simvastatin (generic for Zocor<sup>®</sup>)

### Nonpreferred agents

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- Altoprev<sup>®</sup> (lovastatin ER)
- Atorvaliq<sup>®</sup> suspension (atorvastatin)
- Atorvastatin/Amlodipine (generic for Caduet<sup>®</sup>)
- Caduet<sup>®</sup>
- Crestor<sup>®</sup>
- Fluvastatin sodium (generic for Lescol<sup>®</sup>)
- Livalo<sup>®</sup> (pitavastatin calcium)
- Simvastatin/Ezetimibe (generic for Vytorin<sup>®</sup>)
- Vytorin<sup>®</sup>
- Zocor<sup>®</sup>

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## Human Immunodeficiency Virus (HIV)

*(Implemented 10/1/2023)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) 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)
- 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 and tablet (darunavir ethanolate)—**BRAND only**
- 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)
- Darunavir ethanolate tablet (generic for Prezista)
- 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)
- Eпивir 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)
- 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
  - o Medical necessity over oral PrEP options was not provided
- Prescriber must submit **ALL** of the following:

- o Current chart notes
  - o Current HIV test results
  - o Medical necessity over oral PrEP options (e.g., generic Truvada® or Descovy®)
  - o Document if beneficiary will have the 28-day oral lead-in therapy or begin with Apretude®
  - o Attestation that the prescriber has counseled the patient about the importance of compliance
- Prior authorization will be approved for 12 months.

## QUANTITY EDITS

- 1 injection every 2 months (quantity override will be needed for first 2 months loading dose)

## APPROVAL CRITERIA FOR SELZENTRY

<https://ar.magellanrx.com/forms-documents>

## 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<sup>o</sup>, alternative<sup>\*</sup>, or acceptable<sup>^</sup> 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.

<sup>o</sup>Preferred Regimens (Regimens with optimal and durable efficacy, favorable tolerability and toxicity profile, and ease of use)

<sup>\*</sup>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.)

<sup>^</sup>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  $\geq 2$  agents from  $\geq 3$  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

## Hydroxypropyl Cellulose 5mg Eye Insert (Lacrisert)

(Implemented 01/18/2011)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval 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

Therapeutic duplication with Restasis (Cyclosporine)

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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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## **Ibexafungerp (Brexafemme)**

*(Updated 10/20/2021)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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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## Ibrutinib (Imbruvica) Capsule

*(Implemented 03/18/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Imbruvica 140mg Capsule

### Additional Criteria

- Quantity Limits Apply

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq 1$  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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## Icosapent Ethyl Capsule (Vascepa)

*(Implemented 07/09/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Vascepa

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## **Idelalisib (Zydelig) Tablet**

*(Implemented 01/13/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Zydelig

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## Imiquimod (Aldara)

*(Implemented 06/27/2007)*

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

### Approval criteria

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- > 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

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.**

### Approval criteria

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- > 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

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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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### **Preferred Agents with Criteria**

- Gammagard® Liquid vial
- Gamunex-C® vial
- Hizentra® vial (NOT SYRINGE)

### **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**

- 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
- Hizentra® syringe
- 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
<ul style="list-style-type: none"> <li>•Common variable immunodeficiency</li> <li>•X-linked agammaglobinemia</li> <li>•Congenital agammaglobinemia</li> <li>•Wiskott-Aldrich syndrome</li> <li>•Severe combined immunodeficiency</li> </ul>
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)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- Avonex<sup>®</sup> (interferon beta – 1A injection)
- Copaxone<sup>®</sup> **20 mg** injection- **Brand Only**
- Dimethyl fumarate (generic for Tecfidera<sup>®</sup>)

### Non-Preferred agents

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- Aubagio<sup>®</sup> tablet (teriflunomide)
- Bafiertam<sup>®</sup> (monomethyl fumarate)
- Betaseron<sup>®</sup> (interferon Beta – 1B injection)
- Copaxone<sup>®</sup> 40 mg injection
- Extavia<sup>®</sup> (Interferon Beta – 1B injection)
- Fingolimod capsule (generic for Gilenya<sup>®</sup>)
- Glatiramer acetate injection (generic for Copaxone<sup>®</sup>)
- Glatiramer acetate 20 mg injection (generic for Glatopa<sup>®</sup>)
- Glatopa<sup>®</sup> injection
- Gilenya<sup>®</sup> capsule (fingolimod)
- Kesimpta<sup>®</sup> pen (ofatumumab)
- Mavenclad<sup>®</sup> tablet (cladribine)
- Mayzent<sup>®</sup> tablet (siponimod)
- Plegridy<sup>®</sup> pen and syringe (peginterferon beta – 1A)
- Ponvory<sup>®</sup> tablet (ponesimod)
- Rebif<sup>®</sup>/Rebif Rebidos (interferon beta – 1A/albumin)
- Tascenso<sup>®</sup> ODT (fingolimod)
- Tecfidera<sup>®</sup> (dimethyl fumarate)
- Teriflunomide (generic for Aubagio<sup>®</sup>)
- Vumerity<sup>®</sup> (diroximel fumarate)
- Zeposia<sup>®</sup> capsule (ozanimod)

## Approval criteria

### All Non-preferred medications:

- Confirmed diagnosis of a relapsing form of 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
- 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 of an official Compendia
- Recipient with moderately active disease must have tried at least 2 preferred agents for a minimum of 6 months each and treatment must be considered a failure as defined by any of the following:
  - At least one relapse during therapy with preferred medications
  - MRI indicates additional lesions compared to baseline
  - Recipient demonstrates an increased disability as measured by the Expanded Disability Status Scale (EDSS) compared to baseline
  - Documented adverse effects to the preferred agents
- Recipient with highly active or rapidly evolving aggressive disease will be reviewed on a case-by-case basis
- Recipient 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®, Tecfidera®, Vumerity®

- Recipient 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

### **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 MODULATOR:** Gilenya®, Mayzent®, Ponvory®, Tascenso ODT®, Zeposia®

- Recipient 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
- Gilenya® recipient must be ≥10 years of age
- Mayzent recipient must NOT have a CYP2C9 \*3/\*3 genotype (homozygous)

**MONOCLONAL ANTIBODIES:** Kesimpta® (Briumvi®, Lemtrada®, Ocrevus® and Tysabri® are excluded from the pharmacy program.)

- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Confirmed negative for Hepatitis B
  - Baseline serum immunoglobulin levels (monitor periodically for any decrease)
  - Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive potential

**PYRIMIDINE SYNTHESIS INHIBITOR:** Aubagio®

- Recipient does **NOT** have any of the following:
  - Severe hepatic impairment
  - Concomitant leflunomide or antineoplastic, immunosuppressive or immunomodulator drugs to treat other conditions
  - Severe immunodeficiency, bone marrow disease, or severe, uncontrolled infection
- Prescriber must submit **ALL** of the following (in addition to info requested above):
  - Current labs including LFTs and CBC
  - Documentation of negative tuberculosis test

- Confirmed negative for pregnancy and attestation of contraception use in patient of reproductive potential

**PURINE ANTIMETABOLITE: Mavenclad®**

- Recipient should **NOT** have a diagnosis of clinically isolated syndrome
- Recipient 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**

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- 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

**Additional criteria**

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- Quantity limits apply

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## **Immunomodulators, Monoclonal Antibodies**

*(Implemented 8/1/2003)*

*(Updated criteria 7/19/2023)*

*(Updated PDL 10/1/2023)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 (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
- 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

### **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 12 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  $\geq 150$
    - 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 ( $>1.0 \times 10^9$  /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  $\geq 7.5$  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  $\leq 4$  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

## Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

- 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)  $\geq 10\%$
  - Baseline Eczema Area and Severity Index (EASI) total score of  $\geq 16$
  - Baseline weekly averaged peak pruritus Numeric Rating Scale (NRS)  $\geq 7$
  - Baseline Investigator's Global Assessment (IGA) score  $\geq 3$
  - Baseline Scoring Atopic Dermatitis (SCORAD) score  $\geq 25$
- 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  $\geq 16$  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

## Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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- 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<sub>2</sub> antagonist; AND
- Add a Leukotriene receptor antagonist to the nsAH or H<sub>2</sub> 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<sup>®</sup>, Nucala<sup>®</sup>, and Xolair<sup>®</sup>)**

- 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<sup>®</sup>
- 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<sup>®</sup> 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  $\geq 12$  years of age and at least 40 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  $\geq 15$  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  $\leq 6$  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 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  $\geq 6$  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/ $\mu$ L

- 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)

### **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—#8 150 mg prefilled syringe/vial per 28 days; #1 75 mg prefilled syringe per 28 days

## Inhaled Antibiotics

(Updated 10/01/2016)

(Updated 1/1/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents with Criteria

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- Bethkis<sup>®</sup> (Tobramycin)
- Kitabis Pak<sup>®</sup> (Tobramycin)
- Tobramycin (generic for Tobi<sup>®</sup>)

### Non-Preferred agents

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- Arikayce<sup>®</sup> (amikacin liposome) – Criteria for [Arikayce](#)
- Aztreonam (generic for Cayston<sup>®</sup>)
- Cayston<sup>®</sup> (Aztreonam)
- Tobi<sup>®</sup> (Tobramycin)
- Tobi Podhaler<sup>®</sup> (Tobramycin)
- Tobramycin (generic for Bethkis<sup>®</sup>)
- Tobramycin pak (generic for Kitabis Pak<sup>®</sup>)

### Approval criteria for Preferred Agents

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Diagnosis of cystic fibrosis in medical history

### Denial criteria for Preferred Agents

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History of Cayston<sup>®</sup> in the past 50 days

History of J Code for Tobramycin Injection in the past 60 days

### Additional criteria

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Quantity limits apply

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## **Infigratinib (Truseltiq)**

(Implemented 7/21/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-4247895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age; AND
- Recipient has a diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test OR diagnosis consistent with FDA indications; AND
- Recipient has progressed after at least 1 failed prior systemic therapy. Provide the medical necessity of infigratinib over FOLFOX. Provide documentation of that therapy including any radiation with response; AND
- Prescriber should submit the following:
  - Current chart notes with previous therapies tried; AND
  - Documentation of FGFR2 fusion or other rearrangement; AND
  - Current labs including serum phosphate (initiate phosphate lowering therapy if  $>7.5$  mg/dL with reduction in dose), CBC, LFTs; AND
  - Documentation of comprehensive ophthalmological exam; AND
  - Pregnancy test results for recipient with child-bearing potential; AND
- Initial PA for 2 months.

### **DENIAL CRITERIA:**

- Recipient does not meet the above approval requirements; OR
- Recipient is unable to tolerate 50 mg once daily; OR
- Recipient has persistent symptoms for Retinal Pigment Epithelial Detachment (RPED); OR
- Recipient has life-threatening consequences due to elevated serum phosphate; OR
- Recipient requires concomitant strong or moderate CYP3A inhibitors (e.g., itraconazole, erythromycin, verapamil); if cannot be avoided, reduce Truseltiq™ dose; OR
- Recipient requires strong or moderate CYP3A inducer (e.g., carbamazepine, phenytoin); OR
- Recipient is pregnant

### **QUANTITY EDITS**

1 dose pack per 21 days

## Ingenol Mebutate (Picato Gel)

*(Implemented 03/08/2012)*

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

### Approval criteria

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- $\geq$  to 18 Years of Age
- Submitted diagnosis for actinic keratosis (AK) 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 Imiquimod Cream Topical
- No Therapeutic Duplication with other strengths of Ingenol gel Topical

### Additional criteria

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Quantity limits apply

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## Inotersen (Tegsedi™)

(Implemented 4/17/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Tegsedi

#### Approval Criteria

- Will require manual review PA on a case-by-case basis Age ≥ 18 years
- Diagnosed with polyneuropathy due to hereditary transthyretin-mediated amyloidosis
- Provide chart notes
- Provide current labs including complete blood count (CBC) including platelets, basic metabolic panel (BMP) including SCr and eGFR, urine protein to creatinine ratio (UPCR), and LFTs
- Current urinalysis prior to beginning treatment with TEGREDI and directly following treatment initiation
- Baseline modified Neuropathy Impairment Scale+7 (mNIS+7) composite score and the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score
  - NIS objectively measures deficits in cranial nerve function, muscle strength, reflexes, and sensations, and the Modified +7 assesses heart rate response to deep breathing, postural blood pressure, quantitative sensory testing (touch-pressure and heat-pain), and peripheral nerve electrophysiology.
  - Norfolk QoL-DN scale is a patient-reported assessment that evaluates the subjective experience of neuropathy in the following domains: physical functioning/large fiber neuropathy, activities of daily living, symptoms, small fiber neuropathy, and autonomic neuropathy.
- Provide the medical necessity over preferred neuropathic pain agents UNLESS there is a definitive diagnosis for FAP
- Documented transthyretin variant by genotyping
- Documented amyloid deposit by biopsy
- Provide staging—must be Stage 1 or Stage 2

#### Denial Criteria:

- Platelets < 100 x 10<sup>9</sup> /L on initiation of treatment and stop treatment if platelets are < 100 x 10<sup>9</sup> /L during therapy; only resume if platelets rise above 100 x 10<sup>9</sup> /L
- History of acute glomerulonephritis caused by TEGSEDI™
- Urine protein to creatinine ratio (UPCR) of 1000 mg/g or higher
- Estimated glomerular filtration rate (eGFR) below 45 mL/minute/1.73 m<sup>2</sup>
  - Once UPCR and eGFR are within required range, dosing may be restarted
- Heart failure NYHA class ≥ 3\*
- Pregnancy
- Prior liver transplant or anticipated liver transplant within 1 year
- Primary or leptomenigeal amyloidosis\*
- Not able to adhere to recommended laboratory monitoring

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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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred- Rapid Acting Insulin

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

### Non-Preferred- Rapid Acting Insulin

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

### Preferred- Rapid/Intermediate Acting Combinations

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

### Non-Preferred - Rapid/Intermediate Acting Combinations

- Insulin lispro mix pen (generic for Humalog<sup>®</sup> Mix)

### Preferred - Regular Insulin

- Humulin<sup>®</sup> R U-100 vial (OTC)
- Humulin<sup>®</sup> R U-500 KwikPen
- Humulin<sup>®</sup> R U-500 vial
- Novolin<sup>®</sup> R U-100 vial (OTC)

### Non-Preferred - Regular Insulin

- Novolin® R U-100 FlexPen (OTC)

## **Insulins (cont)**

### 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

- Insulin glargine SoloStar pen/vial (generic for Lantus®)
- 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
- 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)

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## Intranasal Rhinitis Agents

(Effective 4/1/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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

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- Mometasone furoate nasal spray (Nasonex)

### Approval criteria for Non-Preferred agents with criteria

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

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## Intron A (Interferon Alpha-2B)

*(Implemented 02/16/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Diagnosis of Hepatitis C in Medicaid History

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## **Isosorbide Dinitrate/Hydralazine (BiDil)**

*(Implemented 09/18/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan 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 Magellan Medicaid Administration (MMA) 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 155 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 155 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 (Onmel) 200mg Tablet

*(Implemented 03/19/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Onmel

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## Itraconazole Oral Solution (Sporanox)

*(Implemented 10/11/2011)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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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## **Ivabradine Tablet (Corlanor)**

*(Implemented 05/04/2015)*

*(Updated 01/17/2017)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## Ivosidenib (Tibsovo®)

(Implemented 7/17/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Tibsovo

#### Approval Criteria

- Manual review on a case-by-case basis
- ≥18 years old for relapsed or refractory AML and ≥75 years old for newly-diagnosed AML with comorbidities that preclude intensive induction chemotherapy;
- Provide documentation of the presence IDH1 mutations of the R132 gene
- ECOG ≤ 2
- Provide current chart notes with documentation of previous therapy
- Provide the following labs
  - CBC with platelets ≥ 20,000/μL (check weekly for first month, every other week for 2 and month then monthly for treatment duration)
  - Liver function panel (safety in Child-Pugh C is unknown)
  - SCr/BUN (safety in severe renal impairment eGFR)
  - Creatine phosphokinase (weekly for first month of therapy)
- Documentation of pregnancy status if applicable
- Baseline electrocardiogram (ECG) (repeat weekly for first 3 weeks of therapy then at least monthly for treatment duration)

#### Denial Criteria

- Disease progression or unacceptable toxicity
- QTc interval prolongation with signs/symptoms of life-threatening arrhythmia
- Guillain-Barre' syndrome diagnosis
- Multiple cardiac issues were excluded from the clinical trial
  - NYHA class III or IV CHF or LVEF
  - Myocardial infarction in the last 6 months
  - Uncontrolled angina or uncontrolled ventricular arrhythmias
  - Heart-rate corrected QT (QTc) interval ≥450ms with other factors that can prolong QT interval such as medications
- Systemic anticancer therapy or radiation
- Concomitant use with drugs that prolong QTc (e.g. anti-arrhythmic meds, fluoroquinolones, triazole antifungals or 5-HT3 receptor antagonists) and CYP3A4 inhibitors

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## **Ixazomib (Ninlaro) capsule**

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Ninlaro 2.3 mg
- Ninlaro 3 mg
- Ninlaro 4 mg

### **APPROVAL CRITERIA:**

- NINLARO® will require a manual review PA on a case-by-case basis.
- Each approved PA will be for a short period of time (e.g., 3 months).
- Prescriber may request additional PAs as long as the disease is not progressing (e.g., spike in serum or urine monoclonal protein, increase in plasma cells in bone marrow, or other signs of progression such as new plasmacytoma, lytic bone lesion, hypercalcemia) or there is not unacceptable toxicity.
- For each PA request, the prescriber must submit documentation that the disease is not progressing.

### QUANTITY EDITS

- 3 capsules per 28 days' supply.

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- **CENTANY AT 2% OINMENT KIT** (MUPIROCON 2% OINTMENT – STERILE GAUZE – TAPE)
- **HALONATE PAC COMBO PACK** (HALOBETASOL PROPIONATE 0.5% OINTMENT – AMMONIUM LACTATE 12% LOTION)
- **LIDOCAINE-PRILOCAINE 2.5%-2.5% CREAM KIT** (LIDOCAIN- PRILOCAINE 2.5%-2.5% CREAM – OCCLUSIVE DRESSINGS)
- **PEDIADERM AF KIT** (NYSTATIN 100,000 UNITS/GRAM CREAM – EMOLLIENT DIAPER CREAM)
- **PEDIADERM HC 2% KIT** (HYDROCORTISONE 2% LOTION – EMOLLIENT DIAPER CREAM)
- **PEDIADERM TA 0.1% KIT** (TRIAMCINOLONE ACETONIDE 0.1% CREAM – EMOLLIENT DIAPER CREAM)
- **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)
- **TERBINEX KIT** (TERBINAFINE HCL 250 ORAL TABLETS – HYDROXYPROPYL-CHITOSAN 1% NAILLACQUER)
- **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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq 1$  severe or life-threatening laryngeal attack per month or  $\geq 4$  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.
  - 17 $\alpha$ -alkylated androgens (e.g. danazol, stanozolol, oxandrolone, methyltestosterone)
  - Antifibrinolytic agents (e.g.  $\epsilon$ -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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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#### 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 (Helidac) in the last 365 days, OR
- No history of metronidazole/tetracycline/bismuth combination (Pylera) in the last 365 days.

### Additional criteria

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Quantity limits apply

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## Larotrectinib (Vitrakvi®) capsules and oral solution

(Implemented 4/17/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Vitrakvi

#### Approval criteria

- Will require manual review PA on a case-by-case basis
- Must have diagnosis of unresectable or metastatic solid tumors (i.e. salivary gland tumors, soft tissue sarcoma, infantile fibrosarcoma, and thyroid cancer among others) with neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired mutation.
- Must have progressed following systemic therapy or there are no satisfactory alternatives o Patient must have documented and laboratory-confirmed NTRK1, NRK2, or NRK3 gene fusion. Identification of positive NTRK gene fusion status was prospectively determined in local laboratories using next generation sequencing (NGS) or fluorescence in situ hybridization (FISH).\*
- Provide documentation of gene mutation with resistance test
- Current Body Surface Area (BSA) must be provided. Dosing based on BSA—If BSA < 1m2 should be dosed at 100mg/m2 twice daily; If BSA is ≥ 1m2 should be dosed at 100mg twice daily
- Provide baseline LFTs and CBCs (LFTs should be repeated every 2 weeks for the first month then monthly thereafter)
- Reduced dose by 50% with moderate to severe hepatic impairment
- Negative pregnancy test
- ECOG 0-2\*

#### Denial criteria

- Does not meet above approval criteria
- Currently pregnant
- Drug interaction with Strong CYP3A4 Inhibitors causing increased Vitrakvi® plasma concentrations—Avoid co-administration if possible
- Drug interaction with Strong CYP3A4 Inducers due to decrease efficacy—monitor
- Discontinue if does not tolerate 3rd dose modification

#### QUANTITY EDITS:

Vitrakvi® 25mg #180/30 days

Vitrakvi® 100mg #60/30 days

Vitrakvi® 20mg/ml oral solution 100ml bottle/30 days

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## Lapatinib 250mg Tablet (Tykerb)

*(Implemented 01/17/2017)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Tykerb 250mg Tablet

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## Lenalidomide (Revlimid)

*(Updated and Effective 07/15/2020)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq$  18 years of age; AND
- Recipient is diagnosed with one of the following or diagnosis consistent with FDA indication:
  - Multiple Myeloma
  - Myelodysplastic Syndrome
  - Mantle Cell Lymphoma
  - Follicular Lymphoma
  - Marginal Zone Lymphoma
- Prescriber must submit the following:
  - Current chart notes with documentation of specific diagnosis; AND
  - Documentation of previous therapies tried; AND
  - Documentation that the prescriber and pharmacy are certified with the Revlimid® REMS program and provide a patient-physician agreement form that the patient will comply with REMS requirements; AND
  - Current labs including CBC with differential and comprehensive metabolic panel (CMP); AND
- Female patients of childbearing potential must have two (2) negative pregnancy tests before initiating Revlimid® (1st test 10-14 days prior to beginning therapy and 2nd within 24 hours prior to beginning therapy); AND
- Female patients of childbearing potential must use 2 methods of reliable birth control simultaneously; Male patients must always use condoms during sexual contact with females of childbearing potential; AND
- Dose required as prior authorization will be entered for specific dose; AND
- Prior authorizations should be approved monthly until documented lab stability; AND
- Requirements for individual diagnoses:
  - Multiple Myeloma recipient must be taking dexamethasone concomitantly
  - Maintenance dosing for MM patients post autologous hematopoietic stem cell transplant
  - Mantle Cell Lymphoma recipients—provide documentation of two (2) prior failed therapies and one should be bortezomib
  - Follicular Lymphoma recipients—provide documentation taking a rituximab product concomitantly and documentation of previous therapy
  - Marginal Zone Lymphoma recipients—provide documentation taking a rituximab



**DENIAL CRITERIA:**

- Recipient is diagnosed with Chronic Lymphocytic Leukemia; OR
- Recipient is pregnant or breastfeeding; OR
- Recipient cannot tolerate the minimum required doses for their individual indication; OR
- REMS program requirements have not been met by either prescriber, pharmacy or recipient

**QUANTITY EDITS:**

#1 per day for any strength

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## Leniolisib (Joenja®) 70mg tablet

(Effective 7/19/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 (PI3K $\delta$ ) 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

## **Lenvatinib (Lenvima)**

*(Implemented 07/22/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Lenvima

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## Letermovir (Prevymis)

*(Implemented 03/01/2018)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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## Leukotriene Receptor Antagonists

(Implemented 8/11/2009)

(Updated 11/27/2017)

(Updated 4/1/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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 Zflo CR®)
- Zflo® 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

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- 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

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Quantity limits apply

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## Levodopa (Inbrija™)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq$  30 years old and  $\leq$  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
- $\leq$  2 hours per day of “OFF” time
- Hoehn and Yahr Stage  $>3$  in an “ON” state

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## Levofloxacin 500mg/20ml U.D. Cup

*(Implemented 04/08/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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Currently LTC

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## Levoketoconazole (Recorlev)

(Implemented 04/20/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### **APPROVAL CRITERIA:**

- Recipient must be  $\geq 18$  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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## **Levoleucovorin Vial**

*(Implemented 05/04/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 prior authorization

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- Levoleucovorin

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Capsule (Tirosint)

*(Implemented 08/17/2010)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 tablet

### Drugs that require manual review for prior authorization

- Tirosint Capsule

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## Levothyroxine Vial

*(Implemented 04/17/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 mcgvial
- Levothyroxine 500 mcgvial

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## Lidocaine 5% Ointment

*(Implemented 06/29/2017)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) 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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Additional criteria

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Quantity limits apply

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## Lidocaine-Tetracaine Patch (Synera)

*(Implemented 01/17/2017)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Synera Patch

### Additional criteria

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Quantity limits apply

Age restrictions apply

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## Lipotropics

(Implemented 01/18/2011)

(Re-review 5/10/18)

(Effective 7/1/18)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

## Fibric Acid Agents

### PREFERRED AGENTS:

- gemfibrozil
- fenofibrate tablet 48 mg, 54 mg, 145 mg, 160mg

### NONPREFERRED AGENTS

- fenofibrate capsule (e.g., Antara®, Lipogen®, Lofibra®) 30 mg, 67 mg, 90 mg, 134 mg, 200 mg
- fenofibrate tablet (e.g., Fenoglide®, Triglide®) 40 mg, 120 mg, 160 mg
- fenofibric acid (e.g., Fibricor®) tablet 35 mg, 105 mg
- fenofibric acid (e.g., Trilipix®) delayed-release capsule 45 mg, 135 mg

## Bile Acid Sequestrant Agents

### PREFERRED AGENTS:

- colestipol tablet
- colestipol granules
- cholestyramine light powder for oral suspension
- cholestyramine powder for oral suspension

### NONPREFERRED AGENTS

- WELCHOL® (colesevelam) powder pack and tablet

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## Lithium ER or SA

*(Implemented 04/08/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- $\geq$  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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq$  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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## **Lomitapide Mesylate Capsule (Juxtapid)**

*(Implemented 07/09/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Juxtapid

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## Lomustine (Gleostine) Capsules

*(Implemented 04/26/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Gleostine Capsules 100mg, 40mg, 10mg, 5mg

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## Lorlatinib (Lorbrena®)

(Implemented 1/16/2019)

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

LORBRENA® (lorlatinib) tablet will require manual review PA on a case-by-casebasis

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### **APPROVAL CRITERIA, requires all of the following:**

- Beneficiary is an adult age 18 years or older;
- Beneficiary has a diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC);
- Beneficiary has disease that progressed on
  - crizotinib and at least one other ALK inhibitor for metastatic disease; OR
  - alectinib as the first ALK inhibitor therapy for metastatic disease; OR
  - ceritinib as the first ALK inhibitor therapy for metastatic disease;
- Beneficiary documented ALK rearrangement in tumor tissue as determined by fluorescence in situ hybridization (FISH) assay or by Immunohistochemistry (IHC);
- Beneficiary has an ECOG score of 0, 1, or 2;
- Beneficiary is not pregnant, lactating, or planning to become pregnant;
- Dose and quantity limit entered at time of PA approval;
- Beneficiary is not receiving a strong CYP3A inducer;
- Provider must submit current baseline LFTs and lipid panel;
- Beneficiary is not Child-Pugh B or C;
- Provider must submit kidney function tests and beneficiary does not have severe renal impairment;
- Initial approval 1 month

### **DENIAL CRITERIA any one of the following:**

- Disease progression;
- Beneficiary cannot tolerate 50 mg once daily dose;
- Beneficiary is pregnant or lactating;
- Beneficiary is Child-Pugh B or C;

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## Macitentan (Opsumit) Tablet

*(Implemented 03/18/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Opsumit 10 mg

### Additional Criteria

- Quantity Limits Apply

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## **Mannitol (Bronchitol) Inhalation Powder Capsule**

(Implemented 4/21/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age; AND
- Recipient must have a diagnosis of Cystic Fibrosis OR a diagnosis consistent with FDA indications; AND
- Recipient must have passed a BRONCHITOL Tolerance Test (BTT). Chiesi provides the 10 capsules requested for the BTT free of charge (NDC# 10122-216-01 – WAC Price \$0.00). However, if a facility cannot accept “samples” then the work around is the BTT with NDC# 10122-212-04 – WAC Price \$62.18. Both NDCs come with 10 capsules. Failure would include bronchospasms, a decrease in FEV1, or a decrease in oxygen saturation with administration of BRONCHITOL; AND
- Recipient must have a recent claim for a short-acting bronchodilator; AND
- Recipient must continue other standard of care treatments; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Documentation of previous and current medications; AND
  - Current pulmonary function tests results with baseline FEV1  $> 40\%$  and  $< 90\%$  predicted; AND
  - Results from a recent BTT; AND
  - Medical necessity over hypertonic saline and Dornase alfa

### Denial Criteria

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient failed the BTT; OR
- Recipient has an episode of hemoptysis ( $>60$  mL) in the previous 3 months or develops hemoptysis during treatment; OR
- Recipient does not remain compliant on therapy with PA renewal request.

### QUANTITY EDITS:

One (1) four week treatment pack per 28 days (#560/ 28 days)

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## Maralixibat (Livmarli)

(Implemented 4/20/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 ≥1 year of age; AND
- Recipient must have a confirmed diagnosis of Alagille syndrome with a baseline presence of cholestatic pruritis 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 a bile acid sequestrant 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 acid level, LFTs, and fat-soluble vitamins (A,D,E, and INR); AND
  - Current weight for dose determination; AND
- 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 documented hepatic decompensation; OR
- Prescriber orders a daily dose >28.5 mg; OR
- Recipient is not concurrently ordered ursodeoxycholic acid; OR
- Recipient should discontinue LIVMARLI if continued pruritis or has no decrease in serum bile acid after trial with maximum dose of 380 mcg/kg per day.

### **Quantity Edits:**

3 bottles (90 mL)/ 30 days

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## **Maribavir (Livtency)**

*(Implemented 4/20/2022)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 12$  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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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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## Mecamylamine HCL Tablet (Vecamyl)

*(Implemented 09/18/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Vecamyl

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## Meclorothamine HCL Gel(Valchlor)

*(Implemented 03/18/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Valchlor 0.016% Gel

### Additional Criteria

- Quantity Limits Apply

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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)*

### **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**

### **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
- 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 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

**Manual Review MAT Injectables:**

\*\*Products may be billed at point-of-sale in a pharmacy setting or through the patient's medical benefits.

- Brixadi SQ syringe (buprenorphine extended-release)
- Sublocade SQ Injection (buprenorphine extended-release)
- Vivitrol IM (naltrexone for extended-release injectable suspension)

**Additional criteria**

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Quantity limits apply

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## Medroxyprogesterone (Depo-Provera)

(Implemented 02/12/2013)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval Criteria

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- 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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- 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

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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 Magellan 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 Magellan Medicaid Administration (MMA) 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## **Mercaptopurine 20mg/ml Suspension (Purixan)**

*(Implemented 01/13/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Purixan

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## Meropenem-Vaborbactam (Vabomere) Injection

*(Implemented 03/01/2018)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan 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 Magellan Medicaid Administration (MMA) 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## Metformin Oral Solution (Riomet)

*(Implemented 09/21/2009)*

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

### Approval criteria

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- Recipient < 7 years of age, OR
- Diagnosis of NPO within the past 365 days ([Appendix A](#)).

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Otrexup
- Reditrex

### Additional criteria

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- 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

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History of glaucoma

[Link to Memorandum](#)

## Metoclopramide Orally Disintegrating Tablet (Metozolv ODT)

*(Implemented 01/12/2010)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 metoclopramide tablets and syrup are available without a prior authorization.

### Drugs that require manual review for prior authorization

- Metozolv ODT tablet
- Metoclopramide ODT

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## Metronidazole 375 mg capsule (Flagyl)

*(Implemented 08/17/2010)*

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

### Approval criteria

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- Diagnosis of NPO ([Appendix A](#)) in the previous year, OR
- < 7 years of age

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## **Metronidazole ER 750mg(Flagyl)**

*(Implemented 08/17/2010)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Flagyl 750 mg Tablets

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## Metronidazole-Tetracycline-Bismuth (Helidac and Pylera)

(Implemented 01/12/2005)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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#### 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 (Helidac) in the last 365 days, OR
- No history of metronidazole, tetracycline, and bismuth combination (Pylera) in the last 365 days.

### Denial criteria

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#### 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 365 days,

#### Criterion 2:

- History of metronidazole, tetracycline, and bismuth combination (Helidac) in the last 365 days, OR
- History of metronidazole, tetracycline, and bismuth combination (Pylera) in the last 365 days

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## Miconazole 50mg Buccal Tablet(Oravig)

*(Implemented 01/18/2011)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Clotrimazole 10mg troches
- Nystatin 100,000 units/ml oral suspension

### Drugs that require manual review for prior authorization

- Oravig

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## Midostaurin (Rydapt) Capsule

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Rydapt 25mg Capsule

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## **Mifepristone 300mg Tablet (Korlym)**

*(Implemented 07/23/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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## Migalastat – Galafold

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq 18$  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 (Zavesca) Capsule**

*(Implemented 01/13/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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**

- Nurtec ODT

### **Non-Preferred Agents**

- Dihydroergotamine Injection
- Dihydroergotamine Nasal Spray (generic for Migranal)
- Elyxyb (celecoxib) Solution
- Reyvow tablet (lasmiditan)
- Trudhesa Nasal Spray (dihydroergotamine)
- Ubrelvy tablet (Ubrogepant)
- 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.
- Recipient is ≥18 years of age or at least the minimum age listed in the manufacturer's package insert; AND
- Recipient must have a diagnosis of acute migraines with or without auras as defined by the International Classification of Headache Disorders 3rd edition (ICHD-3) OR a diagnosis consistent with FDA indication; AND
- Recipient must have a failure of at least TWO (2) preferred 5HT<sub>1B/1D</sub> receptor agonists (triptans) using two (2) different chemical agents (not just different dosage forms) at maximally tolerated doses unless recipient 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
- A request for a nonpreferred agent requires documentation of the medical necessity over preferred option; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Documentation of migraine frequency and severity/duration; AND
  - List of all therapies trialed with timeframes; AND

- Attestation that medication overuse headaches have been ruled out

### **Denial Criteria**

- Recipient does not meet the FDA approved indication OR have a diagnosis supported in the official Compendia; OR
- Recipient has any of the following:
  - 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 (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
- Ubrelvy recipient is requesting 100 mg and has severe hepatic impairment (Child-Pugh Class C) or severe renal impairment (CrCl 15-29 mL/min)

### **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)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- Sumatriptan succinate tablet (Imitrex)
- Sumatriptan 20mg nasal spray **(Imitrex)-BRAND ONLY**
- Sumatriptan 5mg nasal spray **(Imitrex)-BRAND ONLY**
- Rizatriptan 5mg MLT (Maxalt MLT)
- Rizatriptan 10mg MLT (Maxalt MLT)
- Rizatriptan 5mg tablet
- Rizatriptan 10mg tablet
- Zomig 2.5mg nasal spray **-BRAND ONLY**
- Zomig 5mg nasal spray **-BRAND ONLY**

### Preferred agents with criteria

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- Sumatriptan 4mg/0.5ml kit refill (Imitrex)
- Sumatriptan 6mg/0.5ml kit refill (Imitrex)
- Sumatriptan 6mg/0.5ml vial (Imitrex)

### Nonpreferred agents

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- Almotriptan malate (Axert)
- Eletriptan HBr (Relpax)
- Frovatriptan succinate (Frova)
- Naratriptan HCl (Amerge)
- Rizatriptan benzoate (Maxalt)
- Sumatriptan 4mg/0.5ml syringe
- Sumatriptan 6mg/0.5ml syringe
- Sumatriptan 4mg/0.5ml needle free injection (Sumavel Dosepro)
- Sumatriptan 6mg/0.5ml needle free injection (Sumavel Dosepro)
- Sumatriptan succinate/naproxen sodium (Treximet)
- Sumatriptan 20mg nasal spray **-GENERIC ONLY**
- Sumatriptan 5mg nasal spray **-GENERIC ONLY**
- Zolmitriptan 2.5 mg nasal spray **-GENERIC ONLY**
- Zolmitriptan 5 mg nasal spray **-GENERIC ONLY**

**Approval criteria for preferred agents with criteria**

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**Preferred Injection (Sumatriptan injection 4mg or 6mg)**

- Any serotonin 5-HT 1 receptor agonist within past 365 days

**Denial criteria for all agents:**

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Therapeutic duplication of any serotonin 5-HT 1 receptor agonist

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## Migraine Treatment (Prophylactic Agents)

(Implemented 10/1/2019)

(Updated 7/20/2022)

(Updated 1/1/2023)

(Updated 1/18/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Aimovig<sup>®</sup> (Erenumab-aooe) autoinjector
- Emgality<sup>®</sup> 120 mg (galcanezumab) pen and syringe
- Nurtec ODT<sup>®</sup> (rimegepant)

### Non-Preferred Agents

- Ajovy<sup>®</sup> (fremanezumab-vfrm) injection 225mg syringe
- Emgality<sup>®</sup> (galcanezumab) injection 100 mg pen and syringe
- Qulipta tablets<sup>®</sup> (atogepant)

### 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.

- Recipient is ≥18 years of age or at least the minimum age listed in the manufacturer's package insert; AND
- Recipient 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 (EMGALITY, AJOVY, or AIMOVIG); OR
  - Episodic migraine or episodic cluster headache (EMGALITY, NURTEC ODT, or QULIPTA); OR
  - Diagnosis consistent with FDA indication; AND
- Recipient has documented failure of a 3-month trial of at least **ONE** agent from **TWO** of the following preventative classes:
  - Anticonvulsants (e.g., valproate, topiramate)
  - Antidepressants (e.g., amitriptyline, venlafaxine)
  - Beta blockers (e.g., propranolol, metoprolol, atenolol)
- Recipient 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; AND
- A request for a nonpreferred agent requires documentation of the medical necessity over preferred options; AND

- Prescriber must submit ALL of the following:
  - Current chart notes; AND
  - Documentation of migraine frequency and severity/duration; AND
  - List of all therapies trialed with timeframes; AND
  - Attestation that medication overuse headaches have been ruled out.

### **Denial Criteria for Preferred Agents with Criteria**

- Recipient does not meet the FDA approved indication OR have a diagnosis supported in the official Compendia; OR
- If approved, recipient does not have a reduction from baseline in monthly migraine days or migraine severity; OR
- Recipient is not adherent to prescribed dose; OR
- Recipient has medication overuse headache caused by opiate overuse or other headache medication overuse as identified by the prescriber; OR
- Beneficiary is <18 years of age or >65 years of age; OR
- Recipient has any of the following:
  - Requires continued use of a strong CYP3A4 inhibitor (i.e., ketoconazole, itraconazole, clarithromycin, etc.) – NURTEC ODT
  - Requires continued use of a strong CYP3A inducer (rifampin) – NURTEC ODT
  - End stage renal disease (CrCl <15 mL/min) –NURTEC ODT
  - Severe hepatic impairment (Child-Pugh Class C) – NURTEC ODT and QULIPTA

### **Renewal Requirements**

- Recipient must have a reduction in monthly migraine days and migraine severity after 3<sup>rd</sup> month of treatment; AND
- Prescriber must submit the following:
  - Chart notes since previous PA approval; AND
  - Documentation of current migraine frequency and severity; AND
- Recipient is adherent to therapy; AND
- Recipient has decreased claims of acute migraine treatment

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## **Mipomersen Sodium Syringe (Kynamro)**

*(Implemented 07/09/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Kynamro

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## Misoprostol (Cytotec)

*(Implemented 01/09/2008)*

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

### Approval criteria

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#### 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

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  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  $\leq 10$  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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## Mobocertinib (Exkivity)

(Implemented 01/19/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 locally advanced or metastatic non-small cell lung cancer (NSCLC) (Stage IIIB or IV) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations OR a diagnosis consistent with FDA indications; AND
- Recipient must have disease progression on or after platinum-based chemotherapy; AND
- Female recipients of reproductive potential must use effective non-hormonal contraception AND
- Recipient must have normal lab values for electrolytes (i.e., sodium, potassium, calcium, and magnesium). Prior to beginning medication, electrolyte abnormalities must be corrected; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Documentation of previous therapy; AND
  - Baseline QTc interval; AND
  - Baseline left ventricular ejection fraction; AND
  - Baseline labs including CBC and CMP; AND
  - Documentation of treatment plan for possible diarrhea

### **DENIAL CRITERIA:**

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient is pregnant; OR
- Recipient has severe renal impairment or severe hepatic impairment; OR
- Recipient requires hormonal contraceptives, strong or moderate CYP3A inducer, or strong or moderate CYP3A inhibitor (EXKIVITY dose may need to be adjusted); OR
- Recipient has a prolonged QTc interval (clinical trials included QT intervals of ≤ 450ms for males and ≤ 470ms for females) or being treated with medications known to cause Torsades de Pointes; OR
- Recipient has been diagnosed with interstitial lung disease or pneumonitis; OR
- Recipient has Grade 2 heart failure or Grade 3 or 4 decreased ejection fraction (EF <39%)

### **QUANTITY LIMIT:**

- #124/31 days

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## Mupirocin Cream, Mupirocin Nasal Ointment

*(Implemented 02/16/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Drugs that require manual review for prior authorization

- Mupirocin 2% Cream
- Mupirocin 2% Nasal Ointment

### Drugs that do not require a prior authorization

- Mupirocin 2% Ointment

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## **Mycophenolate (Myfortic)**

*(Suspension Implemented 10/11/2011) (Capsules and Tablets Implemented 12/10/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 PA

- Mycophenolate 250 mg capsules (Cellcept)
- Mycophenolate 500 mg tablets (Cellcept)

### Drugs that require manual review for prior authorization

- Mycophenolate 180mg Tablet DR (Myfortic)
- Mycophenolate 360mg Tablet DR (Myfortic)

### Approval criteria for Suspension

- Diagnosis of Organ Transplant in Medicaid History in the past 3 years
- < 7 years of age, OR
- NPO ([Appendix A](#)) within the past 365 days.

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## Nabilone (Cesamet)

*(Implemented 06/27/2007)*

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

### Approval criteria

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- 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, OR
- Paid drug claim in history within the past 45 days for Marinol.

### Denial criteria

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- 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

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Quantity limits apply

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## Nafarelin Nasal Spray (Synarel)

*(Implemented 09/21/2009)*

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

### Approval criteria

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

### Denial criteria

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Diagnosis of infertility in the previous three years

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## Nandrolone Decanoate Injection

*(Implemented 01/09/2008)*

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

### Approval criteria

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- Diagnosis for anemia secondary to chronic renal failure in the past 90 days, AND
- At least three paid Medicaid claims in the past 90 days for erythropoietin, AND
- No therapeutic duplication with erythropoietin

### Additional criteria

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Quantity limits apply

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## **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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Neo-Synalar

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## Neratinib (Nerlynx)

(Updated 4/18/2018)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 indication for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab based therapy;
- Beneficiary has histologically confirmed stage 2 through stage 3c HER-2/erbB-2 positive breast cancer with node positive disease;
- Beneficiary has been treated for early breast cancer with standard of care duration of trastuzumab or experienced side effects that results in early discontinuation of trastuzumab that have since resolved;
- The last dose of trastuzumab was given > 2 weeks and ≤ 1 year (365 days) from requested start time for NERLYNX™;
- Beneficiary is negative for local or regional recurrence of disease or metastatic disease at the time of the PA request using the following:
  - bone scan or PET scan if alkaline phosphatase (ALP) is ≥ 2 ULN and/or there are symptoms of metastatic disease, and a confirmatory imaging study is required if the results from the bone scan are questionable; CT, MRI or ultrasound of the abdomen and chest is required only if AST, ALT, or ALP is ≥ 2x ULN;
  - chest radiograph;
- The beneficiary's left ventricular ejection fraction (LVEF) is ≥ 50%;
- Beneficiary is not pregnant; women of childbearing age must use a highly effective non-hormonal method of contraception (IUD, bilateral tubal ligation, vasectomized partner) from the time of informed consent to 28 days past last dose;
- The beneficiary's ECOG status is 0 to 1; • Beneficiary is ≥ 18 years of age;
- Prescriber has prescribed loperamide to the beneficiary during the first 2 cycles (56 days) of NERLYNX™ treatment; prescriber shall follow the dose modifications required for diarrhea management;
- Prescriber is required to submit the beneficiary's Child-Pugh score; Child-Pugh C will receive dose reduction to 80 mg per day;
- Prescriber must submit results of liver function tests (ALT, AST, alkaline phosphatase, Fractionated bilirubin and prothrombin time) with initial PA request;
- Prescriber must submit the following screen assessments: absolute neutrophil count (ANC), platelet count, hemoglobin, total bilirubin, Creatinine Clearance;
- The dose and quantity limit is to be entered at the time of PA approval;
- PA approval will be month-to-month due to high rate of adverse effects that require dose modification;

### **DENIAL CRITERIA:**

- Prior treatment with any pan-HER TKI (e.g., lapatinib, afatinib, dacomitinib);
- Clinical or radiologic evidence of local or regional recurrence of disease or metastatic disease prior to initial PA request or at each PA request;
- Currently receiving chemotherapy, radiation therapy, immunotherapy, or biotherapy for breast cancer;
- Screening laboratory assessments outside the following limits:
  - Absolute neutrophil count (ANC) < 1,000/μl (< 1.0 x 10<sup>9</sup>/L)
  - Platelet count < 100,000/μl (< 100 x 10<sup>9</sup>/L)

- Hemoglobin < 9 g/dL
- Total bilirubin > 1.5 x institutional upper limit of normal (ULN) (In case of known Gilbert's syndrome, < 2 x ULN is allowed)
- Creatinine clearance < 30 mL/min (as calculated by Cockcroft-Gault formula or Modification of Diet in Renal Disease [MDRD] formula);
- Chronic gastrointestinal disorder with diarrhea as a major symptom (e.g., Crohn's disease, malabsorption, or Grade ≥ 2 NCI CTCAE v.4.0 diarrhea of any etiology at baseline);
- Clinically active infection with HBV or HCV; Disease progression;
- Unacceptable toxicity;
- Active uncontrolled cardiac disease, including cardiomyopathy, CHF NYHA functional classification of ≥ 2 and including individuals currently on digitalis, beta blockers, or calcium channel blockers, unstable angina, MI with 12 months of PA request, or ventricular arrhythmia;
- QTc interval > 0.450 seconds for males or > 0.470 for females, or known history of QTc prolongation or Torsade de Pointes (TdP);
- Currently pregnant or breast feeding;
- Beneficiary has secondary malignancy, other than adequately treated non-melanoma skin cancers, in situ melanoma or in situ cervical cancer, or if beneficiary had other non-mammary malignancies must be disease-free x 5 years
- Beneficiary will not receive NERLYNX past one year;
- Deny PA for NERLYNX™ for patients who fail to recover to Grade 0-1 from treatment-related toxicity or for Grade 4 toxicity;
- Deny PA for NERLYNX™ for toxicities that result in a treatment delay > 3 weeks,
- Deny PA request for patients that are unable to tolerate 120 mg;
- Deny quantity that exceeds the prescribed reduced dose;

**Quantity Limit:**

- Initial approval dose will not exceed 240 mg (6 tablets) once daily for the initial PA request;
- The package size is a bottle of 180 tablets. However, due to high incidence of adverse events requiring dose reduction, the approved quantity will be entered at the time of each PA approval in the event of a dose reduction

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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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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

### Non-preferred agents:

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- Cymbalta
- Drizalma sprinkle (duloxetine)
- Gabapentin 250mg/5ml solution (Neurontin)\*
- 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:

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- 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## **Nilotinib (Tasigna) Tablet**

*(Implemented 01/17/2017)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Tasigna 150mg Tablet
- Tasigna 200mg Tablet

### Additional criteria

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Quantity limits apply

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## **Nimodipine Solution(Nymalize)**

*(Implemented 12/10/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Nymalize Solution

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## Nintedanib- Ofev®

(Updated 1/15/2020)

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

### **GENERAL APPROVAL CRITERIA:**

- Manual review on a case-by-case basis AND
- Must be at least 18 years of age AND
- Must have one of the FDA approved indications—Idiopathic Pulmonary Fibrosis (IPF) or Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) AND
- Must be a non-smoker AND
- Must not be pregnant (provide pregnancy test results when applicable) AND
- **Prescriber must submit the General Approval Criteria above for IPF patients AND**
  - Current chart notes
  - Specific dose requested (PA entered based on specific dose)
  - Clinical and radiographic diagnosis of idiopathic pulmonary fibrosis (IPF) without evidence or suspicion of an alternative diagnosis for interstitial lung
  - IPF staging classification
  - Liver Function Tests (LFTs)
  - Documentation verifying the smoking status with either exhaled carbon monoxide level (eCO) <6ppm, carboxyhemoglobin (COHb) levels of <3% OR urine cotinine concentration <200ng/mL
  - Baseline pulmonary function tests (PFTs) including % forced vital capacity (%FVC) of ≥50% and carbon monoxide diffusing capacity (%DLCO) 30%-79% of predicted
  - Results of high-resolution CT scan of the lungs with documentation of Basal and peripheral predominance, Honeycombing (usually subpleural), or Reticular opacities, often in combination with traction bronchiectasis
  - Results of 6-minute walk test (6MWT) at baseline
  - Specific measurable goals for treatment outcomes
- **Prescriber must submit the General Approval Criteria above for SSC-ILD patients AND**
  - Current chart notes
  - Specific dose requested (PA entered base on specific dose)
  - Chest high resolution computed tomography (HRCT) scan within the last 12 months with ≥10% fibrosis
  - Liver Function Tests (LFTs)
  - Baseline pulmonary function tests (PFTs) including % forced vital capacity (%FVC) of ≥40% and carbon monoxide diffusing capacity (%DLCO) 30%-89% of predicted
  - Medical necessity over immunosuppressant therapy
  - Results of 6-minute walk test (6MWT) at baseline
  - Specific measurable goals for treatment outcomes

**DENIAL CRITERIA:**

- Does not meet approval criteria OR
- Lung transplant OR
- Pregnant or breastfeeding OR
- Currently smoking OR
- Elevated LFTs with ALT, AST or bilirubin >1.5 X ULN OR
- Child Pugh B or C OR ESRD OR
- Severe diarrhea, nausea or vomiting despite symptomatic treatment OR
- Gastrointestinal perforation OR
- Patient cannot tolerate minimum dose of 100mg twice daily

**Quantity Limits:**

100mg--#62/31 days

150mg--#62/31 days

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## **Niraparib (Zejula) 100mg Capsule and 100mg, 200mg, and 300mg Tablets**

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Zejula 100mg Capsule
- Zejula 100mg, 200mg, and 300mg Tablets

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## Nitisinone Capsule (Orfadin)

*(Implemented 09/23/2014)*

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

### Approval criteria

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- < 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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Reactive Rectal Ointment

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## Nizatidine Oral Solution (Axid)

*(Implemented 12/10/2008)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- At least two paid Medicaid drug claims for ranitidine syrup in the past 60 days, AND
- < 7 years of age, OR
- NPO ([Appendix A](#)) within the past 365 days.

### Approval criteria (Continuation Criteria)

One or more claims in the previous 60 days for Axid Oral Solution.

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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
- Bynfezia

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## Odevixibat (Bylvay)

(Implemented 10/20/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 3$  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 pruritus 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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## Olaparib Capsule (Lynparza)

*(Implemented 04/13/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Lynparza

Additional criteria

Quantity limits apply

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## Olutasidenib (Rezlidhia™) 150mg capsule

(Implemented 1/18/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation **OR** a diagnosis consistent with any updated FDA approved indications or support on the official Compendia
- Recipient should not be approved or continued on this therapy with any of the following:
  - Continued signs of differentiation syndrome despite dosage modification
  - Require concomitant moderate or strong CYP3A inducers
  - Severe renal or hepatic impairment
  - No previous induction therapy
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Previous therapies tried
  - Current labs including CBC with differential and LFTs
  - Report confirming the presence of an IDH1 mutation
  - Treatment plan for hematopoietic cell transplant
- Approved PA requests will be entered for 6 months

### RENEWAL REQUIREMENTS:

- Current chart notes with response to therapy
- Current labs including CBC and LFTs (labs drawn at least once weekly for first 2 months, once every other week for third month, once in fourth month, and once every other month thereafter)
- Lack of disease progression (trial at least 6 months to assess clinical response) or unacceptable toxicities

### QUANTITY EDITS:

#62/31 days

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## Omega-3-acid ethyl esters (Lovaza)

(Implemented 09/18/2013)

(Updated and Effective 7/15/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 hypertriglyceridemia; AND
- Triglyceride level  $\geq$  500mg/dL in the last 180 days; AND
- Recipient's Medicaid pharmacy drug history indicates at least three (3) claims of fibric acid derivatives in the last 365 days; AND
- Recipient'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. Prescriber must submit a letter explaining the medical necessity and submit documentation to support the diagnosis not found.

### Quantity Limits:

#120/30 days

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## Omeprazole, Amoxicillin, and Clarithromycin combination (Omeclamox-Pak)

(Implemented 05/21/2012)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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#### 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 (Helidac) in the last 365 days, OR
- No history of metronidazole/tetracycline/bismuth combination (Pylera) in the last 365 days.

### Denial criteria

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#### 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 (Helidac) in the last 365 days, OR
- No history of metronidazole/tetracycline/bismuth combination (Pylera) in the last 365 days.

### Additional criteria

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Quantity limits apply

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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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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 0.01% eye drops (Patanol®)
- Olopatadine HCl 0.02% 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)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### **Preferred Agents:**

- Bacitracin/ polymyxin B ophthalmic ointment
- Ciprofloxacin 0.3% ophthalmic solution drops
- Erythromycin 0.5% ophthalmic ointment
- Gentamicin 0.3% ophthalmic ointment
- Gentamicin 0.3% ophthalmic solution drops
- Moxifloxacin (**VIGAMOX- BRAND ONLY**) 0.5% ophthalmic solution drops-
- Polymyxin B /trimethoprim ophthalmic solution drops
- Tobramycin 0.3% ophthalmic solution drops

### **Non-Preferred Agents:**

- Azithromycin (AZASITE®) 1% ophthalmic solution drops
- Bacitracin ophthalmic ointment 500 units/gm
- Besifloxacin (BESIVANCE®) 0.6% ophthalmic suspension drops
- Ciprofloxacin (CILOXAN®) 0.3% ophthalmic solution drops
- Ciprofloxacin (CILOXAN®) 0.3% ophthalmic ointment
- Gatifloxacin (ZYMAXID®) 0.5% ophthalmic solution drops
- Levofloxacin 0.5% ophthalmic solution drops
- Moxifloxacin (MOXEZA®) 0.5% ophthalmic solution drops
- **Moxifloxacin (Vigamox- GENERIC ONLY)** 0.5% ophthalmic solution drops-
- Natamycin (NATACYN®) 5% ophthalmic suspension drops
- Neomycin/polymyxin B/ bacitracin ophthalmic ointment
- Neomycin/polymyxin B/ gramicidin ophthalmic solution drops
- Ofloxacin 0.3% ophthalmic solution drops
- Sulfacetamide 10% ophthalmic solution drops
- Tobramycin (TOBREX®) 0.3% ointment

## 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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
- 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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.®)
- 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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)
- Lifitegrast 5% solution (Xiidra)
- Perfluorohexyloctane drops (Miebo)

### Approval criteria for Preferred Agents with Criteria

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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

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- Therapeutic duplication with Lacrisert (hydroxypropyl cellulose)

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## Opicapone (Ongentys)

(Implemented 1/20/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  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)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents with criteria

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- Buprenorphine patch (Butrans)- **BRAND ONLY**
- Morphine sulfate long-acting tablet (MS Contin, Oramorph)
- Tramadol ER Tablet (Ultram ER)

### Nonpreferred agents with criteria

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- Belbuca Films – **PLAN PREFERS BRAND OVER GENERIC IF CRITERIA IS MET**
- Buprenorphine (generic for Belbuca)
- Buprenorphine patch (**GENERIC ONLY**)
- Fentanyl patch (Duragesic)
- Hydrocodone ER Capsule (Zohydro ER)
- Hydrocodone ER (Hysingla ER)
- Hydromorphone HCl extended-release tablet (Exalgo ER)
- Methadone HCl (Dolophine)
- Morphine sulfate extended-release capsule (Avinza, Kadian)
- Morphine sulfate extended-release tablets (Morphabond ER)
- Morphine sulfate/naltrexone (Embeda ER)
- Oxycodone extended-release tablet (Oxycontin)
- Oxycodone extended-release capsule (Xtampza ER)
- Oxymorphone HCl extended-release tablet (Opana ER)
- Tapentadol HCl extended-release tablet (Nucynta ER)
- Tramadol ER capsule (Conzip)
- Tramadol ER tablet (Ryzolt)

### Approval criteria for preferred agents with criteria

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- Medical necessity of using a long-acting opiate for chronic, non-cancer pain
- Claim for long-acting opiate within the previous 60 days (continuation criteria)

### Approval criteria for nonpreferred agents with criteria

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- Fentanyl patch
  - NPO ([Appendix A](#)), OR

## Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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- Currently LTC, OR
  - Cancer with malignancies ([Appendix E](#)) in past 12 months
- AND
- No therapeutic duplication in drug history between long-acting narcotics
- Morphine sulfate long-acting capsule or oxycodone long acting tablet
  - Currently LTC, OR
  - Cancer with malignancies ([Appendix E](#)) in past 12 months
- AND
- No therapeutic duplication in drug history between long-acting narcotics
- Methadone HCl (Dolophine)
  - Cancer with malignancies ([Appendix E](#)) in past 12 months
- AND
- No therapeutic duplication in drug history between long-acting narcotics
  
- Methadone oral solution for NAS (Neonatal Abstinence Syndrome):
  - The infant's age is  $\leq 90$  days of age at the time the drug claim is submitted; AND
  - The quantity of methadone oral solution dispensed is not more than 10 ml for a 30-day supply; AND
  - The incoming claim and the claim in history will not make the accumulated quantity of methadone oral solution more than 10 ml for the previous 30-day supply; AND
  - Methadone oral solution for an infant older than 90-days who does not have malignant cancer diagnosis in the Medicaid diagnosis history, or the methadone oral solution accumulation quantity for a 30-day period will exceed 10 ml, will require manual review PA. The prescriber must send letter explaining medical necessity, quantity requested, dose, and taper plan schedule with the PA request.
- 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.
  - Patients who have a diagnosis of malignant cancer in the past 12 months:
    - Are exempt from the diagnosis check for a poisoning (overdose) of opioids, narcotics, barbiturates, benzodiazepines, or unspecified drug or substance.

### Denial criteria

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- Paid claim for Suboxone or Subutex in the past 90 days
- Therapeutic duplication of long-acting opiates
- No medical necessity of long-acting opiate

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## 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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 (Ultram 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

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- Patients who have a diagnosis of malignant cancer in the past 12 months:
  - 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 solution 120 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
- 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/ml
- Oxycodone 10 mg/ 0.5 ml oral syringe
- 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/lbuprofen tablet 5 mg-400 mg
- Oxymorphone (OPANA®) tablets
- Pentazocine/naloxone tablet
- Seglantis (Tramadol/Celecoxib)
- Tapentadol (NUCYNTA®) tablet and oral solution
- Tramadol 100mg tablets

#### Additional criteria

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Quantity limits apply

Age restrictions apply

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## **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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976**

### Approval criteria

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

### Additional criteria

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- Quantity Limits apply

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## Osilodrostat (Isturisa®)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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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## Osimertinib (Tagrisso) Tablets

*(Implemented 04/26/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Tagrisso Tablets 80mg and 40mg

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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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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®)
- Etidronate tablets
- 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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[Link to Memorandum](#)

[Link to Memorandum \(Prolia\)](#)

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## Oteseconazole (Vivjoa™) 150mg capsule

(Implemented 01/18/2023)

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

### Approval Criteria

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- Recipient is an adult, female with a history of recurrent vulvovaginal candidiasis (RVVC) defined as  $\geq 4$  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  $< 15$  mL/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

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- 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

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#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)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- Ciprodex Otic (ciprofloxacin and dexamethasone suspension drops)
- Neomycin/polymyxin HC Otic solution
- Acetic acid 2% Otic
- Acetic acid-hydrocortisone Otic drops
- Ofloxacin Otic

### Non-Preferred Agents

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- Cipro HC Otic
- Cortisporin-TC Otic
- Coly-Mycin S Otic
- Ciprofloxacin Otic
- Otovel otic
- Otiprio Otic

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## Overactive Bladder Agents

(Implemented 07/14/2009, last reviewed 4/1/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- Oxybutynin chloride syrup, 5mg tablets (generic for Ditropan)
- Oxybutynin chloride extended-release tablet (generic for Ditropan XL Tablet)
- Solifenacin succinate (generic for Vesicare)
- Toviaz tablets- **BRAND ONLY**

### Nonpreferred agents

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- Darifenacin hydrobromide (generic for Enablex)
- Detrol (tolterodine tartrate tablet)
- Detrol LA (tolterodine tartrate extended-release capsule)
- Ditropan XL tablet
- Fesoterodine tablet (generic for Toviaz)
- Flavoxate HCl (generic for Urispas)
- Gemtesa tablets (Vibegron)
- Myrbetriq (mirabegron extended-release)
- Oxybutynin 2.5mg tablets
- Oxytrol (Oxybutynin patch)
- Tolterodine tartrate tablet (generic for Detrol)
- Tolterodine tartrate extended-release capsule (generic for Detrol LA)
- Trospium chloride extended-release capsule (generic for Sanctura XR)
- Trospium chloride immediate-release tablet (generic for Sanctura)
- Vesicare tablets
- Vesicare LS Suspension

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## Oxandrolone (Oxandrin)

(Implemented 01/09/2008)

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

### Approval criteria

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#### Criterion 1:

Diagnosis in the past two years for:

- HIV/AIDS, AND
- Cachexia AND
- Paid drug claims in history for at least three antiretrovirals (either as a single entity or combo drug) within the past 30 days, AND
- Paid drug claim in history for megestrol acetate within the last four weeks

#### Criterion 2:

Diagnosis code in Medicaid history in the past 365 days for one of the following:

- Weight loss secondary to severe trauma (burns, spinal cord injury), OR
- Weight loss due to protein catabolism associated with prolonged administration of high dose corticosteroids.

#### Criterion 3:

- Diagnosis in Medicaid history for osteoporosis, AND
- Concurrent therapy in the past 45 days for one of the following:
  - Bisphosphonate
    - Didronel (etidronate)
    - Fosamax (alendronate)
      - Aminobisphosphonate
    - Actonel (risedronate)
      - Selective estrogen-receptor modulators
    - Evista (raloxifene)
    - Calcitonin injection, OR
  - History of Ibandronate in the past 100 days Criterion 4:
  - Diagnosis in Medicaid history for hereditary angioedema in the past three years.

### Denial criteria

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Diagnosis in Medicaid history for any of the following in the past 365 days:

- Prostate cancer
- Breast cancer – male or female
- Pregnancy
- Nephrosis

**Additional criteria**

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Quantity limits apply

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## Oxymetazoline (Rhofade) Topical Cream

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Rhofade Topical Cream

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## Oxymetholone (Anadrol—50 tablet)

*(Implemented 01/09/2008)*

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

### Approval criteria

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#### Criterion 1:

- Diagnosis of acquired aplastic anemia in the past 365 days, AND
- Five claims in the past six months for Cyclosporine

#### Criterion 2:

- Diagnosis of chronic renal failure in the past 365 days, AND
- History of three paid drug claims of recombinant erythropoietin in the past 90 days.

#### Criterion 3:

- Diagnosis of Fanconi's anemia in the past 365 days

#### Criterion 4:

- Diagnosis for congenital refractory pure red cell aplasia in the past 365 days,  
AND
- At least 30 days of corticosteroid therapy in the past 90 days

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## **Pacritinib (Vonjo)**

*(Implemented 04/20/2022)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age; AND
- Recipient must be diagnosed with intermediate or high-risk primary or secondary myelofibrosis with platelets  $<50 \times 10^9/L$  OR a diagnosis consistent with FDA approved indication or Compendia support; AND
- Recipient should have a treatment plan for diarrhea; AND
- Recipient has palpable splenomegaly  $\geq 5$  cm; AND
- Recipient must have at least 2 hydroxyurea drug claims in Medicaid drug history. If no hydroxyurea drug claims in Medicaid drug history, provider must submit documentation to substantiate that beneficiary had an inadequate response to or was intolerant to hydroxyurea; AND
- Recipient must taper off other kinase inhibitors; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs including CBCs with differential and coagulation testing; AND
  - Baseline electrocardiogram

### **DENIAL CRITERIA:**

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient requires concomitant use of strong CYP3A4 inhibitors or inducers; OR
- Recipient has active bleeding; OR
- Recipient has a baseline QTc  $>480$  msec; OR
- Recipient has moderate or severe hepatic impairment (Child-Pugh B or C); OR
- Recipient has an eGFR  $<30$  mL/min; OR
- Recipient has had a splenectomy; OR
- If approved, the recipient may be denied renewal if does not show a positive response by spleen size reduction or symptom improvement after 6 months of therapy; OR
- Recipient is unable to tolerate the minimum dose of 100 mg once daily

### **QUANTITY EDITS:**

- #124/31 days

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## Pain Medications, Injectable

(Implemented 04/12/2011)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) 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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## Palbociclib (Ibrance)

*(Implemented 07/22/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Ibrance

### 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 4$  years of age and  $\leq 17$  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  $\geq 8$ mm compared to control; OR
  - Documented reaction to peanut upon supervised oral food challenge at a dose of  $\leq 100$  mg peanut protein ( $\leq 200$  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

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## Pancreatic Enzymes

*(Implemented 10/01/2016)*

*(Updated 1/1/2023)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- Creon
- Zenpep

### Nonpreferred agents

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- Pancreaze
- Pertzye
- Viokace

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## **Panobinostat Lactate (Farydak)**

*(Implemented 04/20/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Farydak

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## Papaverine 30mg/ml

*(Implemented 08/10/2007)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Submitted diagnosis for erectile dysfunction
- Submitted diagnosis for Impotence

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## Parathyroid Hormone for Injection (Natpara)

*(Implemented 04/01/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Natpara

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## **Pasireotide Diaspartate (Signifor) Ampule**

*(Implemented 09/18/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## **Pazopanib (Votrient)**

*(Implemented 10/10/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Votrient

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## **Pegcetacoplan (Empaveli)**

*(Implemented 7/21/2021)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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, Neisseria meningitidis types A, C, W, Y, and B, and Haemophilus influenzae type 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, Neisseria meningitidis, and Haemophilus influenzae
- Recipient is pregnant or breastfeeding

### **QUANTITY EDITS**

10 vials/ 30 days

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## **Peginterferon Alfa-2B (Sylatron)**

*(Implemented 05/25/2011)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Submitted diagnosis for Hepatitis C, Acute, Chronic, and Unspecified

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## **Pegvaliase-pqpz (Palynziq)**

*(Implemented 7/18/2018)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age;
- Beneficiary has phenylketonuria and has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L while adherent to a strict Phenylalanine (Phe)-limited diet;
- Prescriber must submit beneficiary's blood phenylalanine concentration with PA request;
- Beneficiary is adherent to a Phe-restricted diet that restricts phenylalanine protein;
- Prescriber must submit chart notes to substantiate that beneficiary was a non-responder to KUVAN while adherent to the Phe-restricted diet;
- If female beneficiary is child-bearing age, she must be willing to use 2 acceptable methods of contraception while receiving PALYNZIQ;
  - Females who have been in menopause for at least 2 years, have had a tubal ligation at least 1 year prior to first dose of PALYNZIQ, or have had a total hysterectomy do not need to use any other forms of contraception while receiving PALYNZIQ.
  - Males post vasectomy 2 years with no known pregnancies for at least 2 years do not need to use any other forms of birth control while receiving PALYNZIQ.
- Prescriber must administer the initial dose of PALYNZIQ and closely observe the beneficiary for at least 60 minutes following the injection;
- Prescriber must ensure beneficiary is capable of recognizing signs and symptoms of anaphylaxis and can administer the autoinjector of epinephrine;
- Prescriber must prescribe and ensure beneficiary filled the Medicaid preferred autoinjector of epinephrine;
- If approved, due to the recommended dosing schedule, the initial PA will be approved for 5 weeks at 2.5 mg once weekly for 4 weeks, and 2.5 mg twice weekly for 1 week, for a total of six 2.5 mg syringes; quantity will be entered at the time of the PA approval;

### **DENIAL CRITERIA:**

- HIV positive;
- Beneficiary is pregnant;
- Beneficiary is  $< 18$  years of age;
- Beneficiary has a history of substance abuse in the past 12 months or current alcohol or drug abuse; • Beneficiary was not adherent to a strict Phe-restricted diet;
- Beneficiary did not have adequate trial of Kuvan;
- Beneficiary was not adherent to prescribed dose of PALYNZIQ;
- Beneficiary did not show at least a 20% reduction in blood phenylalanine concentration from pretreatment baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily

### **QUANTITY 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.**

### Approval criteria

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No Therapeutic duplication allowed between different strengths of Somavert

### Additional criteria

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Quantity limits apply

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## Pemigatinib (Pemazyre™)

(Effective 7/15/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 has a diagnosis of previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test **OR** diagnosis consistent with FDA indications; **AND**
- Recipient has progressed after at least 1 failed prior systemic therapy. Provide the medical necessity of pemigatinib over FOLFOX. (NCCN guidelines currently recommend FOLFOX as preferred therapy after progression with gemcitabine/cisplatin. But FOLFOX does not have current data about the specific FGFR2 fusion mutation.) Provide documentation of that therapy including any radiation with response; **AND**
- Prescriber should submit the following:
  - Current chart notes with previous therapies tried; **AND**
  - Documentation of FGFR2 fusion or other rearrangement; **AND**
  - Current labs including serum phosphate (initiate phosphate lowering therapy if >7mg/dL with reduction in dose), CBC, LFTs; **AND**
  - Documentation of comprehensive ophthalmological exam; **AND**
  - Pregnancy test results for recipient with child-bearing potential.
- Initial PA for 2 months

### Denial Criteria

- Recipient does not meet the above approval requirements; **OR**
- Recipient is unable to tolerate 4.5 mg once daily; **OR**
- Recipient has persistent symptoms for Retinal Pigment Epithelial Detachment (RPED); **OR**
- Recipient has continued serum phosphate >10mg/dL despite 2 dose reductions; **OR**
- Recipient requires concomitant strong or moderate CYP3A inhibitors (e.g. itraconazole, erythromycin, verapamil); if cannot be avoided, reduce Pemazyre dose; **OR**
- Recipient has not failed previous systemic therapy, and the medical necessity over FOLFOX was not provided; **OR**
- Recipient is pregnant.

### Quantity Edits

- 4.5 mg tablets — #14/21 days
- 9 mg tablets — #14/21 days
- 13.5 mg tablets — #14/21 days

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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)

### **Non- Preferred Agents:**

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

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## **Pexidartinib (Turalio™)**

*(Implemented 10/16/2019)*

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

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case; AND
- Must be ≥ 18 years of age; AND
- Beneficiary has a diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) (also known as pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT- TS)) associated with severe morbidity or functional limitations and not amenable to improvement with surgery; AND
- Provide documentation that provider and beneficiary are enrolled in REMS program; AND
- Beneficiary should not be pregnant or breastfeeding; AND
- Provide beneficiary's current chart notes with description of current range of motion and treatment history (if applicable); AND
- Provide MRI results confirming diagnosis; AND
- Provide the medical necessity of Turalio™ over surgery and/or radiation; AND
- Provide the following labs:
  - LFTs including ALT/AST, ALP, GGT and bilirubin (labs monitored weekly for first 8 weeks, every 2 weeks for the next month and every 3 months thereafter); AND
  - Renal function including serum creatinine and BUN; AND
  - CBC with differential; AND
- Documentation of stable prescription of analgesic regimen which can include opioids, anti- inflammatories or corticosteroids for at least 2 weeks with continued pain and mobility difficulties; AND
- Provider must attest to counseling sexually active patients (male and female) that are not surgically sterile to use condoms or other forms of birth control; AND
- Provide physical therapy notes if available; if not receiving PT, provider should explain rationale; AND
- PA's approved month-to-month for at least first 3 months to monitor labs

**DENIAL CRITERIA:**

- Beneficiary does not meet approval criteria; OR
- Beneficiary is pregnant or breastfeeding; OR
- Discontinue if cannot tolerate dose of 200mg twice daily; OR
- Discontinue if the following:
  - ALT and/or AST >10 x ULN
  - ALP and GGT >2 x ULN
  - Total bilirubin  $\geq$ 2 x ULN or Direct bilirubin >1.5 x ULN
- Concomitant use of proton pump inhibitors; OR
- Concomitant use of strong CYP3A inhibitor (e.g., itraconazole) or uridine diphosphoglucuronosyltransferase (UGT) inhibitor (e.g., probenecid)—if unavoidable, reduce Turalio™ dose; OR
- Provider or beneficiary are not enrolled in the REMS program; OR
- Active or chronic infection with hepatitis C virus, hepatitis B virus or human immunodeficiency virus

**QUANTITY EDITS:**

#120 per 30 days

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## Phenoxybenzamine (Dibenzylamine)

*(Implemented 05/04/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Dibenzylamine

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## 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### PREFERRED AGENTS

- Calcium Acetate capsule
- Calcium Acetate tablet
- Renvela<sup>®</sup> (sevelamer carbonate) TABLET (**BRAND ONLY**)

### NON-PREFERRED AGENTS

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

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## **Pilocarpine (Vuity)**

*(Implemented 01/19/2022)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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)

(Updated 1/15/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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**

- Esbriet
- Pirfenidone

### **GENERAL APPROVAL CRITERIA:**

- Manual review on a case-by-case basis AND
- Must be at least 18 years of age AND
- Clinical and radiographic diagnosis of idiopathic pulmonary fibrosis (IPF) without evidence or suspicion of an alternative diagnosis for interstitial lung AND
- Must be a non-smoker and prescriber must submit documentation verifying the smoking status with either exhaled carbon monoxide level (eCO) <6ppm, carboxyhemoglobin (COHb) levels of <3% OR urine cotinine concentration <200ng/mL **AND**
- Must not be pregnant (provide pregnancy test results when applicable) AND

### **Prescriber must submit the General Approval Criteria above for IPF patients AND**

- Current chart notes
- Specific dose requested (PA entered based on specific dose)
- Clinical and radiographic diagnosis of idiopathic pulmonary fibrosis (IPF) without evidence or suspicion of an alternative diagnosis for interstitial lung
- IPF staging classification
- Liver Function Tests (LFTs)
- Baseline pulmonary function tests (PFTs) including % forced vital capacity (%FVC) of ≥50% and carbon monoxide diffusing capacity (%DLCO) 30%- 79% of predicted
- Results of high-resolution CT scan of the lungs with documentation of Basal and peripheral predominance, Honeycombing (usually subpleural), or Reticular opacities, often in combination with traction bronchiectasis
- Results of 6-minute walk test (6MWT) at baseline
- Specific measurable goals for treatment outcome

**Prescriber must submit the General Approval Criteria and the following for SSC-ILD patients AND**

- Current chart notes
- Specific dose requested (PA entered base on specific dose)
- Chest high resolution computed tomography (HRCT) scan within the last 12 months with  $\geq 10\%$  fibrosis
- Liver Function Tests (LFTs)
- Baseline pulmonary function tests (PFTs) including % forced vital capacity (%FVC) of  $\geq 40\%$  and carbon monoxide diffusing capacity (%DLCO) 30%- 89% of predicted
- Medical necessity over immunosuppressant therapy
- Results of 6-minute walk test (6MWT) at baseline
- Specific measurable goals for treatment outcomes

**DENIAL CRITERIA:**

- Does not meet approval criteria OR
- Lung transplant OR
- Pregnant or breastfeeding OR
- Currently smoking OR
- Elevated LFTs with ALT, AST or bilirubin  $> 1.5 \times$  ULN OR
- Child Pugh B or C OR ESRD OR
- Severe diarrhea, nausea or vomiting despite symptomatic treatment OR
- Gastrointestinal perforation OR
- Patient cannot tolerate minimum dose of 100mg twice daily

**QUANTITY EDITS:**

- 100mg--#62/31 days
- 150mg--#62/31 days

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## Pirtobrutinib (Jaypirca™) 50mg and 100mg tablet

(Implemented 5/10/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor **OR** a diagnosis consistent with any new FDA-approved indications or support on the official Compendia
- Beneficiary with severe renal impairment requires a dose adjustment
- Beneficiary should not be approved with any of the following:
  - Cannot tolerate the minimum daily dose of 50 mg
  - Pregnancy
  - Avoid strong CYP3A inhibitors if possible. If unavoidable, JAYPIRCA dose should be decreased
  - Avoid strong or moderate CYP3A inducers if possible. If unavoidable, JAYPIRCA dose should be increased.
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Documentation of previous therapies tried
  - Current labs including CBC with differential, renal function

### **RENEWAL REQUIREMENTS:**

- Prescriber must submit current chart notes and labs
- Prescriber must submit response to therapy (approval requires the lack of disease progression and lack of unacceptable toxicity)
- Beneficiary continues to meet approval criteria

### **QUANTITY EDITS:**

50 mg—#31/31 days

100 mg—#62/31 days

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## Pituitary Suppressive Agents

(Implemented 7/1/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq 11$  years and male  $\geq 12$  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

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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  $<7$ cm/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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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®
- ZONTIVITY® (vorapaxar sulfate)

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.**

### Approval criteria

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#### Podofilox 0.5% Topical Solution (Condylox)

- $\geq$  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)

- $\geq$  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

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- Absence of approval criteria
- $<$  18 years of age
- Therapeutic duplication of gel/solution

### Additional criteria

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Quantity limits apply

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## Pomalidomide Capsule (Pomalyst)

*(Implemented 07/09/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Pomalyst

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## **Ponatinib HCl Tablet (Iclusig)**

*(Implemented 07/09/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Iclusig

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## Posaconazole (Noxafil) Suspension

(Implemented 01/09/2008)

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

### Approval criteria

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#### 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 30 days. Criterion 4:
- ≥ 13 years of age, AND
- History of paid claim for requested drug (Noxafil) in the past 180 days.

### Denial criteria

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- < 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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
- Potassium chloride 25 mEq powder packet [Klor-Con 25 mEq 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.**

### Approval criteria

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

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## **Pralsetinib (Gavreto)**

*(Implemented 1/20/2021)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age if diagnosed with NSCLC and  $\geq 12$  years of age for thyroid cancer; AND
- Recipient must be diagnosed with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC), advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy, or advanced/metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory OR a diagnosis consistent with FDA indications; AND
- Recipient must have non-resectable disease; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Documentation of diagnosis with lab work confirming the presence of a RET gene fusion or gene mutation; AND
  - Current labs including CBC with differential, complete metabolic panel, calcitonin levels for medullary thyroid cancer; AND
  - Current blood pressure (hypertension must be controlled); AND
  - Documentation of previous therapies including radioactive iodine in RET fusion-positive thyroid cancer; AND
    - NSCLC—may be used first-line, but many patients start on platinum therapy
    - MTC—may have used cabozantinib, vandetanib, or naïve to both agents
    - TC—failure of standard therapy with radioactive iodine and sorafenib and/or lenvatinib
  - Attestation that recipients of reproductive potential are not pregnant and counseled to use effective non-hormonal contraception; AND
- Initial approval will be three (3) months

### **Denial Criteria**

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient has no documentation of RET gene fusion or RET gene mutation; OR
- Recipient cannot tolerate the minimum dose of 100 mg once daily; OR
- Recipient has recurrent interstitial lung disease/pneumonitis (grade 1 or 2) OR grade 3 or 4 reaction; OR
- Recipient has uncontrolled hypertension (180/100 mmHg)—HTN therapy may be required; OR
- Recipient has a history of severe or life-threatening hemorrhage; OR
- Recipient has moderate or severe hepatotoxicity (may require dose decrease initially); OR

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- Recipient is pregnant or breastfeeding; OR
- Recipient requires concomitant strong CYP3A inhibitor or combined P-gp and strong CYP3A inhibitor (e.g., clarithromycin, ketoconazole, ritonavir); OR • Recipient baseline labs o Platelets < 75 X 10<sup>9</sup> /L o ANC < 1.0 X 10<sup>9</sup> /L o Hb < 9 g/dL o CrCl < 40 ml/min o Total serum phosphorus > 5.5 mg/dL

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## **Pramipexole ER (Mirapex ER)**

*(Implemented 03/19/2013)*

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

### Approval criteria

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- Diagnosis of Parkinson's Disease in Medicaid history in previous 2 years, AND
- >= 90 days of therapy of Pramipexole ER in the past 120 days

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## Prednisolone

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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*

[Link to Memorandum: Millipred Tablets, Dose Pack](#)

[Link to Memorandum: Millipred Solution](#)

[Link to Memorandum: Orapred ODT](#)

[Link to Memorandum: Veripred](#)

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## **Prednisone (Rayos DR)**

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq$  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 Department of 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  $>500$ ms 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.**

### Approval criteria

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- $\geq$  90 days of Propafenone SR therapy in the past 120 days

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## Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Modulators

(Updated 02/16/2016)

(Effective 10/1/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- None currently

### Non- Preferred Agents

- Leqvio<sup>®</sup> (inclisiran)
- Praluent<sup>®</sup> (alirocumab)
- Repatha<sup>®</sup> (evolocumab)

### Approval Criteria for Praluent and Repatha

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis consistent with FDA approved indications; **AND**
- Provider must submit current chart notes; **AND**
- Provider must submit chart notes during trials of statins **AND** ezetimibe; **AND**
- Compliance on previous lipid therapy is required unless contraindicated. Recipient's Medicaid claims history will be consulted, and a pharmacy printout may be requested to ensure compliance; **AND**
- Provider should submit current labs including lipids as well as labs corresponding with previous trials of statins **AND** ezetimibe taken concomitantly; **AND**
- Recipient 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 recipient has a contraindication; **AND**
- Provider must submit diet plan for lowering cholesterol; **AND**
- If recipient smokes, provider should submit a smoking cessation plan or documentation that the recipient has been counseled on smoking cessation; **AND**
- Initial approval for 2 months

### Approval Criteria for Leqvio

- Recipient must be ≥ 18 years of age; **AND**
- Recipient must have a diagnosis of heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C) OR a diagnosis consistent with the FDA approved indication; **AND**
- Recipient must be compliant on maximally tolerated statin doses **AND** ezetimibe use concomitantly: **AND**

## Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

- Recipient should have an LDL-C  $\geq$  70mg/dL and/or non-HDL-C  $\geq$  100mg/dL after a compliant trial of moderate-high intensity statins and ezetimibe unless the recipient has a contraindication; AND
- If approved, recipient must continue statin at maximally tolerated dose
- Prescriber must submit the following:
  - Current chart notes; AND
  - Chart notes during trials of statins and ezetimibe; AND
  - Current labs including lipids along with labs corresponding with previous trials of statin and ezetimibe used concomitantly; AND
  - Treatment goals with goal LDL-C; AND
  - Medical necessity over PCSK9 inhibitors; AND
  - Diet plan for lowering cholesterol; AND
  - If recipient smokes, provider should submit a smoking cessation plan or documentation that the recipient has been counseled on smoking cessation; AND
- Initial approval for 3 months

### **Denial Criteria for All Agents**

- Recipient does not meet approval criteria or have a diagnosis consistent with FDA approved indications; **OR**
- Recipient does not have baseline lipids meeting approval criteria; **OR**
- Recipient has not compliantly trialed concomitant therapy of statins with ezetimibe.

### **QUANTITY EDITS**

- Leqvio 284 mg syringe - #1 syringe per 6 months (except for the extra dose needed at 3 months)
- Repatha<sup>®</sup> 140mg syringe/autoinjector—2 injections per month
- Repatha<sup>®</sup> 420mg injection—1 injection per month
- Praluent<sup>®</sup> 75mg syringe/pen—2 injections per month
- Praluent<sup>®</sup> 150mg syringe/pen—2 injections per month

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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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents with criteria

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

### Nonpreferred agents

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- 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

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- 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  $\leq$  4 years of age
- Protonix® suspension
  - Recipient  $<$  7 years of age
  - 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  $\geq$  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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Treprostinil vials (**generic only**)
- Veletri vials (epoprostenol)- **BRAND ONLY**

### Preferred PAH Agents with PA Criteria

- Ambrisentan (generic for Letairis)
- Sildenafil tablets (generic for Revatio)
- Sildenafil vials
- Tadalafil tablets (generic for Adcirca)
- Tracleer tablets (bosentan) – **BRAND ONLY**

### Non-Preferred PAH agents

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- 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)
- Orenitram tablets (treprostinil)
- Remodulin (treprostinil)
- Revatio (sildenafil) Suspension (**BRAND PREFERRED OVER GENERIC when approved**)
- Revatio tablets
- Sildenafil suspension (generic for Revatio)
- Tadliq suspension (tadalafil)
- Tracleer suspension (bosentan)
- Tyvaso vials and Tyvaso DPI (treprostinil)
- Uptravi injection and tablets (selexipag)
- Ventavis (iloprost)

Denial Criteria

- **THERAPEUTIC DUPLICATION (TD) edit for the preferred drugs to not allow therapeutic duplication within same drug class type (ERA, PDE5, and Prostacyclin) or same pathway (endothelin, NO/cGMP, and prostacyclin).**

PDL STATUS	DRUG	DRUG CLASS	PATHWAY
PREFERRED	LETAIRIS (ambrisentan) Tablet	ENDOTHELIN RECEPTOR TYPE A (ERA)	endothelin pathway
PREFERRED	TRACLEER (bosentan) Tablet	ENDOTHELIN RECEPTOR TYPE A (ERA)	endothelin pathway
PREFERRED	REVATIO (sildenafil) Tablet	phosphodiesterase type 5 (PDE-5is)	NO/cGMP pathway
PREFERRED	ADCIRCA (tadalafil) Tablet	phosphodiesterase type 5 (PDE-5is)	NO/cGMP pathway

- LETAIRIS® (ambrisentan), TRACLEER® (bosentan), ADCIRCA® (tadalafil), OR generic sildenafil (aka REVATIO®): Deny claim for diagnosis of current pregnancy in Medicaid medical history.
- LETAIRIS®: Deny incoming LETAIRIS claim if diagnosis of idiopathic pulmonary fibrosis (ICD- 10 code J84.112) is in Medicaid medical history in previous 2 years.
- TRACLEER®: Deny incoming TRACLEER® claim if beneficiary has a drug claim for glyburide in Medicaid drug history in previous 45 days, and vice-versa (deny incoming claim for glyburide if beneficiary has drug claim for TRACLEER® in Medicaid drug history in previous 45 days.)
- ADCIRCA®: Deny incoming ADCIRCA® claim if beneficiary has a drug claim for ADEMPAS® (riociguat) in Medicaid drug history in previous 45 days.

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## **Pyridostigmine Timespan (Mestinon Timespan)**

*(Implemented 04/08/2014)*

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

### Approval criteria

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- $\geq$  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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.**

### Approval criteria

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- 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

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Absence of approval criteria

### Additional criteria

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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 Magellan 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 Magellan Medicaid Administration (MMA) 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 (Aspruzo Sprinkle)

*(Implemented 7/4/2022)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) 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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Denial criteria

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Diagnosis of hepatic impairment in the last 12 months

### Additional criteria

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Quantity limits apply

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## Regorafenib (Stivarga) 40mg Tablet

*(Implemented 03/19/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Stivarga

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## Relugolix (Orgovyx)

(Implemented 04/21/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age; AND
- Recipient must be a male; AND
- Recipient must have a diagnosis of advanced prostate cancer OR a diagnosis consistent with FDA indications; AND
- Recipient requires at least a year of Androgen Deprivation Therapy (ADT); AND
- Recipient has a baseline testosterone level  $> 50$  ng/dL; AND
- Prescriber must submit the following:
  - Chart notes; AND
  - Current labs including baseline prostate-specific antigen (PSA) and testosterone; AND
  - Previous therapies; AND
  - Medical necessity over other options for ADT including degarelix and leuprolide; AND
  - Baseline ECG if patient is a risk for QT prolongation

### Denial Criteria

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient is a female; OR
- Recipient has end-stage renal disease with or without hemodialysis or severe hepatic impairment (Child-Pugh C); OR
- Recipient requires a P-gp inhibitor or combined P-gp and strong CYP3A inducers. If coadministration is unavoidable, separate dosing for those requiring P-gp inhibitors and increase the ORGOVYX dose for those requiring combined P-gp and strong CYP3A inducers; OR
- Baseline testosterone level (without ADT) is  $<50$  ng/dL; OR
- Testosterone level does not remain at castration level on renewal request ( $<50$  ng/dL).

### QUANTITY EDITS:

#31/ 31 days

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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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

**Arkansas Medicaid will follow ACIP/CDC recommendations for RSV prophylaxis.**

- **SYNAGIS (palivizumab)**
  - The SYNAGIS form has been removed from the Magellan website.
  - SYNAGIS will continue to require prior authorization (PA), but a PA form is not required.
  - 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
    - 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.
- **RSVpreF (maternal vaccine)**
  - RSVpreF is available through the Vaccines for Children (VFC) program for pregnant women less than 19 years of age.
  - RSVpreF will be covered as a normal adult vaccine and not require prior authorization for pregnant women 19 years of age and older.
  - ACIP/CDC recommended this product for pregnant women who are 32-36 weeks into pregnancy.
  - Providers should bill procedure code 90678.
- **ABRYSVO (RSV vaccine)**
  - ABRYSVO will be covered as a normal adult vaccine and not require a prior authorization.
  - ACIP/CDC recommended this product be available for adults 60 years of age and older given in one single dose and using shared clinical decision-making.

## Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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- Providers should bill procedure codes 90678 or 90679.
- **AREXVY (RSV vaccine)**
  - AREXVY will be covered as a normal adult vaccine and not require a prior authorization.
  - ACIP/CDC recommended this product be available for adults 60 years of age and older given in one single dose and using shared clinical decision-making.
  - Providers should bill procedure codes 90678 or 90679.

## **Ribociclib (Kisqali) Tablet/Ribociclib and Letrozole (Kisqali Femara Co-Pack)**

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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**

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- Kisqali 200mg Tablet
- Kisqali Femara Co-Pack

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## Rifamycin (Aemcolo)

(Implemented 10/20/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq$  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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- Diagnosis of Hepatic Encephalopathy in the previous 2 years.

### Additional criteria

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Quantity limits apply

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## Rilonacept Injection (Arcalyst)

*(Implemented 07/09/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Arcalyst Injection

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## Ripretinib (Qinlock)

(Implemented 10/21/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Qinlock

### Approval Criteria:

- Recipient must be  $\geq 18$  years of age; AND
- Recipient must have a diagnosis of advanced gastrointestinal stromal tumor (GIST) and previously treated with 3 or more TKIs including imatinib OR a diagnosis consistent with FDA indications; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs including CBC and LFTs; AND
  - Baseline echocardiogram or MUGA scan to monitor ejection fraction; AND
  - Current blood pressure; AND
  - Documentation of dermatologic evaluations as baseline due to possible cutaneous squamous cell carcinoma; AND
  - Pregnancy test for women of childbearing potential

### Denial Criteria:

- Recipient does not meet the FDA approved indication OR have a diagnosis supported in the official Compendia; OR
- Recipient is pregnant or breastfeeding; OR
- Recipient requires strong CYP3A inducers; OR
- Recipient is unable to tolerate 100 mg once daily dose; OR
- Recipient has Grade 4 uncontrolled hypertension or Grade 3 or 4 left ventricular systolic dysfunction LVEF  $< 50\%$ ; OR •
- Recipient has moderate or severe hepatic impairment; OR •
- Recipient has documented disease progression or unacceptable toxicity.

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## **Risdiplam (Evrysdi)**

*(Implemented 10/21/2020)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 2$  months of age; AND
- Recipient has a diagnosis of Type 1 spinal muscular atrophy (SMA)—all other SMA types will be reviewed on a case-by-case basis. (At the time of this memo, available trial data was insufficient in demonstrating clinically significant efficacy for Type 2 and Type 3 patients.); AND
- Prescriber must be a neurologist with expertise in treating SMA; AND
- Recipient is non-ambulatory; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current weight; AND
  - Genetic testing results documenting the SMA diagnosis and SMA type; AND
    - Documentation of SMN1 gene deletion or mutation
    - Documentation of at least 2 or more copies of SMN2 gene
- Current labs including liver function tests; AND
- Female recipients of childbearing potential must have a negative pregnancy test prior to beginning EVRYSDI therapy OR has documentation of contraception usage; AND
- Documentation that female members of childbearing potential have been counseled about contraception; AND
- Documentation that male members have been counseled about potential infertility with EVRYSDI therapy; AND
- Documentation of physical therapy; AND
- Documentation of all previous therapies tried; AND
- Baseline results of one of the following:
  - Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); 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

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria; OR
- Dosing requested is not consistent with recipient's age and weight; OR
- Recipient is ambulatory; OR
- Recipient is pregnant; OR
- Recipient has hepatic impairment; OR
- Recipient takes a Multidrug and Toxin Extruder (MATE1) substrate such as metformin, cimetidine or acyclovir; OR
- Recipient has concomitant or previous administration of a SMN2-targeting antisense oligonucleotide, SMN2 splicing modifier or gene therapy either in a clinical study or as part of medical care;
  - Recipient has been given Zolgensma® (onasemnogene abeparvovec-xioi); OR
  - Recipient has history of taking Spinraza® (nusinersen) unless recipient had an intolerable medically documented adverse reaction; OR
- Recipient has the presence of advanced SMA with permanent ventilation dependence which is defined as requiring a tracheostomy OR more than 21 consecutive days of either non-invasive ventilation for  $\geq 16$  hour per day or intubation; OR
- Recipient has been hospitalized in the past 60 days with a pulmonary event; OR
- Recipient has had surgery for scoliosis or hip fixation in the last year.

**QUANTITY EDITS:**

- Based on max dose of 5 mg per day, 3 bottles (240mL 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### **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  $\geq$  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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## Ropeginterferon alfa-2b (BESREMI)

(Implemented 04/20/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 polycythemia vera OR a diagnosis consistent with the FDA approved indication; AND
- Recipient meets one of the following:
  - Males: Hemoglobin > 16.5 g/dL or hematocrit ≥ 49% or increased red cell mass; OR
  - Females: Hemoglobin > 16 g/dL or hematocrit ≥ 48% or increased red cell mass;
- Accompanied by one or more the following: (per UpToDate)
  - Splanchnic vein thrombosis
  - Unusual thrombosis
  - Aquagenic pruritus
  - Splenomegaly
  - Leukocytosis
  - Thrombocytosis
  - Microvascular symptoms
  - Documentation of JAK2 V617F mutation (per clinical trial)
- Recipient must have at least 2 hydroxyurea drug claims in Medicaid drug history in previous 3 months. If no hydroxyurea drug claims in Medicaid drug history, provider must submit documentation to substantiate that beneficiary had an inadequate response to or was intolerant of hydroxyurea; AND
- Recipient of reproductive potential must have a negative pregnancy test; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current negative pregnancy test results if of reproductive potential; AND
  - If recipient takes hydroxyurea, provide the discontinuation taper schedule and initial dose must be 50 mcg every 2 weeks; AND
  - Current labs including CBC, LFTs; AND
  - Medical necessity over Pegasys; AND
  - Monitoring plan for patients with underlying depression diagnosis

**DENIAL CRITERIA:**

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient has moderate or severe hepatic impairment (Child-Pugh B or C); OR
- Recipient has a history or active serious or untreated autoimmune disease; OR
- Recipient is an immunosuppressed transplant patient; OR
- Recipient has a diagnosis of severe psychiatric disorder (i.e., severe depression, suicidal ideation, or suicide attempt)

**QUANTITY EDITS:**

- #2 injections per month

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## **Ropinirole XL (Requip XL)**

*(Implemented 03/19/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 Parkinson's Disease in Medicaid history in previous 2 years AND
- >= 90 days of therapy of Ropinirole XL in the past 120 days

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## Rotigotine (Neupro) Patch

*(Implemented 03/19/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

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### Approval criteria

- Diagnosis of Parkinson's Disease in Medicaid history in previous 2 years

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## Rosacea Treatment

(Implemented 06/19/2006)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) 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

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- 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

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- History of acne vulgaris in the last 60 days

### Drugs that do not require a PA

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- 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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## Rucaparib tablet, film coated (Rubraca)

(Memo 5/30/2017)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Rubraca 200 mg
- Rubraca 250 mg
- Rubraca 300 mg

### APPROVAL CRITERIA

- RUBRACA™ will require a manual review PA on a case-by-case basis using the package insert data and data available in the clinical trials listed in the package insert to guide approval or denial of the request.
- Prescriber must provide the results of the FoundationFocus™ CDxBRCA diagnostic test, which is the FDA approved-for-selection of patients for RUBRACA™. Even though the result of this specific test, FoundationFocus™ CDxBRCA, is a requirement as part of the Prior Approval review for the drug itself, this requirement does not guarantee approval from Medicaid medical utilization review for the use of the diagnostic test nor does it guarantee payment from Medicaid for the diagnostic test. The provider must contact Medicaid medical utilization review and follow their processes for approval and/or for Medicaid payment for the diagnostic test FoundationFocus™ CDxBRCA.
- Prescribing provider must submit the drug PA request in writing and provide all data to substantiate the request, including but not limited to
  - chart notes,
  - all data on the prior use of at least two platinum-based chemotherapies,
  - dates for prior chemotherapies,
  - date of initial response to each prior chemotherapy,
  - dates showing progression of disease during the course of the therapy,
  - the treatment-free interval length of time between the therapies.

### DENIAL CRITERIA

- Platinum-refractory patients who do not respond to platinum-based chemotherapy and show progression during the course of the platinum-based chemotherapy will not be approved for use of Rubraca

### QUANTITY LIMITS

- quantity limit of 4 tablets per day will be applied to all strengths

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## Ruxolitinib Tablets (Jakafi)

(Implemented 04/17/2012)

(Memo 2/14/2019)

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

APPROVAL CRITERIA, requires all of the following:

- Beneficiary is  $\geq 18$  years of age;
- Beneficiary must have a diagnosis of intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF or post-essential thrombocythemia MF, or polycythemia vera (PV);
- Beneficiary must have at least 2 hydroxyurea drug claims in Medicaid drug history in previous 3 months in those with diagnoses of post-essential thrombocythemia MF or polycythemia vera (PV); If no hydroxyurea drug claims in Medicaid drug history, provider must submit documentation to substantiate that beneficiary had an inadequate response to or was intolerant of hydroxyurea;
- Provider must submit results of a current complete blood count (CBC) and platelet count before initiating therapy;
- Provider must submit Child-Pugh Class score or all LFTs to calculate (Class A, B, or C);
- Provider must submit baseline lipid panel;
- Approved starting dose will be based on the platelet count and follow all FDA approved dosing recommendations in the package insert;
- Initial PA will be for the specific strength required for dose; approval time will be for 1 month;

DENIAL CRITERIA, any one of the following:

- Beneficiary is  $<18$  years of age;
- Beneficiary does not have appropriate diagnosis;
- Dose increase requested during 1st 4 weeks of therapy;
- After the 1st month of therapy, the dose increase is requested more frequently than every 2 weeks;
- Provider did not submit current lab data – CBC w/ differential, AST/ALT, fasting lipids;
- There is no spleen size reduction (w/ CT or MRI) or symptom improvement after 6 months of therapy;
- Beneficiary has current active bleed requiring intervention;
- For polycythemia vera:
  - Interrupt treatment for hemoglobin less than 8 g/dL, platelet counts less than  $50 \times 10^9/L$  or ANC less than  $1.0 \times 10^9/L$ .
  - After recovery of the hematologic parameter(s) to acceptable levels, dosing may be restarted.

- Restart dose will not exceed drug package insert dose in restarting Jakafi® after a previous interruption;
- Renal impairment:
  - Moderate-severe renal impairment PLUS PLT < 50 X 10<sup>9</sup>/L – avoid use for MF;
  - Patients on hemodialysis, regardless of PLT count, may use Jakafi® for either MF or PV;
  - For ESRD without hemodialysis, use is not recommended for either PV or MF;
- Hepatic impairment:
  - PV permits use with any PLT count and Child-Pugh class A, B, or C
  - For MF, avoid use with PLT Less than 50 X 10<sup>9</sup>/L and Child-Pugh class A, B, C
- Beneficiary has active serious infection(s);
- Beneficiary has positive TB test for either active TB or latent TB;
- Beneficiary currently receiving fluconazole doses of greater than 200 mg daily;

**QUANTITY LIMIT:**

- Not to exceed 2 tablets per day for each strength tablet;
- Quantity limit of #60/30 days' supply;

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## Sacubitril and Valsartan (Entresto)

*(Implemented 02/16/2016)*

*(Updated 4/15/2020)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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, requires the following:

- Diagnosis in Medicaid medical history in previous 2 years of congestive heart failure;

### DENIAL CRITERIA

- Female recipient is currently pregnant.

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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## Satralizumab (Enspryng)

(Implemented 10/21/2020)

(Updated 1/18/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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:
    - 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 diagnoses (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  $\leq 6.5$
- 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)

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## **Secnidazole (Solosec)**

*(Updated 4/18/2018)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 female;
- Beneficiary must be  $\geq$  18 years of age;
- Prescriber must submit documentation to substantiate the medical necessity of beneficiary receiving SOLOSEC™ over other more cost effective medications that do not require prior authorization and are indicated for treating bacterial vaginosis or the DrugDex information supports the effectiveness of treating bacterial vaginosis.

### **QUANTITY EDITS:**

- The quantity limit is 1 dose per claim

## 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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**

<u>Product</u>	<u>Minimum Age</u>	<u>Product</u>	<u>Minimum Age</u>
DARIDOREXANT (QUVIVIQ®)	<u>18</u>	SUVOREXANT (BELSOMRA®)	<u>18</u>
DOXEPIN (SILENOR®)	<u>18</u>	TEMAZEPAM (RESTORIL®)	<u>18</u>
ESTAZOLAM (PROSOM®)	<u>18</u>	TRIAZOLAM (HALCION®)	<u>N/A</u>
ESZOPICLONE (LUNESTA®)	<u>18</u>	ZALEPLON (SONATA®)	<u>18</u>
FLURAZEPAM (DALMANE®)	<u>18</u>	ZOLPIDEM (AMBIEN®)	<u>18</u>
LEMBOREXANT (DAYVIGO®)	<u>18</u>	ZOLPIDEM ER (AMBIEN CR®)	<u>18</u>
RAMELTEON (ROZEREM®)	<u>18</u>	ZOLPIDEM SL (EDLUAR®)	<u>18</u>

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## Selinexor (Xpovio™)

(Implemented 10/16/2019)

(Updated 1/20/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 multiple myeloma OR diffuse large B-cell lymphoma OR a diagnosis consistent with FDA indications; AND
- Recipient with multiple myeloma requires one of the following:
  - Recipient must have at least one prior therapy and will take XPOVIO in combination with bortezomib and dexamethasone; OR
  - Recipient with relapsed or refractory disease has received at least four prior therapies and disease is refractory to at least two proteasome inhibitors (e.g., bortezomib, ixazomib and carfilzomib), at least two immunomodulatory agents (e.g., lenalidomide, pomalidomide and thalidomide), and an anti-CD38 monoclonal antibody (e.g., daratumumab) and will take XPOVIO in combination with dexamethasone
- Recipient with relapsed or refractory diffuse large B-cell lymphoma requires a failure of at least 2 lines of systemic therapy; AND
- Prescriber must submit the following:
  - Current chart notes with documentation of diagnosis and previous therapies; AND
  - Current labs including CBC with differential, complete metabolic panel, and LFTs; AND
  - Required dosage since dose adjustments are required for thrombocytopenia, neutropenia, anemia, extreme nausea/vomiting, diarrhea, hyponatremia, and ocular toxicity (refer to manufacturer's package insert); AND
  - Verification that recipient has been prescribed concomitant 5-HT3 receptor antagonists or other anti-nausea agents; AND
  - Treatment plan for potential nausea and dehydration; AND
- PA's approved month-to-month until stable due to significant thrombocytopenia and neutropenia risks.

### **DENIAL CRITERIA:**

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipients with DLBCL that had an autologous hematopoietic stem cell transplantation; OR
- Recipient cannot tolerate the following minimum dosages; OR
  - 40 mg weekly for multiple myeloma in combination with bortezomib and dexamethasone
  - 60 mg weekly for multiple myeloma in combination with dexamethasone

- 40 mg weekly for diffuse large B-cell lymphoma
- Recipient is pregnant or breastfeeding; OR
- Multiple myeloma recipients are not prescribed the required concomitant therapy based on FDA indications; OR
- Recipient has active smoldering multiple myeloma; OR
- Recipient has active plasma cell leukemia; OR
- Recipient has documented systemic amyloid light chain amyloidosis; OR
- Recipient has active CNS multiple myeloma; OR
- Recipient with DLBCL has not failed at least two prior therapies; OR
- Recipient with relapsed or refractory multiple myeloma has not failed at least four prior therapies

**QUANTITY EDITS:**

32 tablets per 28 days

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## Selpercatinib (Retevmo™)

(Effective 7/15/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 with diagnosis of NSCLC must be ≥ 18 years of age and with diagnosis of thyroid cancer must be ≥ 12 years of age; **AND**
- Recipient must have a diagnosis of either metastatic RET Fusion-positive NSCLC, advanced or metastatic RET-Mutant Medullary Thyroid Cancer requiring systemic therapy or advanced or metastatic RET Fusion-Positive Thyroid Cancer who are refractory to radioactive iodine (if radioactive iodine is appropriate) **OR** diagnosis consistent with FDA indications; **AND**
- Prescriber must submit the following:
  - Current labs including CBC, BMP, LFTs and TSH; **AND**
  - Current chart notes with documentation of diagnosis and previous therapies including radioactive iodine in RET Fusion-Positive Thyroid Cancer; **AND**
  - Documentation with the presence of a RET gene fusion or RET gene mutation; **AND**
  - Baseline ECG; **AND**
  - Current blood pressure; **AND**
- Recipient must be able to swallow pills; **AND**
- Hypokalemia, hypomagnesemia and hypocalcemia should be corrected prior to treatment and if developed during treatment; **AND**
- Initial PA would be approved for 1 month; once recipient demonstrates tolerability the PA can be approved for 3months.

### Denial Criteria

- Recipient does not meet approval criteria; **OR**
- Recipient has been unable to tolerate Retevmo after 3 dose reductions (40 mg per day if <50kg and 40 mg twice daily if >50kg); **OR**
- Recipient has Grade 4 or uncontrolled hypertension; **OR**
- Recipient has Grade 4 QT Interval prolongation; **OR**
- Recipient has severe or life-threatening hemorrhagic events; **OR**
- Recipient should avoid strong and moderate CYP3A inhibitors (e.g. ketoconazole, clarithromycin or verapamil). Retevmo dose must be decreased if concomitant use is required; **OR**
- Recipient requires concomitant use of a proton pump inhibitor, histamine-2 receptor antagonist or locally acting antacid that cannot be taken at a separate time from Retevmo; **OR**
- Recipient with severe hepatic impairment requires dose decrease; **OR**
- Recipient is pregnant or breastfeeding

### Quantity Edits

- 40 mg capsules — #180/30 days
- 80 mg capsules — #120/30 days

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## Selumetinib (Koselugo™)

(Effective 7/15/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 2$  years of age; **AND**
- Recipient must have a diagnosis of neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN) **OR** diagnosis consistent with FDA indications; **AND**
- Recipient must have at least one measurable PN measuring at least 3 cm **AND** either a positive genetic test for NF1 **OR** have at least one other diagnostic criterion listed below:
  - 6 or more café-au-lait macules; **OR**
  - Freckling in axilla or groin; **OR**
  - Optic glioma; **OR**
  - 2 or more Lisch nodules; **OR**
  - Distinctive bony lesion; **OR**
  - First-degree relative with NF1
- Provider should submit the following:
  - Current chart notes with status of plexiform neurofibromas; **AND**
  - Current baseline left ventricular ejection fraction (LVEF); **AND**
  - Documentation of comprehensive ophthalmic assessment; **AND**
  - Current labs including serum CPK, baseline INR, CBC, and LFTs; **AND**
    - ANC  $\geq 1500/\mu\text{L}$
    - Hemoglobin  $\geq 9\text{g/dl}$
    - Platelets  $\geq 100,000/\mu\text{L}$
  - Current body surface area (BSA)—no recommended dosage for recipients with BSA  $< 0.55\text{m}^2$ .
- Prescriber should provide plan for monitoring patients that require coadministration with vitamin-K antagonists or platelet antagonists; **AND**
- Initial PA for 3 months

### Denial Criteria

- Recipient does not meet age requirement; **OR**
- Recipient does not have a diagnosis consistent with FDA approved indications; **OR**
- Recipient has disease progression or unacceptable toxicity and is unable to tolerate after 2 dose reductions; **OR**
- Recipient is unable to swallow a whole capsule; **OR**
- Recipient's BSA is  $< 0.55\text{m}^2$ ; **OR**
- Recipient has retinal vein occlusion; **OR**
- Recipient has symptomatic or Grade 3 or 4 decreased LVEF; **OR**
- Recipient has Grade 4 diarrhea or Grade 3 or 4 colitis; **OR**
- Recipient has rhabdomyolysis; **OR**
- Recipient has severe hepatic impairment (Child-Pugh C); **OR**
- Recipient is pregnant; **OR**
- Recipient is not using birth control when has reproductive potential; **OR**
- If recipient requires strong or moderate CYP3A4 inducers, Koselugo should be avoided; strong or moderate CYP3A4 inhibitors require dose decrease for Koselugo.

**Quantity Edits:**

- 10 mg capsule — #270/30 days
- 25 mg capsule — #120/30 days

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## Serostim

*(Implemented 10/18/2006)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Serostim

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## Sildenafil tablets (Revatio)

(Implemented 10/11/2005)

(updated 2/13/17)

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

### Approval criteria

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- 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

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- One of the following diagnoses in the last 180 days:
  - Caverosal 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

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[Pulmonary Arterial Hypertension](#)

Quantity limits apply

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## **Siltuximab vial (Sylvant)**

*(Implemented 09/23/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Sylvant

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## Sinecatechins (Veregen ointment 15%)

*(Implemented 06/19/2008)*

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

### Approval criteria

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- 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

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 2$  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  $\geq 2$  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

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## Skeletal Muscle Relaxants

(Implemented 03/20/2006)

(Updated 10/1/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred agents

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- Baclofen tablet (generic for Lioresal<sup>®</sup>)
- Chlorzoxazone 500 mg tablet (generic for Parafon<sup>®</sup>)
- Cyclobenzaprine tablets (generic for Flexeril<sup>®</sup>)
- Metaxalone tablet (generic for Skelaxin<sup>®</sup>)
- Methocarbamol tablets (generic for Robaxin<sup>®</sup>)
- Tizanidine HCl tablet (generic for Zanaflex<sup>®</sup>)

### Nonpreferred agents

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- Amrix<sup>®</sup> ER capsule (cyclobenzaprine)
- Baclofen Suspension (generic for Fleqsuvy<sup>®</sup>)
- Baclofen Suspension (generic for Ozobax<sup>®</sup>)
- Carisoprodol tablets (generic Soma<sup>®</sup>)
- Carisoprodol/Aspirin tablets (generic for Soma<sup>®</sup> Compound)
- Carisoprodol/Aspirin/Codeine tablets (generic for Soma Compound w/ Codeine)
- Chlorzoxazone 375 mg, 750 mg tablet (generic for Lorzone<sup>®</sup>)
- Cyclobenzaprine HCl 5mg, 7.5mg tablet (generic for Fexmid<sup>®</sup>)
- Cyclobenzaprine HCl extended-release capsule (generic for Amrix<sup>®</sup>)
- Dantrolene capsule (generic for Dantrium<sup>®</sup>)
- Fexmid<sup>®</sup> tablet (cyclobenzaprine 7.5 mg)
- Fleqsuvy (baclofen suspension)
- Lyvispah (baclofen granules)
- Lorzone<sup>®</sup> tablet (generic for chlorzoxazone)
- Norgesic Forte<sup>®</sup> tablet (orphenadrine/aspirin/caffeine)
- Orphenadrine citrate tablet (generic for Norflex<sup>®</sup>)
- ~~Ozobax<sup>®</sup> solution (baclofen) \*no longer rebateable~~
- Soma<sup>®</sup> tablet (carisoprodol)
- Tizanidine HCL capsule (generic for Zanaflex<sup>®</sup> Capsule)

### QUANTITY EDITS:

- ~~Baclofen, both strengths, up to 4 tablets/24 hours; #124/31 days' supply redacted~~
- Methocarbamol, both strengths, up to 8 tablets/24 hours; #248/31 days' supply

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## Sodium Chloride 7% Inhalation Solution (Hyper-Sal 7%)

*(Implemented 05/24/2011)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- Diagnosis of cystic fibrosis within the past three years

### Additional criteria

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Quantity limits apply

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## Sodium Zirconium Cyclosilicate (Lokelma)

*(Implemented 01/01/2019)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## **Sonidegib (Odomzo)**

*(Implemented 04/26/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Odomzo 200mg Capsules

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## **Sotalol (Sotylize) Solution**

*(Implemented 07/22/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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## Sotorasib (Lumakras)

(Updated 7/21/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq$  18 years of age; AND
- Recipient must have a diagnosis of KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer who have received at least one prior systemic therapy OR a diagnosis consistent with FDA-approved indications; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Current labs including LFTs; AND
  - Test results verifying the KRAS G12C mutation from tumor or plasma specimens; AND
  - Documentation of previous therapies tried including an immune checkpoint inhibitor (anti-PD-1/PD-L1) (e.g., pembrolizumab, atezolizumab) and/or platinum-based chemotherapy (e.g., cisplatin, carboplatin); AND
  - Initial PA for maximum of 3 months

### Denial Criteria:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient requires acid-reducing agents (PPIs or H2 receptor antagonists) or a strong CYP3A inducer (e.g., phenytoin or rifampin) due to a decrease in sotorasib concentration; OR
- Recipient requires a CYP3A4 substrate (e.g., cyclosporin or ketoconazole) due to a decrease in plasma concentration of the substrate or a P-glycoprotein substrate (e.g., digoxin) due to an increase in plasma concentration of the substrate; OR
- Recipient cannot tolerate the minimum dose of 240 mg daily; OR
- Recipient has confirmed interstitial lung disease/pneumonitis; OR
- Recipient is pregnant or breastfeeding

### QUANTITY EDITS

120mg - #248/ 30 days

320mg - #93/30 days

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## Sparsenten (Filspari™) 200mg and 400mg tablet

(Implemented 5/10/2023)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 proteinuria associated with primary immunoglobulin A nephropathy (IgAN) **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's urine protein-to-creatinine ratio (UPCR) must be  $\geq 1.5$  g/g or total urine protein must be  $\geq 1$  g/day at baseline while on RAAS inhibitor treatment
- 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)
  - eGFR  $< 30$  mL/min/1.73m<sup>2</sup>
  - Prescribed concomitant ACEI or ARB (cannot be on an ACEI or ARB with this med)
- Prescriber must submit **ALL** of the following:
  - Current chart notes
  - Previous therapies
  - Current labs including LFTs, eGFR, urine protein or UPCR
  - Confirmation of the IgAN diagnosis with renal biopsy results and labs
  - Attestation that patient has tested negative for pregnancy if of reproductive potential

### **RENEWAL REQUIREMENTS:**

- Beneficiary has been compliant with therapy (defined as: 75% utilization based on Medicaid claims)
- Beneficiary has documented improvement in proteinuria with a reduction in UPCR or urine protein from baseline
- Prescriber must submit the following:
  - Current chart notes
  - Current labs including LFTs, eGFR, urine protein or UPCR
  - Attestation that patient has tested negative for pregnancy if of reproductive potential

### **QUANTITY EDITS:**

200 mg—#31/31 days

400 mg—#31/31 days

## Spironolactone Suspension (Carospir)

*(Implemented 10/18/2017)*

*(Effective 1/17/2018)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq$  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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

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- < 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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

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

Approval criteria

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Currently LTC

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## Sunitinib (Sutent) Capsule

*(Implemented 01/13/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Drugs that require manual review for prior authorization

- Sutent

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## Tacrolimus (Astagraf XL)

*(Implemented 12/10/2013)*

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

### Approval criteria

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- 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

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- One of the following diagnoses in the last 180 days:
  - Cavernosal fibrosis, 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

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[Pulmonary Arterial Hypertension](#)

Quantity limits apply

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## Tafamidis (Vyndaqel® and Vyndamax®)

(Implemented 7/17/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## Talazoparib (Talzenna)

(Implemented 4/17/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Talzenna

### Approval criteria

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- Will require manual review PA on a case-by-case basis
- Age  $\geq$  18 years
- Provide documentation that the beneficiary has a diagnosis of:
  - Deleterious or suspected deleterious germline breast cancer that is locally advanced or metastatic with a BRCA1 or BRCA2 mutation and is HER2 negative based on laboratory findings **OR**
  - HRR gene-mutated metastatic castration-resistant prostate cancer (mCRPC) in combination with enzalutamide
- ECOG 0-2\*
- Provide current chart notes
- Provide current labs including CBC, basic metabolic panel and LFTs
- Pregnancy test
- Dosing for patient taking amiodarone, carvedilol, clarithromycin, itraconazole, and verapamil must be 0.75mg once daily
- Dosing for CrCl 30-59 mL/min: 0.75mg once daily
- $\leq$ 3 prior cytotoxic chemotherapy regimens for metastatic or locally advanced disease\*
- Treatment with an anthracycline and/or a taxane unless contraindicated\*

### Denial criteria

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- Does not meet above approval criteria
- Pregnant
- Moderate to severe hepatic impairment (total bilirubin  $>$ 1.5 and any AST)
- Severe renal impairment (CrCl  $<$ 30mL/min)
- Prior treatment of PARP inhibitor (Olaparib)\*
- Discontinue if requires  $>$ 3 dose reductions (minimum of 0.25mg per day)
- Confirmed Myelodysplastic Syndrome or AML

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## Tamoxifen 10mg/5ml Oral Solution (Soltamox)

*(Implemented 03/19/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Soltamox

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## Tapinarof (Vtama) Cream

(Implemented 10/19/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Preferred Agents with Criteria

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- ENBREL (etanercept)
- HUMIRA (adalimumab)
- OTEZLA (apremilast)

### Non-Preferred Agents

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- ACTEMRA (tocilizumab)
- ADALIMUMAB-ADAZ (generic for Hyrimoz)
- ADALIMUMAB-ADBM (generic for Cyltezo)
- ADALIMUMAB-FKJP (generic for Hulio)
- AMJEVITA (adalimumab-atto)
- ARCALYST (rilonacept)
- CIBINQO (abrocitinib)
- CIMZIA (certolizumab)
- COSENTYX (secukinumab)
- CYLTEZO (adalimumab-adbm)
- ENSPRYNG (satralizumab-mwge)
- ENTYVIO PEN (vedolizumab)
- HADLIMA (adalimumab-bwwd)
- HULIO (adalimumab-fkjp)
- HYRIMOZ (adalimumab-adaz)
- IDACIO (adalimumab-aacf)
- ILARIS (canakinumab)
- ILUMYA (tildrakizumab-asmn)
- KEVZARA (sarilumab)
- KINERET (anakinra)
- LITFULO (ritlecitinib)
- OLUMIANT (baricitinib)
- ORENCIA CLICKJECT AND SYRINGE (abatacept)
- RINVOQ (upadacitinib)
- SILIQ (brodalumab)
- SIMPONI (golimumab)
- SKYRIZI (risankizumab-rzaa)
- SOTYKTU (deucravacitinib)
- STELARA (ustekinumab)
- TALTZ (ixekizumab)
- TREMFYA (guselkumab)
- XELJANZ, XELJANZ XR (tofacitinib)
- YUFLYMA (adalimumab-aaty)
- YUSIMRY (adalimumab-aqvh)

**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

## Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

- 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-aminosalicylic 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 imaging 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:

#### Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

- Immunosuppressants (e.g., azathioprine, 6-mercaptopurine, cyclosporine)
- Oral/rectal glucocorticoids (e.g., enteric coated budesonide, prednisone, hydrocortisone)
- Oral/rectal 5-aminosalicylic 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  $\geq$  220) or Simple Endoscopic Score for Crohn's disease (SES-CD) (clinical trials included patients with score  $\geq$  6 or  $\geq$ 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  $\geq$  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  $\geq$  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)  $\geq 10\%$
  - Baseline Eczema Area and Severity Index (EASI) total score of  $\geq 16$
  - Baseline weekly averaged peak pruritus Numeric Rating Scale (NRS)  $\geq 7$
  - Baseline Investigator's Global Assessment (IGA) score  $\geq 3$
  - Baseline Scoring Atopic Dermatitis (SCORAD) score  $\geq 25$
- 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:

## Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

- 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 DISEASE**

- 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

## Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

(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  $\geq 3$  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

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

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## Tasimelteon Capsule and Suspension (Hetlioz)

(Implemented 09/23/2014)

(Updated 7/21/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $\geq$  18 years of age, and recipient with SMS diagnosis must be  $\geq$  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 Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

**Drug**

Tazorac

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### 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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## Tazemetostat (Tazverik)

(Implemented 4/15/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 ≥ 16 years of age; AND
- Recipient is diagnosed with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection or diagnosis consistent with FDA indication; AND
- Female recipients must not be pregnant or breastfeeding and attest to using effective contraception if of reproductive potential. Male recipients with female partners of reproductive potential must attest to using effective contraception AND
- Prescriber must submit the following:
  - Liver function tests including AST, ALT, Bilirubin, and INR
  - Complete blood count with differential
  - Current chart notes with documentation of previous treatments
  - Results of any recent MRI, CT or biopsy
- Initial PA for 3 months

### Denial Criteria:

- Recipient does not meet approval criteria; OR
- Recipient must be able to tolerate the minimum dose of 400mg twice daily; OR
- Recipient must not be pregnant or breastfeeding

### QUANTITY EDITS:

#240/30 days

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## Tedizolid (Sivextro)

*(Implemented 01/13/2015)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq$  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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## Telithromycin (Ketek)

*(Implemented 09/12/2007)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Submitted diagnosis myasthenia gravis in the past 730 days.
- Submitted diagnosis hepatitis in the past 730 days.
- Submitted diagnosis hepatic impairment in the past 730 days.

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## Telotristat Ethyl (Xermelo) Tablet

*(Implemented 11/22/2017)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Xermelo 250mg Tablet

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## Temazepam 7.5mg and 22.5mg Capsule (Restoril)

(Implemented 07/09/2012)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Temazepam 7.5mg capsule
- Temazepam 22.5 mg capsule

### Exceptions (Beneficiaries that do not require a Prior Authorization)

- Temazepam 7.5mg capsule
  - Long Term Care Beneficiaries
  - Beneficiaries that are 65 years of age or older

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

### Additional criteria

- Daily quantity limits apply

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## Temozolomide (Temodar)

(Implemented 4/1/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Temodar

#### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis AND
- $\geq 18$  years of age; AND
- Diagnosis consistent with the FDA approved; AND
- With diagnosis of Glioblastoma Multiforme, beneficiary must also receive radiotherapy in the initial treatment phase “Concomitant Phase”; AND
- Provide current chart notes; AND
- Provide the body surface area for dosing; AND
- If in concomitant phase for treatment of Glioblastoma, beneficiary must also receive Pneumocystis pneumonia (PCP) prophylaxis; AND
- Approval month-to-month due to continued monitoring of labs

#### **DENIAL CRITERIA:**

- Diagnosis not consistent with FDA approved indications; OR
- Beneficiary not tolerating the minimum dose of 100mg/m<sup>2</sup> OR
- Pregnancy or breast-feeding OR
- Severe hepatic impairment OR
- Drug interaction with Valproic Acid—consider medical necessity

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## Tepotinib (Tepmetko)

(Implemented 4/21/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age; AND
- Recipient must have a diagnosis of metastatic non-small lung cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping alterations OR a diagnosis consistent with FDA indications; AND
- Prescriber must submit the following:
  - Current chart notes with documentation of previous therapies; AND
  - Documentation of the presence of MET exon 14 skipping alterations; AND
  - Current labs including liver function tests and CBCs; AND
  - Attestation that patient has been counseled on contraception (both male and female); AND
- Recipient should not take concomitant dual strong CYP3A inhibitors and P-gp inhibitors (e.g., clarithromycin, itraconazole, verapamil) OR strong CYP3A inducers (e.g., phenytoin, rifampin); AND
- Recipient must have a negative status for epidermal growth factor receptor (EGFR) wild-type and anaplastic lymphoma kinase (ALK) gene mutations; AND
- Initial PA may be approved for 3 months

### Denial Criteria

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient is diagnosed with interstitial lung disease/pneumonitis; OR
- Recipient cannot tolerate the minimum dose of 225 mg daily; OR
- Recipient is pregnant; OR
- Recipient has severe renal impairment; OR
- Recipient has Grade 4 increase in ALT and/or AST without increased total bilirubin OR ALT and/or AST  $>3X$  ULN with total bilirubin  $>2X$  ULN OR Grade 4 increase in total bilirubin without increased ALT and/or AST; OR
- Recipient requires coadministration with dual strong CYP3A inhibitors and P-gp inhibitors OR strong CYP3A inducers.

QUANTITY EDITS:

#62/ 31 days

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## Terbinafine 125mg and 187.5mg Granules Packet (Lamisil)

(Implemented 04/12/2011)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Administration (MMA) pharmacy unit at 1-800-424-7976.**

### Approval criteria

- At least one paid claim in Medicaid history for fluconazole suspension in the past 14-90 days, AND
- At least 2 paid claims in Medicaid history for griseofulvin suspension in the previous 14-90 days

AND

- No therapeutic duplication between two different strengths of Lamisil granules.

### Additional criteria

- Quantity edits apply

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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 (DEPO-TESTOSTERONE **-BRAND ONLY**)
- Testosterone enanthate (Xyosted® autoinjector)
- Testosterone Undecanoate (Tlando®)
- Testosterone gel packet (Androgel®, Vogelxo®)
- Testosterone gel pump (Androgel® pump **-BRAND ONLY**)
- Testosterone gel pump (Fortesta®, Vogelxo®)
- Testosterone gel tube (Testim®, Vogelxo®)
- Testosterone nasal gel (Natesto® nasalgel)
- Testosterone patch (Androderm® patch)
- Testosterone pump (Axiron®)
- Testosterone undecanoate injection (Aveed® injection)

### Criteria for Preferred Agents with Criteria

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

### Denial criteria

- Female
- Diagnosis of one of the following diagnoses in the previous 2years:
  - 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

[Link to Memorandum](#)

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[Link to Updated Criteria](#)

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## Tetrabenazine Tablet (Xenazine)

*(Implemented 09/21/2009)*

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

### Approval criteria

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Diagnosis of Huntington's Disease with Chorea in the past 3 years.

### Additional criteria

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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  $< 50,000/\mu\text{L}$ ; 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  $\geq 1$  year of age; AND
- Dose requirements
  - 1-5 years of age begin with 25 mg once daily
  - $\geq 6$  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  $\geq 18$  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  $\geq 2$  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
  - $\geq 12$  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—
  - $\geq 12$  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  $\geq 50,000/\mu\text{L}$  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  $>400,000/\mu\text{L}$  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**

- 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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## **Tivozanib (Fotivda)**

(Updated 7/21/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age; AND
- Recipient must have a diagnosis of relapsed or refractory advanced renal cell carcinoma OR a diagnosis consistent with FDA-approved indications; AND
- Recipient must have had two or more prior systemic therapies including at least one VEGFR kinase inhibitor (e.g., axitinib); AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - Documentation of previous therapies tried; AND
  - Documentation of current blood pressure (monitor often during therapy); AND
  - Current labs including CBCs and LFTs; AND • Initial approval for 1 month

### Denial criteria:

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient has systolic blood pressure  $\geq 150$  mmHg or diastolic blood pressure  $\geq 100$  mmHg despite anti-hypertensive therapy; OR
- Recipient had a severe or life-threatening venous or arterial thromboembolic event; OR
- Recipient had a severe or life-threatening hemorrhagic event; OR • Recipient develops nephrotic syndrome/proteinuria; OR
- Recipient develops reversible posterior leukoencephalopathy syndrome; OR
- Recipient had a major surgery  $< 2$  weeks prior to request; OR
- Recipient is pregnant or breastfeeding; OR
- Recipient with moderate hepatic impairment requires a dose reduction

### QUANTITY EDITS

#21/28 day

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## Tolvaptan (Jynarque™)

(Implemented 7/18/2018)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  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 Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) pharmacy unit at 1-800-424-7976**

### Preferred Agents

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- 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

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- Croton® 10% Lotion (crotamiton)
- 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**
- Vanallice™ Gel (piperonyl butoxide, pyrethrins)

### \*\*Additional criteria

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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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## Topical Products

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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#### **Altabax 1% ointment**

*Implemented 09/21/2009*

- Generic mupirocin is available without prior authorization

#### **Bensal® HP (benzoic acid 6%, salicylic Acid 3%, Oak Bark Extract) Ointment**

*Implemented April 6, 2010*

#### **Nucort lotion (hydrocortisone acetate-aloe vera)**

*Implemented 01/12/2010*

- Generic hydrocortisone is available without prior authorization

○

#### **Nuzon gel (hydrocortisone acetate-aloe vera)**

*Implemented 01/12/2010*

- Generic hydrocortisone is available without prior authorization

○

[Link to Memorandum Bensal HP](#)

[Link to Memorandum Altabax](#)

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## **Tramadol Immediate-Release (Ultram, Ultracet)**

(Implemented 04/21/2009)

**Prescribers with questions on how to obtain a PA should call the Magellan 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 Magellan Medicaid Pharmacy Administration (MMA) 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 (Ultram 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
- Greater than 93 units of any solid oral short acting opioid paid by Medicaid per the previous 31 calendar days.

*\*\*Additional information listed under Exemptions\*\**

## Exemptions

- Patients who have a diagnosis of malignant cancer in the past 12 months:
  - Are exempt from the therapeutic duplication requirement.
  - 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.

## Additional criteria

Quantity limits apply

## Tramadol IR Age Edit

≥17 years of age

## Tramadol/APAP Age Edit

≥16 years of age

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## Trametinib (Mekinist) Tablets and Solution

*(Implemented 09/18/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Mekinist

### Additional Criteria

- Quantity Limits Apply

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 Magellan system for the previous 30 days indicates a hemoglobin (Hgb) level of  $\leq 12$  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

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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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with appropriate supporting documentation. PA requests for manual review products may be faxed to the state pharmacy unit at 1-800-424-5851.**

### Approval criteria

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- ≥ 12 years of age, OR
- History of at least one paid claim in the past 60 days for transdermal scopolamine

### Additional criteria

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Quantity limits apply

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## Trintine HCl (Syprine) Capsule

*(Implemented 09/18/2013)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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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## **Trifluridine and Tipiracil Tablets 20mg/8.19 mg and 15 mg/6.14 mg (Lonsurf)**

*(Implemented 04/26/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Lonsurf

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## Triheptanoin Liquid (Dojolvi)

(Implemented 10/21/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 3 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

## Tucatinib (Tukysa™)

(Effective 7/15/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 the diagnosis of advanced unresectable or metastatic HER2-positive breast cancer with at least one treatment in history and taking trastuzumab with capecitabine **OR** RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy **OR** diagnosis consistent with FDA indications; **AND**
- Recipient must have previously received trastuzumab (Herceptin), pertuzumab (Perjeta®) and ado- trastuzumab emtansine (T-DM1) (Kadcyla®) separately or in combination; **AND**
- Recipient should have no history of failure with other TKIs specific for HER2-positive breast cancer (i.e. neratinib and lapatinib); **AND**
- Prescriber should submit the following:
  - Current chart notes with documentation of previous therapies; **AND**
  - Documentation that the recipient is taking trastuzumab (Herceptin) and capecitabine (Xeloda); **AND**
  - Current labs including CBC, renal function, and LFTs; **AND**
  - Pregnancy test results for recipient with child-bearing potential;
- Prescriber should add anti-diarrheal medication to recipient medication list for use as needed (81% of patients develop some grade of diarrhea); **AND**
- Prescriber should advise females of reproductive potential to use effective contraception as well as female partners of male patients.
- Initial PA for 1 month.

### Denial Criteria

- Recipient does not meet the above approval requirements; **OR**
- Recipient cannot tolerate the minimum dose of 150 mg twice daily; **OR**
- Recipient has history of failure with other TKIs specific for HER2-positive breast cancer (i.e. neratinib and lapatinib);
- Recipient is pregnant or breastfeeding; **OR**
- Recipient must be able to swallow pills; **OR**
- Recipient has Grade 4 diarrhea; **OR**
- Recipient has either one of the following:
  - Grade 4 ALT or AST (>20X ULN) **OR** Grade 4 Bilirubin (>10X ULN); **OR**
  - ALT or AST >3X ULN **AND** Bilirubin >2X ULN
- Recipient requires a strong CYP3A inducer (e.g. rifampin or phenytoin), moderate CYP2C8 inducer (e.g. rifampin) or a strong CYP2C8 inhibitor (e.g. gemfibrozil)—if unavoidable, dose may need to be adjusted; **OR**

Arkansas Medicaid Prescription Drug Program Prior Authorization Criteria

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- Recipients with severe renal impairment ( $\text{CrCl} < 30\text{mL/min}$ ) because these patients should not take capecitabine.

### Quantity Edits

- 50 mg tablets — #120/30 days
- 150 mg tablets — #120/30 days

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## Valbenazine (Ingrezza) Capsule

(Implemented 11/22/2017)

(Updated 11/27/2019)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Ingrezza 40mg Capsule

### APPROVAL CRITERIA

- Manual review on a case-by-case basis; AND
- Beneficiary must be 18 years of age or older; AND
- Prescriber must submit chart notes with documentation on the impact of TD symptoms with activities of daily living; AND
- Beneficiary must have a diagnosis of moderate to severe tardive dyskinesia meeting the following DSM-5 criteria:
  - Involuntary athetoid or choreiform movements; AND
  - History of treatment with dopamine receptor blocking agent (DRBA) (e.g. antipsychotics or metoclopramide); AND
  - Symptom duration lasting longer than 4 to 8 weeks;
- Ingrezza® must be prescribed by a neurologist or psychiatrist; or prescriber has consulted with a neurologist or psychiatrist if symptoms are due to antipsychotic usage. Ingrezza® may also be prescribed by gastroenterology if symptoms are due to metoclopramide usage; AND
- Beneficiary must not be suicidal or have violent behavior; AND
- Prescriber must submit the completed Medicaid “Ingrezza® / Austedo® Statement of Medical Necessity” form with the initial request as part of the manual review. Updated form can be found at :  
[https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx\\_SMN\\_Form\\_Ingrezza\\_Austedo.pdf](https://arkansas.magellanrx.com/provider/docs/rxinfo/ARRx_SMN_Form_Ingrezza_Austedo.pdf) AND
- Prescriber must submit a baseline Abnormal Involuntary Movement Scale (AIMS) form as part of the manual review; AND
- Female beneficiary must not be pregnant or breastfeeding; AND
- Beneficiary must not be taking monoamine oxidase inhibitors (MAOIs), any other VMAT2 inhibitor or concomitant strong CYP3A4 inducers (e.g. rifampin, carbamazepine, and phenytoin); AND
- Beneficiary must not exceed Ingrezza® 40mg daily if also taking strong CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, and clarithromycin); AND
- Beneficiary must not exceed Ingrezza® 40mg daily if has moderate or severe hepatic impairment (Child-Pugh score 7 to 15); AND

- Beneficiary must not have congenital long QT Syndrome (LQTS) or cardiac arrhythmias associated with a prolonged QT interval and prescriber must provide attestation; AND
- If beneficiary has taken benztropine, or any other agent for EPS symptoms, provider must submit data documenting the response to the agent; AND
- Beneficiary must not have severe renal impairment (creatinine clearance < 30ml/min) and prescriber must provide attestation; AND
- Initial PA's not to exceed 3 months; once compliant on maintenance dose, PA's may be approved for a maximum of 6 months.

**DENIAL CRITERIA:**

- Beneficiary is < 18 years of age; OR
- Beneficiary is not compliant on prescribed dose after previous approval; OR
- Prescriber requests a dose > 80mg/ day; OR
- Prescriber requests a dose > 40mg/ day for beneficiaries with moderate or severe hepatic impairment or beneficiary takes strong CYP3A4 inhibitors; OR
- Beneficiary does not have an improvement from baseline AIMS score or a positive clinical response to therapy; OR
- Beneficiary does not meet the approval criteria

**QUANTITY EDITS:**

40mg capsules = #30 per 30 days

80mg capsules = #30 per 30 days

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## Valganciclovir Oral Solution (Valcyte)

*(Implemented 01/18/2011)*

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

### Approval criteria

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- Less than 9 years of age, OR
- History of diagnosis of NPO within the past 365 days.

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## Vandetanib (Caprelsa) Tablet

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Caprelsa 100mg and 300mg Tablet

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## Vemurafenib Tablet (Zelboraf)

(Implemented 04/17/2012)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Zelboraf tablet

### Information required for the manual review process

- Confirmation of BRAFV600E mutation-positive melanoma as detected by an FDA-approved test
- In addition to requirement of diagnosis and lab results showing BRAFV600E mutation-positive melanoma, the following data will be required for the manual review process:
  - Baseline EKG and then every 3 months thereafter to monitor for QTc
  - Liver function tests baseline and then periodic
  - Baseline and periodic dermatology evaluation for squamous cell carcinomas

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## Venetoclax- (Venclexta)

*(Implemented 7/20/2016)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

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- Venclexta tablet

### Approval Criteria

- Confirmed diagnosis of CLL with 17p deletion
- Documentation of one prior therapy
- Risk assessment for TLS
- TLS prophylaxis AND monitoring documentation

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## Vericiguat- (Verquvo)

(Updated 7/21/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  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
  - 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

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## Vismodegib Capsule (Erivedge)

*(Implemented 07/09/2012)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Erivedge capsule

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## Voclosporin Capsule (Lupkynis)

(Implemented 4/21/2021)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq 18$  years of age; AND
- Recipient must have a diagnosis of biopsy-proven active lupus nephritis (Class III, IV or V) OR a diagnosis consistent with FDA indications; AND
- Recipient must also take mycophenolate mofetil (MMF) and corticosteroids concomitantly with Lupkynis; AND
- Recipient must have an elevated urine protein to creatinine (UPCR) ratio; AND
- Prescriber must submit the following:
  - Current chart notes; AND
  - 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; AND
  - Current blood pressure

### Denial Criteria

- Recipient does not meet approval criteria OR have a diagnosis supported in the official Compendia; OR
- Recipient is pregnant; OR
- Recipient has a baseline eGFR  $\leq 45$  mL/min/1.73m<sup>2</sup> OR
- Recipient has a baseline blood pressure  $>165/105$  mmHg or with hypertensive emergency; OR
- Recipient is not taking concomitant mycophenolate mofetil and corticosteroids; OR
- Recipient is taking cyclophosphamide; OR
- Recipient requires concomitant strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin); OR
- Prescriber orders a dose  $> 23.7$  mg twice daily OR  $< 7.9$  mg twice daily; OR
- Recipient has severe hepatic impairment; OR
- If approved, recipient has not experienced therapeutic benefit by 24 weeks.

### QUANTITY EDITS:

#180/ 30 days

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## Vorinostat (Zolinza) 100mg Capsule

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Zolinza 100mg Capsule

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## **Vorapaxar (Zontivity)**

*(Implemented 09/23/2014)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in 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

- Zontivity

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## **Vosoritide (Voxzogo)**

*(Implemented 01/19/2022)*

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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 5-17 years of age; AND
- Recipient must have a diagnosis of achondroplasia (ACH) OR a diagnosis consistent with FDA approved indications; AND
- Recipient must have open epiphyses; AND
- Prescriber who specializes in skeletal dysplasia (orthopedics, geneticist, or endocrinologist) must submit the following:
  - Current chart notes; AND
  - Genetic test results and radiologic findings confirming the diagnosis of achondroplasia; AND
  - Baseline standing height; AND
  - Current weight; AND
  - Requested dose; AND
  - X-ray report demonstrating epiphyses status for patients yearly

### **DENIAL CRITERIA:**

- Recipient does not meet approval criteria OR have a diagnosis supported on the official Compendia; OR
- Recipient has closed epiphyses; OR
- Recipient has a diagnosis of hypochondroplasia or short stature condition other than ACH; OR
- Recipient has been treated with growth hormone in the previous 6 months

### **QUANTITY EDITS:**

- Each strength--#30 vials/30 days (packaged in 10 vials per kit)

## **Voxelotor –(Oxbryta)**

*(Effective 1/15/2020)*

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

### **APPROVAL CRITERIA:**

- Manual review on a case-by-case basis AND
- Must be at least 4 years old AND
- Must have a diagnosis of Sickle Cell Disease AND
- Must not be pregnant AND
- Has had from 1 to 10 vasoocclusive crisis (VOC) events in the last 12 months AND
- Must have hemoglobin (Hb) level  $\geq 5.5$  to  $\leq 10.5$  g/dL AND
- Prescriber should submit the following:
  - Chart notes
  - History of Sickle Cell treatment including VOC events and hospitalization in the last 12 months
  - Documentation of Hydroxyurea usage (previous usage is required unless contraindicated)
  - Current labs including CBC and LFTs

### **DENIAL CRITERIA:**

- Does not have a diagnosis of Sickle Cell Disease OR
- Received an RBC transfusion in the last 60 days or erythropoietin within the last 28 days OR
- Pregnancy or breastfeeding OR
- Severe hepatic impairment

### **Quantity limits**

#90/30

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## Vutrisiran (Amvuttra) Syringe

(Effective 10/19/2022)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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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## Zanubrutinib (Brukinsa)

(Effective 4/15/2020)

**Prescribers with questions on how to obtain a PA should call the Magellan Help Desk at 1-800-424-7895. All PA requests must be submitted in writing with 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  $\geq$  18 years of age; AND
- Recipient must have one of the following diagnoses OR a diagnosis consistent with FDA indication:
  - Mantle Cell Lymphoma
  - Waldenstrom's Macroglobulinemia
  - Marginal Zone Lymphoma
  - Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
- Recipient must have disease which has relapsed, or is refractory, following at least one line of systemic or targeted therapy; AND
- Prescriber must provide the following:
  - Liver function tests including AST, ALT, Bilirubin, and INR
  - Complete blood count with differential
  - Current chart notes with documentation of previous treatments
  - Baseline computed tomography (CT) scan (if available)
- Dose reduction recommended for severe hepatic impairment (Child-Pugh C) OR concomitant use of moderate or strong CYP3A inhibitors OR grade 3 or grade 4 cytopenias; AND
- Consider prophylaxis for herpes simplex virus, *pneumocystis jiroveci* pneumonia and other infections for patients with increased risk of infection (e.g. patients with low neutrophil counts or taking immunosuppressants); AND
- Prescriber must provide plan for monitoring patients that require concomitant antiplatelet or anticoagulant medications; AND
- Initial approval for 3 months; renewal timeframe will be determined by tolerance and response to therapy

### DENIAL CRITERIA:

- Recipient does not meet the FDA approved indication; OR
- Recipient has no history of at least one prior therapy; OR
- Recipient requires concomitant use of CYP3A inducers; OR
- Recipient is pregnant or lactating women; OR
- Prescriber should discontinue for any grade of intracranial hemorrhage; OR
- Recipient has disease progression or unacceptable toxicity that cannot be resolved by decreasing the dose

### QUANTITY EDITS:

#120/30 days

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**Appendix A – Nil per os (NPO)**

<b>Procedure codes</b>	<b>Description</b>
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
Kaposi 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 OBSTR CJ
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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