

# ACITRETIN

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## MEDICATION(S)

ACITRETIN

## PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documentation of diagnosis. For psoriasis: inadequate response, intolerance, or contraindication to methotrexate or cyclosporine. Applies to new starts only.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **ACTIMMUNE**

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## **MEDICATION(S)**

ACTIMMUNE

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **ACUTE SEIZURE AGENTS**

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### **MEDICATION(S)**

NAYZILAM, VALTOCO 10 MG DOSE, VALTOCO 15 MG DOSE, VALTOCO 20 MG DOSE, VALTOCO 5 MG DOSE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Acute narrow-angle glaucoma.

### **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. Applies to new starts only.

### **AGE RESTRICTION**

12 years of age and older for Nayzilam (midazolam). 6 years of age and older for Valtoco (diazepam).

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **ADALIMUMAB-AACF**

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### **MEDICATION(S)**

ADALIMUMAB-AACF (2 PEN), IDACIO, IDACIO FOR CROHNS DISEASE/UC, IDACIO FOR PLAQUE PSORIASIS

**PENDING CMS APPROVAL**

# **ADEMPAS**

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## **MEDICATION(S)**

ADEMPAS

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Female patients who are pregnant or planning on becoming pregnant. Concurrent use with nitrates or nitric oxide donors in any form. Concurrent use with phosphodiesterase inhibitors. Pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP).

## **REQUIRED MEDICAL INFORMATION**

Diagnosis of Pulmonary Arterial Hypertension WHO Group 1 with New York Heart Association (NYHA) Functional Class II-III by complete right heart catheterization (RHC) with results attached. Mean pulmonary artery pressure (mPAP) greater than 20 mmHg, pulmonary vascular resistance (PVR) greater than 3 wood units, and a mean pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. For WHO group IV: Confirmed diagnosis of Chronic Thromboembolic Pulmonary Hypertension (CTEPH) with documentation verifying that patient has recurrent or persisting pulmonary hypertension following pulmonary thromboendarterectomy or inoperable CTEPH. For all diagnosis: Confirmation treatment plan is in place.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a cardiologist, pulmonologist, or practitioner at a Pulmonary Hypertension Association-Accredited center.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

# **ALOSETRON**

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## **MEDICATION(S)**

ALOSETRON HCL

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Exclude if male gender.

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis of severe diarrhea-predominant irritable bowel syndrome. Documentation of inadequate response, intolerance, or contraindication to one of the following: an anti-diarrheal agent (e.g. loperamide), an anti-spasmodic agent (e.g. dicyclomine), or a tricyclic antidepressant (e.g. amitriptyline, nortriptyline, desipramine, imipramine).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# ALPHA1-PROTEINASE INHIBITORS

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## MEDICATION(S)

PROLASTIN-C

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Immunoglobulin A (IgA) deficient patients with antibodies against IgA.

## REQUIRED MEDICAL INFORMATION

Diagnosis of emphysema due to severe congenital deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Documentation of testing that confirms one of the following homozygous protein phenotypes: Pi\*ZZ, Pi\*Z(null) or Pi\*(null)(null) AND labs that show baseline (pretreatment) serum alpha1-antitrypsin concentration of less than 11 micromol/L as documented by either of the following: less than 57 mg/dL as determined by nephelometry OR less than 80mg/dL as determined by radial immunodiffusion. Confirmation that the member does not have selective IgA deficiencies with known antibodies against IgA (anti-IgA antibodies).

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a pulmonologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



# **ALVAIZ**

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## **MEDICATION(S)**

ALVAIZ

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis: 1) chronic immune thrombocytopenia (ITP), 2) thrombocytopenia in patients with chronic hepatitis C, or 3) severe aplastic anemia. For ITP: Documentation that baseline platelet count is less than 30,000/mcL. Documentation of inadequate response, intolerance, or contraindication to glucocorticoids (prednisone, dexamethasone or methylprednisolone), immunoglobulins, or splenectomy. For chronic hepatitis C: Documentation of patient's degree of thrombocytopenia (e.g. less than 75,000/mcL) that prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. For severe aplastic anemia: Documentation that baseline platelet count is less than 30,000/mcL. Documentation of inadequate response, intolerance, or contraindication to immunosuppressive therapy.

## **AGE RESTRICTION**

For ITP: 6 years or older. For thrombocytopenia in patients with chronic hepatitis C and severe aplastic anemia: 18 years or older.

## **PRESCRIBER RESTRICTION**

For ITP and severe aplastic anemia: hematologist. For thrombocytopenia in patients with chronic hepatitis C: hematologist, hepatologist, or infectious disease specialist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: Confirmation that patient had a positive clinical response and remains at risk for

bleeding complications.

**PART B PREREQUISITE**

N/A

## **ANTIANDROGEN ORAL ONCOLOGY AGENTS**

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### **MEDICATION(S)**

ABIRATERONE ACETATE, ERLEADA, NUBEQA, XTANDI

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. For Nubeqa: Documentation of inadequate response, intolerance, or contraindication to one of the following: abiraterone, Erleada, or Xtandi. Applies to new starts only.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **APOMORPHINE INJECTION**

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## **MEDICATION(S)**

APOMORPHINE HCL 30 MG/3ML SOLN CART

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Concomitant use with 5-HT<sub>3</sub> receptor antagonists, including antiemetics (e.g., ondansetron, granisetron, palonosetron, alosetron).

## **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of Parkinson's disease (PD) with intermittent off episodes. Documentation showing an inadequate response, intolerance, or contraindication to at least two conventional oral therapies (e.g., carbidopa-levodopa, pramipexole, ropinirole, bromocriptine, amantadine, selegiline, rasagiline, trihexyphenidyl, benzotropine, entacapone, tolcapone).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# ARCALYST

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## MEDICATION(S)

ARCALYST

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Confirmed diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Deficiency of Interleukin-1 Receptor Antagonist (DIRA), Recurrent Pericarditis (RP). For DIRA: Patient weight of at least 10 kg. Documentation showing need for maintenance of remission. For RP: Documentation showing a trial of, intolerance to, or contraindication to at least one of the following: nonsteroidal anti-inflammatory drugs, colchicine, or corticosteroids.

## AGE RESTRICTION

For CAPS, FCAS, MWS, RP: 12 years of age or older.

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# ARIKAYCE

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## MEDICATION(S)

ARIKAYCE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of Mycobacterium avium complex (MAC) lung disease. Confirmation that the medication is being used as part of a combination antibacterial drug regimen. Confirmation that the patient did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy.

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a pulmonologist or an infectious disease specialist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# AUSTEDO

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## **MEDICATION(S)**

AUSTEDO, AUSTEDO XR, AUSTEDO XR PATIENT TITRATION

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Congenital long QT syndrome. History of cardiac arrhythmias. Hepatic impairment. Concurrent use of MAO inhibitors. Concurrent use of reserpine, tetrabenazine or valbenazine. For a diagnosis of Chorea associated with Huntington's Disease: suicidal patients and patients with untreated or inadequately treated depression.

## **REQUIRED MEDICAL INFORMATION**

Initial: For Tardive Dyskinesia: Documented diagnosis of Tardive Dyskinesia including copy of Abnormal Involuntary Movement Scale (AIMS) assessment. Documentation that other movement disorders (such as Parkinson's disease, Chorea associated with Huntington's Disease) have been excluded with documentation attached. Documentation of current or former chronic use of a dopamine antagonist (e.g., antipsychotic [first or second generation], metoclopramide, prochlorperazine, droperidol, promethazine, etc). For Chorea associated with Huntington's Disease: Documentation showing that other movement disorders (such Tardive Dyskinesia, or Parkinson's disease) have been excluded with documentation attached. Documentation showing confirmation of a diagnosis of Chorea associated with Huntington's Disease with documentation attached.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist or psychiatrist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: For Tardive Dyskinesia: Improvement in symptoms of Tardive Dyskinesia with an updated AIMS assessment. Documentation must be attached. For Chorea associated with Huntington's Disease: Improvement in symptoms of Chorea with medical records attached.

**PART B PREREQUISITE**

N/A



# **BENLYSTA**

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## **MEDICATION(S)**

BENLYSTA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Confirmation of diagnosis of either systemic lupus erythematosus (SLE) or active lupus nephritis (LN). For SLE: Documentation of inadequate response, intolerance, or contraindication to at least 1 standard therapy (e.g. hydroxychloroquine, mycophenolate, azathioprine). For LN: Documentation of inadequate response, intolerance, or contraindication to at least 1 standard therapy (e.g. mycophenolate, IV or oral cyclophosphamide, azathioprine, oral glucocorticoid).

## **AGE RESTRICTION**

5 years or older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a rheumatologist or nephrologist

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: Documentation of a positive clinical response.

## **PART B PREREQUISITE**

N/A

# **BERINERT**

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## **MEDICATION(S)**

BERINERT

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Subject to Part B vs Part D review. Documentation of a diagnosis of hereditary angioedema (HAE). Confirmation that Berinert is being used for the treatment of acute HAE attacks. Not to be used in combination with other approved treatments for acute HAE attacks.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or prescriber who specializes in the management of HAE.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: Confirmation of reduction in severity or duration of attacks.

## **PART B PREREQUISITE**

N/A

# **BESREMI**

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## **MEDICATION(S)**

BESREMI

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. Documentation of inadequate response, intolerance, or contraindication to hydroxyurea.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a hematologist or oncologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **BEXAROTENE GEL**

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### **MEDICATION(S)**

BEXAROTENE 1 % GEL

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. Applies to new starts only.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Dermatologist, hematologist, oncologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **BOTULINUM TOXINS**

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## **MEDICATION(S)**

BOTOX, XEOMIN

## **PA INDICATION INDICATOR**

4 - All FDA-Approved Indications, Some Medically-Accepted Indications

## **OFF LABEL USES**

Sialorrhea associated with disorders of the nervous system or neurologic dysfunction. Hemifacial spasm. Laryngeal dystonia. Spasticity associated with cerebral palsy.

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

FOR ALL REQUESTS: Documentation of diagnosis, proposed injection site(s) and the dose that will be injected into each site. IN ADDITION: FOR INITIAL REQUESTS: (1)For OAB with symptoms of urge urinary incontinence, urgency, and frequency: documentation of inadequate response or intolerance to an anticholinergic medication, dose no more than 100 units/treatment. (2)For urinary incontinence due to detrusor overactivity associated with a neurologic condition: inadequate response or intolerance to an anticholinergic medication, dose no more than 200 units/treatment. (3)For prophylaxis of headaches in adult patients with chronic migraine (at least 15 days per month with headache lasting 4 hours a day or longer): documentation of inadequate response or intolerance to at least 2 different classes of prophylactic medications (i.e., beta blockers [such as propranolol, metoprolol], amitriptyline, topiramate, valproic acid or its derivatives, verapamil), dose no more than 155 units/treatment. (4)For severe primary axillary hyperhidrosis: documentation of dose no more than 100 units/treatment. (5)For upper or lower limb spasticity in muscle groups FDA-approved for treatment: documentation of dose no more than 400 units/treatment. (6)For blepharospasm associated with dystonia: dose no more than 200 units/treatment. (7)For strabismus associated with dystonia: dose no more than 25 units per muscle per injection. (8)For sialorrhea associated with disorders of the nervous system or neurologic dysfunction, documentation of diagnosis and inadequate response or intolerance to at least 1 anticholinergic medication (e.g., glycopyrrolate). (9)For cervical dystonia: dose no more than 300 units/treatment. FOR RENEWAL REQUESTS: Dose consistent with total units for diagnosis (per initial request criteria). Documentation supporting the need for repeat treatment(s) occurring no sooner than every 3 months.

## **AGE RESTRICTION**

18 years of age or greater for diagnoses of OAB, urinary incontinence, prophylaxis of headaches in patients with chronic migraine, severe primary axillary hyperhidrosis. 16 years of age or greater for diagnosis of cervical dystonia. 12 years of age or greater for diagnoses of blepharospasm or strabismus associated with dystonia.

**PRESCRIBER RESTRICTION**

Urologist/neurologist: OAB, urinary incontinence. Neurologist: Migraine headaches.  
Neurologist/Physiatrist: Upper limb spasticity, cervical dystonia. Ophthalmologist: Blepharospasm, strabismus. Dermatologist/Neurologist/Physiatrist: Severe primary axillary hyperhidrosis.

**COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

## **BRAND MAJOR DEPRESSIVE DISORDER AGENTS**

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### **MEDICATION(S)**

AUVELITY, EMSAM, FETZIMA, FETZIMA TITRATION

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of Major Depressive Disorder. Documentation of an inadequate response, intolerance, or contraindication to two of the following: selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, atypical agents, serotonin modulators, tricyclics. Applies to new starts only.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **BRIVIACT**

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## **MEDICATION(S)**

BRIVIACT

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of partial-onset seizures. Documentation of an inadequate response, intolerance, or contraindication to levetiracetam and at least one of the following: carbamazepine, divalproex, gabapentin, lacosamide, lamotrigine, oxcarbazepine, topiramate. Applies to new starts only.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



# **BRONCHITOL**

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## **MEDICATION(S)**

BRONCHITOL

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. Confirmation that patient has passed a Bronchitol Tolerance Test. Confirmation that Bronchitol will be used in conjunction with standard therapies (e.g., bronchodilators, inhaled antibiotics) to improve pulmonary function. For reauthorization, confirmation of improvement in condition.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **CARGLUMIC ACID**

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## **MEDICATION(S)**

CARGLUMIC ACID

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. Documentation showing use as adjunctive therapy to standard of care for treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency.

Documentation showing use for maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency. Documentation showing use as adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with prescriber experienced in metabolic disorders.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **CAYSTON**

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### **MEDICATION(S)**

CAYSTON

**PENDING CMS APPROVAL**

# CERDELGA

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## **MEDICATION(S)**

CERDELGA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of type 1 Gaucher Disease (GD1) and documentation that patient is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an FDA-approved genetic test.

## **AGE RESTRICTION**

18 years of age or older.

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **CFTR MODULATORS**

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### **MEDICATION(S)**

KALYDECO, ORKAMBI, TRIKAFTA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Chart notes that show that the diagnosis of cystic fibrosis is confirmed. Chart notes that show that appropriate genetic testing has been conducted. Chart notes showing that lab work (baseline liver function tests, including alanine aminotransferase, aspartate aminotransferase and bilirubin) has been assessed prior to initiation of treatment. For Kalydeco: Confirmation of one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data. For Orkambi: Confirmation of homozygous for the F508del mutation in the CFTR gene. For Trikafta: Confirmation of at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with pulmonologist, endocrinologist, or pediatrician.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **CGRP ANTAGONISTS**

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### **MEDICATION(S)**

AIMOVIG, EMGALITY, EMGALITY (300 MG DOSE)

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Notes showing diagnosis and patient having at least 4 migraine days per month. For migraine: Confirmation of intolerance or inadequate response to a trial with at least one preventive medication from two of the following classes: beta blockers, antidepressants, anticonvulsants. For episodic cluster headaches (Emgality only): Confirmation of a history of inadequate response, intolerance, or contraindication to at least one other preventative medication recommended by current consensus guidelines for episodic cluster headache (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# CINRYZE

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## MEDICATION(S)

CINRYZE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Subject to Part B vs Part D review. Documentation of a diagnosis of hereditary angioedema (HAE). Confirmation that Cinryze is being used for prophylaxis against HAE attacks. Not to be used in combination with other approved treatments for prophylaxis against HAE attacks.

## AGE RESTRICTION

6 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or prescriber who specializes in the management of HAE.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

For reauthorization: Confirmation of reduction in severity or duration of attacks.

## PART B PREREQUISITE

N/A



# **CLOBAZAM**

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## **MEDICATION(S)**

CLOBAZAM

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS), refractory seizures/epilepsy, or seizures associated with Dravet syndrome (DS). For LGS: documentation of an inadequate response, intolerance, contraindication, or is concomitantly receiving one of the following: valproate, lamotrigine, rufinamide, cannabidiol (Epidiolex), felbamate. For refractory seizures/epilepsy: documentation of an inadequate response, intolerance, contraindication, or is concomitantly receiving two antiepileptics such as: felbamate, lamotrigine, levetiracetam, topiramate, valproate, zonisamide. Applies to new starts only.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **CORLANOR**

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## **MEDICATION(S)**

CORLANOR

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

One of the following: 1) Documentation of diagnosis of chronic heart failure (CHF). Stable symptomatic NYHA class II to IV heart failure with reduced left ventricular ejection fraction (EF). Documentation of EF less than or equal to 35 percent. Patient is in sinus rhythm with resting heart rate greater than or equal to 70 beats per minute. Patient has intolerance, contraindication, or is on maximally tolerated doses of beta-blockers. Or, 2) Documentation of diagnosis of stable symptomatic heart failure due to Dilated Cardiomyopathy (CHF-DC). Patient is in sinus rhythm with an elevated heart rate.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: patient has a positive clinical response.

## **PART B PREREQUISITE**

N/A

# **CYSTARAN**

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## **MEDICATION(S)**

CYSTARAN

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis of cystinosis. Documentation showing patient has corneal cystine crystal accumulation.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# DEFERASIROX

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## MEDICATION(S)

DEFERASIROX, DEFERASIROX GRANULES

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Estimated glomerular filtration rate (GFR) less than 40 mL/min or serum creatinine more than 2 times the age-appropriate upper normal limit, platelet counts less than 50,000/mL, high-risk myelodysplastic syndromes (MDS), and advanced malignancies.

## REQUIRED MEDICAL INFORMATION

For the treatment of chronic iron overload caused by blood transfusions: Documentation of serum ferritin levels consistently greater than 300 mcg/L. For chronic iron overload in nontransfusion-dependent thalassemia syndromes: Documentation of liver iron concentration (LIC) of at least 5 mg of iron per gram of liver dry weight (mg Fe/g dw) AND documentation of serum ferritin level greater than 300 mcg/L on 2 consecutive measurements 1 month apart.

## AGE RESTRICTION

Treatment of chronic iron overload caused by blood transfusions: 2 years of age and older. Chronic iron overload in nontransfusion-dependent thalassemia syndromes: 10 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a hematologist, oncologist, or hepatologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



# DEFERIPRONE

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## MEDICATION(S)

DEFERIPRONE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documentation of transfusional iron overload due to thalassemia syndromes, sickle cell disease or other anemias. Documentation of Absolute Neutrophil Count (ANC) greater than or equal to  $1.5 \times 10^9$  (10 to the ninth power) per liter.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with hematologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# DIACOMIT

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## MEDICATION(S)

DIACOMIT

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of Dravet syndrome (DS). Documentation of an inadequate response, intolerance, or contraindication to at least two of the following: clobazam, valproic acid derivatives, topiramate, levetiracetam, cannabidiol (pharmaceutical). Applies to new starts only.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with neurologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **DIHYDROERGOTAMINE NASAL SPRAY**

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## **MEDICATION(S)**

DIHYDROERGOTAMINE MESYLATE 4 MG/ML SOLUTION

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Uncontrolled hypertension. Use as management of hemiplegic basilar migraine. Ischemic heart disease (e.g. angina pectoris, history of myocardial infarction, or documented silent ischemia) or coronary artery vasospasm including Prinzmetal's variant angina. Concomitant use or use within 24 hours of ergotamine containing or ergot type medications or methysergide. Coadministration with strong CYP3A4 inhibitors and peripheral and central vasoconstrictors. Peripheral arterial disease, sepsis, following vascular surgery, and severely impaired hepatic or renal function. Hypersensitivity to ergot alkaloids.

## **REQUIRED MEDICAL INFORMATION**

Documentation to confirm diagnosis of acute treatment of migraine headaches with or without aura. Confirmation that drug will not be used for prophylactic migraine therapy. Documentation of an inadequate response, intolerance, or contraindication to two generic triptans (such as sumatriptan, zolmitriptan, rizatriptan) OR an inadequate response, intolerance, or contraindication to one generic triptan AND a gepant.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist, headache specialist, or pain specialist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A



**PART B PREREQUISITE**

N/A

## **DOPTELET**

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### **MEDICATION(S)**

DOPTELET

**PENDING CMS APPROVAL**

## **DRIZALMA SPRINKLE**

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### **MEDICATION(S)**

DRIZALMA SPRINKLE 20 MG CAP DR, DRIZALMA SPRINKLE 30 MG CAP DR, DRIZALMA SPRINKLE 60 MG CAP DR

**PENDING CMS APPROVAL**

# **DRONABINOL**

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## **MEDICATION(S)**

DRONABINOL

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

One of the following: Documented diagnosis of anorexia associated with weight loss in patients with AIDS OR documented diagnosis of chemotherapy-induced nausea and vomiting in patients with inadequate response to conventional antiemetic treatments [such as 5-HT<sub>3</sub> (serotonin) receptor antagonists, NK<sub>1</sub> (neurokinin-1) receptor antagonists, glucocorticoids]. Medication may be covered under Medicare Part B or D depending upon the circumstances. Information to be submitted describing the use and setting of the drug to make the determination.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **DROXIDOPA**

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## **MEDICATION(S)**

DROXIDOPA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of neurogenic orthostatic hypotension (nOH) caused by one of the following: (1) primary autonomic failure (e.g. Parkinson's disease, multiple system atrophy, and pure autonomic failure), (2) dopamine beta-hydroxylase deficiency, or (3) non-diabetic autonomic neuropathy.

Documentation of an inadequate response, intolerance, or contraindication to fludrocortisone or midodrine.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a cardiologist or a neurologist.

## **COVERAGE DURATION**

3 months.

## **OTHER CRITERIA**

For reauthorization: the patient has had a positive clinical response with improvement in symptoms.

## **PART B PREREQUISITE**

N/A

# **DUPIXENT**

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## **MEDICATION(S)**

DUPIXENT

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Active helminth infection.

## **REQUIRED MEDICAL INFORMATION**

For moderate-to-severe atopic dermatitis when disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable: For patients under age 2, documentation showing a trial of, intolerance to, or contraindication to at least one topical steroid. For patients over age 2, documentation showing a trial of, intolerance to, or contraindication to at least one topical corticosteroid and at least one topical calcineurin inhibitor. For add on maintenance therapy for the treatment of moderate to severe asthma with eosinophilic type: Documentation showing a diagnosis of eosinophilic asthma including eosinophil count greater than or equal to 150 cells per microliter (lab results required). Documentation showing a trial of, intolerance to, or contraindication to at least one combination therapy (inhaled steroids, long acting beta-agonists, antileukotrienes, theophylline). For add on maintenance therapy for the treatment of oral corticosteroid dependent asthma: Documentation showing oral corticosteroid dependent asthma. Documentation showing trial of, intolerance to, or contraindication to at least one combination therapy (inhaled steroids, long acting beta-agonists, antileukotrienes, theophylline). For patients with chronic rhinosinusitis with nasal polyposis (CRSwNP): Documentation of a diagnosis of CRSwNP. Documentation showing a trial of, intolerance to, or contraindication to at least one intranasal corticosteroid and at least one systemic corticosteroid. Documentation showing the patient will be treated with Dupixent in combination with intranasal corticosteroids. For patients with eosinophilic esophagitis: Documentation of a diagnosis of eosinophilic esophagitis. Documentation showing a trial of, intolerance to, or contraindication to at least one proton pump inhibitor. Documentation showing a trial of, intolerance to, or contraindication to inhaled fluticasone propionate. Continued in OTHER CRITERIA.

## **AGE RESTRICTION**

6 months of age or older for atopic dermatitis. 6 years of age and older for eosinophilic phenotype or

oral corticosteroid dependent asthma. 18 years of age and older for CRSwNP and prurigo nodularis. 1 year of age and older for EOE.

**PRESCRIBER RESTRICTION**

Pulmonologist, allergist, immunologist, dermatologist, otolaryngologist, gastroenterologist.

**COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

For prurigo nodularis: Documentation of diagnosis. Documentation showing a trial, intolerance, or contraindication to one high potency topical steroid. For reauthorization: Confirmation of positive clinical response.

**PART B PREREQUISITE**

N/A

# **ENBREL**

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## **MEDICATION(S)**

ENBREL, ENBREL MINI, ENBREL SURECLICK

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of the results of PPD test and treatment plan to address latent or active infection. Confirmation of diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA), juvenile psoriatic arthritis (jPsA), plaque psoriasis (PsO), polyarticular juvenile idiopathic arthritis (pJIA), or ankylosing spondylitis (AS). For RA or PsA or jPsA: Documentation of inadequate response intolerance, or contraindication to at least one conventional DMARD. For PsO (moderate to severe disease): Documentation that patient is a candidate for systemic therapy or phototherapy and documentation of inadequate response, intolerance, or contraindication to methotrexate OR UVB therapy OR Acitretin (requires prior authorization). For PsO (limited disease): Documentation of inadequate response, intolerance, or contraindication to one topical steroid (high or very high potency) AND calcipotriene. For moderately to severely active polyarticular pJIA: Documentation of inadequate response, intolerance, or contraindication to one conventional DMARD. For AS: Documentation of inadequate response, intolerance, or contraindication to at least two non-steroidal anti-inflammatory drugs (NSAIDs).

## **AGE RESTRICTION**

For RA, AS: 18 years of age and older. For PsO: 4 years of age and older. For pJIA, PsA: 2 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a rheumatologist or dermatologist.

## **COVERAGE DURATION**

12 months.



**OTHER CRITERIA**

For reauthorization: Confirmation of positive clinical response.

**PART B PREREQUISITE**

N/A

# **ENDOTHELIN RECEPTOR ANTAGONISTS**

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## **MEDICATION(S)**

AMBRISENTAN, BOSENTAN

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Pregnancy. For ambrisentan, a diagnosis of idiopathic pulmonary fibrosis. For bosentan, use with glyburide and/or cyclosporine A.

## **REQUIRED MEDICAL INFORMATION**

Confirmation of diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1. Diagnosis confirmed by a complete right heart catheterization (RHC). PAH defined as a resting mean pulmonary artery pressure (mPAP) of greater than 20 mmHG, pulmonary capillary wedge pressure (PCWP), left atrial pressure, or left ventricular end-diastolic pressure of less than or equal to 15 mmHg, and pulmonary vascular resistance (PVR) of greater than 3 Wood units. RHC results must be provided. Confirmation that hemoglobin, liver function tests, and bilirubin are being monitored. If female of childbearing age, documentation showing reliable contraception will be used during and after treatment and confirmation of negative pregnancy test prior to starting medication.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a cardiologist, pulmonologist, or practitioner at a Pulmonary Hypertension Association-Accredited center.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: documentation showing treatment response and monitoring.

**PART B PREREQUISITE**

N/A

# EPIDIOLEX

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## MEDICATION(S)

EPIDIOLEX

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Hypersensitivity to cannabidiol or any of the ingredients in the product.

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of Dravet syndrome (DS), Lennox-Gastaut syndrome (LGS) or Tuberous Sclerosis Complex (TSC). Documentation of baseline serum transaminases (ALT and AST) and total bilirubin levels prior to initiation of treatment and confirmation that these labs will be monitored periodically during treatment. Documentation showing that patient has failed to become seizure-free with at least 2 antiepileptic drugs (specify drugs tried). Confirmation that Epidiolex is adjunctive therapy with documentation of antiepileptic drug(s) with which Epidiolex will be used. Applies to new starts only.

## AGE RESTRICTION

1 year of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a neurologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

Request is within FDA approved labeled dose not exceeding 20 mg/kg/day for treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome or dose not exceeding 25 mg/kg/day for treatment of seizures associated with Tuberous Sclerosis Complex.

## PART B PREREQUISITE

N/A



# **EPRONTIA**

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## **MEDICATION(S)**

EPRONTIA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. Confirmation of difficulty swallowing solid dosage forms. Documentation of an inadequate response, intolerance, or contraindication to generic formulary topiramate. Applies to new starts only.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **FASENRA**

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## **MEDICATION(S)**

FASENRA, FASENRA PEN

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation showing confirmation of the following: diagnosis of severe asthma with an eosinophil count greater than or equal to 150 cells per microliter (lab results required) AND inadequate response, intolerance or contraindication to treatment with an inhaled ICS/LABA (inhaled corticosteroid/long-acting beta-agonist) with or without other controllers, including systemic steroids, antileukotrienes.

## **AGE RESTRICTION**

6 years of age and older.

## **PRESCRIBER RESTRICTION**

Pulmonologist, allergist, immunologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: Confirmation of positive clinical response.

## **PART B PREREQUISITE**

N/A

## **FENTANYL CITRATE TRANSMUCOSAL LOZENGE**

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### **MEDICATION(S)**

FENTANYL CITRATE 1200 MCG LOZ HANDLE, FENTANYL CITRATE 1600 MCG LOZ HANDLE,  
FENTANYL CITRATE 200 MCG LOZ HANDLE, FENTANYL CITRATE 400 MCG LOZ HANDLE,  
FENTANYL CITRATE 600 MCG LOZ HANDLE, FENTANYL CITRATE 800 MCG LOZ HANDLE

### **PENDING CMS APPROVAL**



## **FILGRASTIM AGENTS**

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### **MEDICATION(S)**

ZARXIO

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation or chart notes supporting medication is being used for a medically accepted indication not otherwise excluded from Part D. For all diagnoses, chart notes that show that lab work (complete blood count with differential including ANC) is being monitored prior to initiation of medication and during therapy based on recommendation for that specific diagnosis.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **FINTEPLA**

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## **MEDICATION(S)**

FINTEPLA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Hypersensitivity to fenfluramine or any of the components of Fintepla. Concomitant use of, or within 14 days of administration of monoamine oxidase inhibitors.

## **REQUIRED MEDICAL INFORMATION**

Confirmation that the patient will have required echocardiogram monitoring. Documented diagnosis of Dravet syndrome (DS) or Lennox-Gastaut syndrome (LGS). For Dravet Syndrome (DS): Documentation showing an inadequate response or intolerance to at least two of the following: clobazam, valproic acid derivatives, topiramate, levetiracetam, cannabidiol (pharmaceutical), or stiripentol (include dates, duration, and outcome of drugs tried). For Lennox-Gastaut syndrome: Documentation showing inadequate response or intolerance to at least two of the following: lamotrigine, rufinamide, topiramate, cannabidiol (pharmaceutical), clobazam, felbamate (include dates, duration, and outcome of drugs tried). Applies to new starts only.

## **AGE RESTRICTION**

2 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **FIRDAPSE**

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## **MEDICATION(S)**

FIRDAPSE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of Lambert-Eaton myasthenic syndrome (LEMS). Diagnosis confirmed by neurophysiology studies or a positive anti-P/Q type voltage-gated calcium channel antibody test.

## **AGE RESTRICTION**

6 years of age or older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist or neuromuscular specialist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: confirmation of positive clinical response.

## **PART B PREREQUISITE**

N/A

# **FYCOMPA**

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## **MEDICATION(S)**

FYCOMPA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of partial-onset seizures or generalized tonic-clonic seizures. Documentation of an inadequate response, intolerance, or contraindication to two of the following: carbamazepine, divalproex, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, topiramate, valproate, zonisamide. Applies to new starts only.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **GATTEX**

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## **MEDICATION(S)**

GATTEX

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation showing a diagnosis of short bowel syndrome and patient is dependent on parenteral support. For continuation: Documentation of reduction in parenteral support.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **GLP-1 AGONISTS**

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### **MEDICATION(S)**

MOUNJARO, OZEMPIC (0.25 OR 0.5 MG/DOSE), OZEMPIC (1 MG/DOSE), OZEMPIC (2 MG/DOSE), RYBELSUS, TRULICITY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Use for weight loss.

### **REQUIRED MEDICAL INFORMATION**

Documentation showing that the member is diagnosed with type 2 diabetes mellitus. Prior authorization does not apply to patients whose claim is submitted with an ICD-10 code indicating a diagnosis of type 2 diabetes mellitus or to patients who have a history of an antidiabetic drug (excluding a history of glucagon-like peptide receptor agonists (GLP-1 RAs) and combination glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 RAs).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# HAEGARDA

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## MEDICATION(S)

HAEGARDA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documentation of a diagnosis of hereditary angioedema (HAE). Confirmation that Haegarda is being used for prophylaxis against HAE attacks. Not to be used in combination with other approved treatments for prophylaxis against HAE attacks.

## AGE RESTRICTION

6 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or prescriber who specializes in the management of HAE.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

For reauthorization: Confirmation of reduction in severity or duration of attacks.

## PART B PREREQUISITE

N/A



# HARVONI

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## MEDICATION(S)

HARVONI

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

## REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of chronic Hepatitis C (CHC). Lab results must be attached: Hepatitis C virus (HCV) genotype, quantitative HCV RNA, complete blood count (CBC), international normalized ratio (INR), hepatic function panel (albumin, total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase levels), transient elastography (such as FibroScan) or noninvasive serologic tests (such as FibroSure or calculate FIB-4 score), Hepatitis B surface antigen (HBsAg), and HIV antigen/antibody test. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 to 24 weeks. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

## OTHER CRITERIA

Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

## PART B PREREQUISITE

N/A

## **HIGH RISK MEDICATION - ANTICHOLINERGIC AGENTS**

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### **MEDICATION(S)**

BENZTROPINE MESYLATE 0.5 MG TAB, BENZTROPINE MESYLATE 1 MG TAB, BENZTROPINE MESYLATE 2 MG TAB, CYCLOBENZAPRINE HCL 10 MG TAB, CYCLOBENZAPRINE HCL 5 MG TAB, PROMETHAZINE HCL 12.5 MG TAB, PROMETHAZINE HCL 25 MG TAB, PROMETHAZINE HCL 50 MG TAB, PROMETHAZINE HCL 6.25 MG/5ML SOLUTION, SCOPOLAMINE, TRIHEXYPHENIDYL HCL

### **PENDING CMS APPROVAL**

## **HIGH RISK MEDICATION - BUTALBITAL COMBINATIONS**

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### **MEDICATION(S)**

BAC, BUTALBITAL-APAP-CAFFEINE 50-325-40 MG TAB, BUTALBITAL-ASPIRIN-CAFFEINE 50-325-40 MG CAP

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Confirmation of the patient's diagnosis and indication for use of the High Risk Medication. Confirmation that a risk-versus-benefit assessment has been completed for use of the High Risk Medication.

Confirmation that the benefit outweighs the potential risk of the High Risk Medication.

### **AGE RESTRICTION**

Apply if patient is 65 years of age or older to ensure safe use of a potentially high risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

For reauthorization: Confirmation that the benefit continues to outweigh the potential risk of the High Risk Medication.

### **PART B PREREQUISITE**

N/A

## **HIGH RISK MEDICATION - NON-BENZODIAZEPINE SEDATIVE HYPNOTICS**

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### **MEDICATION(S)**

ESZOPICLONE, ZALEPLON, ZOLPIDEM TARTRATE 10 MG TAB

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Confirmation of the patient's diagnosis and indication for use of the High Risk Medication. Confirmation that a risk-versus-benefit assessment has been completed for use of the High Risk Medication. Confirmation that the benefit outweighs the potential risk of the High Risk Medication. Confirmation of an inadequate response or inability to tolerate two safer formulary alternatives, such as trazodone, ramelteon, or doxepin (generic Silenor).

### **AGE RESTRICTION**

Apply if patient is 65 years of age or older to ensure safe use of a potentially high risk medication in older adults. Patients under 65 years of age are not subject to the prior authorization requirements.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

For reauthorization: Confirmation that the benefit continues to outweigh the potential risk of the High Risk Medication.

### **PART B PREREQUISITE**

N/A

# HUMIRA

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## MEDICATION(S)

HUMIRA, HUMIRA (2 PEN), HUMIRA (2 SYRINGE), HUMIRA-CD/UC/HS STARTER, HUMIRA-PED $\geq$ 40KG UC STARTER, HUMIRA-PSORIASIS/UVEIT STARTER

## PA INDICATION INDICATOR

4 - All FDA-Approved Indications, Some Medically-Accepted Indications

## OFF LABEL USES

Active non-radiographic axial spondyloarthritis (nr-axSpA).

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documentation of PPD test results and treatment plan for active or latent infection. Documentation of diagnosis. For RA, PsA: Documentation of inadequate response, intolerance or contraindication to at least 1 conventional disease modifying anti-rheumatic drug (cDMARD) (e.g., methotrexate, hydroxychloroquine, sulfasalazine). For JIA: Documentation of inadequate response, intolerance, or contraindication to 1 cDMARD (e.g., methotrexate). For AS and nr-axSpA: Documentation of inadequate response, intolerance, or contraindication to at least 2 nonsteroidal anti-inflammatory drugs (NSAIDs). For PsO (moderate to severe disease): Documentation that patient is a candidate for systemic therapy or phototherapy and documentation of inadequate response, intolerance, or contraindication to methotrexate OR UVB therapy OR Acitretin (requires prior authorization). For PsO (limited disease): Documentation of inadequate response, intolerance, or contraindication to 1 topical steroid (high or very high potency) AND calcipotriene. For active CD: Documentation of inadequate response, intolerance, or contraindication to one of the following therapies: corticosteroids or a cDMARD (e.g., azathioprine, 6-mercaptopurine, methotrexate), or lost response to or intolerant to infliximab. For active UC: Documentation of inadequate response, intolerance, or contraindication to 1 of the following therapies: corticosteroids or a cDMARD (e.g., azathioprine, 6-MP).

## AGE RESTRICTION

RA, PsA, AS, nr-axSpA, and PsO: 18 years of age and older. For CD: 6 years of age and older. UC: 5 years of age and older. HS: 12 years of age and older. JIA and Uveitis: 2 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a rheumatologist, dermatologist, gastroenterologist, or

ophthalmologist.

**COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

For HS: Documentation of inadequate response, intolerance, or contraindication to 2 of the following therapies: topical antibiotics (e.g., clindamycin), oral antibiotics (e.g., doxycycline, minocycline, amoxicillin-clavulanic acid, clindamycin, rifampin, dapson), or intralesional triamcinolone injections. For Uveitis: Documentation of inadequate response, intolerance, or contraindication to at least 1 of the following: oral or topical glucocorticoids (e.g., prednisone), an immunosuppressant agent, or periocular or intraocular injection (e.g., triamcinolone). For reauthorization: Confirmation of positive clinical response.

**PART B PREREQUISITE**

N/A

# ICATIBANT

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## **MEDICATION(S)**

ICATIBANT ACETATE, SAJAZIR

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of a diagnosis of hereditary angioedema (HAE). Confirmation that icatibant is being used for the treatment of acute HAE attacks. Not to be used in combination with other approved treatments for acute HAE attacks.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with allergist, immunologist, pulmonologist, or prescriber who specializes in the management of HAE.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: Documentation of reduction in severity or duration of attacks.

## **PART B PREREQUISITE**

N/A

# **INBRIJA**

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## **MEDICATION(S)**

INBRIJA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of Parkinson's disease. Documentation that patient is experiencing OFF episodes. Confirmation that patient is currently being treated with carbidopa/levodopa.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: confirmation of positive clinical response.

## **PART B PREREQUISITE**

N/A



# **INCRELEX**

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## **MEDICATION(S)**

INCRELEX

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Closed epiphyses.

## **REQUIRED MEDICAL INFORMATION**

One of the following: Documentation of diagnosis of severe primary IGF1 deficiency. Diagnosis confirmed by: height standard deviation score of -3.0 or less, basal IGF-1 standard deviation score of -3.0 or less, and normal or elevated growth hormone (GH). Or, Documentation of diagnosis of growth hormone (GH) gene deletion with neutralizing antibodies to GH.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an endocrinologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: patient has a positive clinical response.

## **PART B PREREQUISITE**

N/A

## **INJECTABLE TESTOSTERONE PRODUCTS**

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### **MEDICATION(S)**

TESTOSTERONE CYPIONATE 100 MG/ML SOLUTION, TESTOSTERONE CYPIONATE 200 MG/ML SOLUTION, TESTOSTERONE ENANTHATE 200 MG/ML SOLUTION

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation confirming diagnosis. For hypogonadism: Confirmed low testosterone levels in comparison to lab reference values on two separate occasions. Explanation of symptoms experienced as a result of testosterone deficiency. Applies to new starts only.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

For reauthorization: Evaluation of response to testosterone therapy.

### **PART B PREREQUISITE**

N/A

## **INTRAVENOUS IMMUNE GLOBULIN (IVIG)**

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### **MEDICATION(S)**

BIVIGAM, FLEBOGAMMA DIF, GAMMAGARD, GAMMAGARD S/D LESS IGA, GAMMAKED, GAMMAPLEX, GAMUNEX-C, OCTAGAM, PANZYGA, PRIVIGEN

### **PENDING CMS APPROVAL**

# KERENDIA

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## MEDICATION(S)

KERENDIA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Concomitant treatment with strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin). Adrenal insufficiency. Estimated glomerular filtration rate (GFR) less than 25 mL/min. Serum potassium is greater than 5 mEq/L.

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of chronic kidney disease associated with type 2 diabetes (CKD with T2D). Documentation of concomitant therapy with an angiotensin-converting enzyme (ACE) inhibitor (e.g., lisinopril, ramipril) or angiotensin II receptor blocker (ARB) (e.g., losartan, irbesartan, valsartan) at maximally tolerated dose for diabetic nephropathy unless there is an intolerance or contraindication to these therapies. Documentation of inadequate response, intolerance, or contraindication to one sodium-glucose co-transporter 2 (SGLT2) inhibitor used for chronic kidney disease (e.g., Farxiga).

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



# **KESIMPTA**

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## **MEDICATION(S)**

KESIMPTA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Active HBV infection.

## **REQUIRED MEDICAL INFORMATION**

Documentation to show inadequate response, contraindication, or intolerance to 2 different agents used to treat MS.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Neurologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **L-GLUTAMINE ORAL POWDER**

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### **MEDICATION(S)**

L-GLUTAMINE 5 GM PACKET

**PENDING CMS APPROVAL**

## **LANREOTIDE EXTENDED RELEASE**

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### **MEDICATION(S)**

LANREOTIDE ACETATE, SOMATULINE DEPOT 60 MG/0.2ML SOLUTION, SOMATULINE DEPOT 90 MG/0.3ML SOLUTION

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of acromegaly. Baseline insulin-like growth factor-1 (IGF-1) level for age and/or gender is above the upper limit of normal based on laboratory reference range. The patient has had an inadequate response to surgery or radiation therapy OR there is a clinical reason why the patient has not had surgery or radiation therapy. Documented diagnosis of unresectable, well or moderately differentiated, locally advanced, or metastatic gastroenteropancreatic neuroendocrine tumors. Documented diagnosis of carcinoid syndrome with symptoms of flushing and/or diarrhea.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an endocrinologist, oncologist, or gastroenterologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

For reauthorization: the patient has had a positive clinical response.

### **PART B PREREQUISITE**

N/A



# **LIBERVANT**

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## **MEDICATION(S)**

LIBERVANT

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Acute narrow-angle glaucoma.

## **REQUIRED MEDICAL INFORMATION**

Confirmation of diagnosis. Applies to new starts only.

## **AGE RESTRICTION**

2 to 5 years of age.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist or pediatric specialist trained in management of epilepsy.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **LIDOCAINE PATCHES**

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### **MEDICATION(S)**

LIDOCAINE 5 % PATCH, LIDOCAN

### **PA INDICATION INDICATOR**

4 - All FDA-Approved Indications, Some Medically-Accepted Indications

### **OFF LABEL USES**

Diabetic peripheral neuropathy, cancer-related neuropathic pain.

### **EXCLUSION CRITERIA**

Patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

### **REQUIRED MEDICAL INFORMATION**

Documentation to confirm the diagnosis of pain associated with post-herpetic neuralgia, diabetic peripheral neuropathy, or cancer-related neuropathic pain.

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **LIVTENCITY**

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### **MEDICATION(S)**

LIVTENCITY

**PENDING CMS APPROVAL**

# **LUCEMYRA**

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## **MEDICATION(S)**

LUCEMYRA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Diagnosis of acute opioid withdrawal documented by an opioid withdrawal scale (such as Objective Opioid Withdrawal Scale [OOWS], Clinical Opioid Withdrawal Scale [COWS], Subjective Opioid Withdrawal Scale [SOWS]). Documentation must be attached. Documentation of an inadequate response, inability to tolerate, or contraindication to clonidine.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

14 days.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# MAVYRET

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## MEDICATION(S)

MAVYRET

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

## REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of chronic Hepatitis C (CHC). Lab results must be attached: Hepatitis C virus (HCV) genotype, quantitative HCV RNA, complete blood count (CBC), international normalized ratio (INR), hepatic function panel (albumin, total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase levels), transient elastography (such as FibroScan) or noninvasive serologic tests (such as FibroSure or calculate FIB-4 score), Hepatitis B surface antigen (HBsAg), and HIV antigen/antibody test. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

8 to 16 weeks. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

## OTHER CRITERIA

Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

## PART B PREREQUISITE

N/A

# **METYROSINE**

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## **MEDICATION(S)**

METYROSINE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. Documentation of inadequate response, intolerance, or contraindication to a selective alpha-blocker (e.g., doxazosin, prazosin, terazosin).

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# **MIFEPRISTONE**

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## **MEDICATION(S)**

MIFEPRISTONE 300 MG TAB

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Concurrent use of lovastatin, simvastatin, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinine, sirolimus, tacrolimus. Concurrent use of systemic corticosteroids for life-saving purposes such as immunosuppression following organ transplant.

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



## **MIGLUSTAT**

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### **MEDICATION(S)**

MIGLUSTAT, YARGESA

**PENDING CMS APPROVAL**

## **MYALEPT**

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### **MEDICATION(S)**

MYALEPT

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Patients with general obesity not associated with congenital leptin deficiency. Patients with HIV-related lipodystrophy. Patients with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of congenital or acquired generalized lipodystrophy.

### **REQUIRED MEDICAL INFORMATION**

Documentation showing confirmation of a diagnosis of congenital or acquired generalized lipodystrophy. Documentation of baseline labs (hemoglobin A1c, fasting plasma glucose, triglycerides).

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an endocrinologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

For reauthorization: Documentation showing benefit of treatment (as evidenced by decrease in at least one of the following: hemoglobin A1c, fasting glucose, and/or triglycerides).

### **PART B PREREQUISITE**

N/A

## **NEXLETOL AND NEXLIZET**

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### **MEDICATION(S)**

NEXLETOL, NEXLIZET

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. Documentation of prior treatment with statin therapy. Documentation discussing statin-associated side effects (rhabdomyolysis, muscle pain, muscle weakness associated with statin use) or contraindication (active liver disease, persistent elevation of serum transaminases) if statin therapy cannot be used. Documentation of prior treatment with ezetimibe therapy or intolerance/contraindication to ezetimibe. Documentation of baseline labs (lipid profile).

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

For reauthorization: Documentation of updated labs (lipid profile).

### **PART B PREREQUISITE**

N/A

# **NORDITROPIN**

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## **MEDICATION(S)**

NORDITROPIN FLEXPRO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For children: (1) Growth failure due to growth hormone deficiency (GHD) diagnosed via clinical assessment of appropriate auxological findings documented and attached (such as growth chart, height, height velocity, chronological and bone age) and at least 1 of the following: (a) Subnormal response to at least 2 provocative growth hormone (GH) stimulation tests (resulting in peak GH levels less than 10ng/mL) OR (b) Subnormal response to at least 1 provocative GH stimulation test (resulting in peak GH level less than 10ng/mL) AND subnormal insulin-like growth factor-1 (IGF-1) level OR (c) Subnormal IGF-1 level AND panhypopituitarism, pituitary disease, hypothalamic disease, hypothalamic/pituitary surgery, radiation therapy, or trauma. (2) Short stature associated with Noonan Syndrome, Prader-Willi Syndrome, or Turner Syndrome with attached documentation of appropriate genetic testing and assessment of characteristic clinical manifestations. (3) For short stature born small for gestational age with no catch-up growth by age 2-4 years, chart notes confirming diagnosis. (4) Idiopathic Short Stature (ISS) with (a) documentation of a height standard deviation score (SDS) less than -2.25 and associated with growth rates unlikely to allow one to reach normal adult height and (b) documentation of growth chart, growth potential, impaired height velocity for age group, and bone age. For adults: (5) Diagnosis of adult GHD (a) as a result of childhood onset of GHD due to organic disease (attach documentation) or (b) adult onset as a result of pituitary or hypothalamic disease, panhypopituitarism, hypothalamic/pituitary surgery, radiation therapy, or trauma, (c) confirmation of adult GHD via subnormal IGF-1 prior to or while off of GH, and (d) If IGF-1 is questionable or uncertain, confirmation of adult GHD via a subnormal GH response to provocative testing prior to or while off of GH therapy.

## **AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

Endocrinologist.

**COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

RENEWAL REQUESTS: chart notes (for children include documentation of growth chart, height velocity, chronological age, bone age, and linear growth potential remaining with open epiphyses) and for children and adults, documentation that the patient has tolerated the medication and has a normal IGF-1 level or will have their growth hormone dose adjusted to attain a normal IGF-1 concentration.

**PART B PREREQUISITE**

N/A

# **NUEDEXTA**

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## **MEDICATION(S)**

NUEDEXTA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Concomitant use with quinidine, quinine, or mefloquine. Patients with a history of quinidine, quinine or mefloquine-induced thrombocytopenia, hepatitis, or other hypersensitivity reactions. Use with an MAOI or within 14 days of stopping an MAOI. Prolonged QT interval, congenital long QT syndrome, torsades de pointes, heart failure, or complete atrioventricular (AV) block without implanted pacemaker. Concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimozone).

## **REQUIRED MEDICAL INFORMATION**

Confirmation of diagnosis of pseudobulbar affect (PBA). For patients at risk of QT prolongation and torsades de pointes, baseline ECG and an ECG evaluation 3-4 hours after the first dose.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# NUPLAZID

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## MEDICATION(S)

NUPLAZID

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of Parkinson's disease. Documentation of symptoms of psychosis with at least one of the following: hallucinations or delusions. Documentation of an inadequate response, intolerance, or contraindication to at least one of the following: quetiapine or clozapine. Applies to new starts only.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# NUZYRA

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## **MEDICATION(S)**

NUZYRA 100 MG RECON SOLN

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of community acquired bacterial pneumonia OR diagnosis of an acute bacterial skin and skin structure infection (ABSSSI). One of the following: (1) documentation of an inadequate response, intolerance, or contraindication to two antibiotics to which the organism is susceptible, (2) Nuzyra is the only antibiotic to which the organism is susceptible, (3) Therapy with Nuzyra was initiated in an inpatient setting.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with infectious disease specialist.

## **COVERAGE DURATION**

14 days.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



# OCALIVA

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## MEDICATION(S)

OCALIVA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Patients with decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event. Patients with compensated cirrhosis who have evidence of portal hypertension. Complete biliary obstruction.

## REQUIRED MEDICAL INFORMATION

Chart notes that document the patient's diagnosis of primary biliary cholangitis (PBC) confirmed by two of the following: a positive antimitochondrial antibody test, elevated serum alkaline phosphatase level, liver biopsy, or ultrasound scan of the liver. Confirmation that the patient was taking UDCA for at least one year without response and will continue treatment with UDCA while on Ocaliva or is unable to tolerate UDCA. Labs documenting liver function (AST/ALT, alkaline phosphatase, total bilirubin) and lipid panel. For renewals, updated labs documenting liver function and lipid panel and confirmation showing disease improvement while on therapy.

## AGE RESTRICTION

18 years of age or older.

## PRESCRIBER RESTRICTION

Hepatologist or gastroenterologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# OCTREOTIDE

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## MEDICATION(S)

OCTREOTIDE ACETATE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of acromegaly. Baseline insulin-like growth factor-1 (IGF-1) level for age and/or gender is above the upper limit of normal based on laboratory reference range. The patient has had an inadequate response to surgery or radiation therapy OR there is a clinical reason why the patient has not had surgery or radiation therapy. Documented diagnosis of metastatic carcinoid tumor. Patient requiring symptomatic treatment of severe diarrhea or flushing episodes. Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with an endocrinologist, oncologist, or gastroenterologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

For reauthorization: the patient has had a positive clinical response.

## PART B PREREQUISITE

N/A

## **OFEV**

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### **MEDICATION(S)**

OFEV

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation showing a diagnosis of idiopathic pulmonary fibrosis OR documentation showing a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype OR documentation showing that the medication will be used to slow the rate of decline in pulmonary function in patients with a diagnosis of systemic sclerosis-associated interstitial lung disease.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a pulmonologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## ORAL ONCOLOGY AGENTS

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### MEDICATION(S)

AKEEGA, ALECENSA, ALUNBRIG, AUGTYRO, AYVAKIT, BALVERSA, BEXAROTENE 75 MG CAP, BOSULIF, BRAFTOVI, BRUKINSA, CABOMETYX, CALQUENCE, CAPRELSA, COMETRIQ (100 MG DAILY DOSE), COMETRIQ (140 MG DAILY DOSE), COMETRIQ (60 MG DAILY DOSE), COPIKTRA, COTELLIC, DAURISMO, ERIVEDGE, ERLOTINIB HCL, EVEROLIMUS 10 MG TAB, EVEROLIMUS 2 MG TAB SOL, EVEROLIMUS 2.5 MG TAB, EVEROLIMUS 3 MG TAB SOL, EVEROLIMUS 5 MG TAB, EVEROLIMUS 5 MG TAB SOL, EVEROLIMUS 7.5 MG TAB, FOTIVDA, FRUZAQLA, GAVRETO, GEFITINIB, GILOTRIF, GLEOSTINE, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA 140 MG CAP, IMBRUVICA 140 MG TAB, IMBRUVICA 280 MG TAB, IMBRUVICA 420 MG TAB, IMBRUVICA 70 MG CAP, IMBRUVICA 70 MG/ML SUSPENSION, INLYTA, INQOVI, INREBIC, IWILFIN, JAKAFI, JAYPIRCA, KISQALI (200 MG DOSE), KISQALI (400 MG DOSE), KISQALI (600 MG DOSE), KISQALI FEMARA (200 MG DOSE), KISQALI FEMARA (400 MG DOSE), KISQALI FEMARA (600 MG DOSE), KOSELUGO, KRAZATI, LAPATINIB DITOSYLATE, LENALIDOMIDE, LENVIMA (10 MG DAILY DOSE), LENVIMA (12 MG DAILY DOSE), LENVIMA (14 MG DAILY DOSE), LENVIMA (18 MG DAILY DOSE), LENVIMA (20 MG DAILY DOSE), LENVIMA (24 MG DAILY DOSE), LENVIMA (4 MG DAILY DOSE), LENVIMA (8 MG DAILY DOSE), LONSURF, LORBRENA, LUMAKRAS, LYNPARZA, LYTGOBI (12 MG DAILY DOSE), LYTGOBI (16 MG DAILY DOSE), LYTGOBI (20 MG DAILY DOSE), MEKINIST, MEKTOVI, NERLYNX, NINLARO, ODOMZO, OGSIVEO, OJEMDA, OJJAARA, ONUREG, ORGOVYX, ORSERDU, PAZOPANIB HCL, PEMAZYRE, PIQRAY (200 MG DAILY DOSE), PIQRAY (250 MG DAILY DOSE), PIQRAY (300 MG DAILY DOSE), POMALYST, QINLOCK, RETEVMO, REZLIDHIA, ROZLYTREK, RUBRACA, RYDAPT, SCEMBLIX, SORAFENIB TOSYLATE, SPRYCEL, STIVARGA, SUNITINIB MALATE, TABRECTA, TAFINLAR, TAGRISSO, TALZENNA, TASIGNA, TAZVERIK, TEPMETKO, THALOMID, TIBSOVO, TRUQAP, TUKYSA, TURALIO 125 MG CAP, VANFLYTA, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VONJO, WELIREG, XALKORI, XOSPATA, XPOVIO (100 MG ONCE WEEKLY) 50 MG TAB THPK, XPOVIO (40 MG ONCE WEEKLY) 40 MG TAB THPK, XPOVIO (40 MG TWICE WEEKLY) 40 MG TAB THPK, XPOVIO (60 MG ONCE WEEKLY) 60 MG TAB THPK, XPOVIO (60 MG TWICE WEEKLY), XPOVIO (80 MG ONCE WEEKLY) 40 MG TAB THPK, XPOVIO (80 MG TWICE WEEKLY), ZEJULA 100 MG TAB, ZEJULA 200 MG TAB, ZEJULA 300 MG TAB, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA

### PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

### OFF LABEL USES

N/A

**EXCLUSION CRITERIA**

N/A

**REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. Applies to new starts only.

**AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

# OTEZLA

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## MEDICATION(S)

OTEZLA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Concomitant use with other disease-modifying antirheumatic drugs (DMARDs).

## REQUIRED MEDICAL INFORMATION

Confirmation of diagnosis. For active psoriatic arthritis and plaque psoriasis: Documentation showing a trial of, intolerance to, or contraindication to at least one DMARD indicated for the diagnosis. For oral ulcers associated with Behcets Disease: Documentation showing a trial of, intolerance to, or contraindication to colchicine.

## AGE RESTRICTION

6 years of age and older for treatment of plaque psoriasis, 18 years or older for treatment of psoriatic arthritis or Behcets Disease.

## PRESCRIBER RESTRICTION

Psoriatic arthritis: dermatologist or rheumatologist. Plaque psoriasis: dermatologist. Behcets Disease: rheumatologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

For reauthorization: Confirmation of positive clinical response.

## PART B PREREQUISITE

N/A

# **OXERVATE**

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## **MEDICATION(S)**

OXERVATE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Ophthalmologist.

## **COVERAGE DURATION**

8 weeks.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



# PANRETIN

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## MEDICATION(S)

PANRETIN

## PA INDICATION INDICATOR

3 - All Medically-Accepted Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documentation of diagnosis. Applies to new starts only.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Dermatologist, oncologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **PART D INSULIN SUPPLIES**

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### **MEDICATION(S)**

BD ALCOHOL PADS, GAUZE PADS & DRESSINGS - PADS 2 X 2, INSULIN PEN NEEDLE (NOVO/BD/ULTIMED/OWEN/TRIVIDIA), INSULIN SYRINGE (DISP) U-100 0.3 ML (BD/ULTIMED/ALLISON/TRIVIDIA/MHC), INSULIN SYRINGE (DISP) U-100 1 ML (BD/ULTIMED/ALLISON/TRIVIDIA/MHC) , INSULIN SYRINGE (DISP) U-100 1/2 ML (BD/ULTIMED/ALLISON/TRIVIDIA/MHC), ISOPROPYL ALCOHOL 0.7 ML/ML MEDICATED PAD, NEEDLES, INSULIN DISP., SAFETY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation showing that the member is diagnosed with diabetes mellitus. Documentation showing the patient will be using the requested product for the purpose of delivering insulin to the body. Prior authorization does not apply to patients who have filled insulin in the last 180 days.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A



## **PART D VS PART B**

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### **MEDICATION(S)**

ABELCET, ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, ACYCLOVIR SODIUM, ADRUCIL, ALBUTEROL SULFATE (2.5 MG/3ML) 0.083% NEBU SOLN, ALBUTEROL SULFATE (5 MG/ML) 0.5% NEBU SOLN, ALBUTEROL SULFATE 0.63 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 1.25 MG/3ML NEBU SOLN, ALBUTEROL SULFATE 2.5 MG/0.5ML NEBU SOLN, AMINOSYN II 10 % SOLUTION, AMINOSYN-PF, AMPHOTERICIN B 50 MG RECON SOLN, AMPHOTERICIN B LIPOSOME, APREPITANT, ARFORMOTEROL TARTRATE, AVASTIN, AZACITIDINE, AZATHIOPRINE 50 MG TAB, AZATHIOPRINE SODIUM, BORTEZOMIB 3.5 MG RECON SOLN, BUDESONIDE 0.25 MG/2ML SUSPENSION, BUDESONIDE 0.5 MG/2ML SUSPENSION, BUDESONIDE 1 MG/2ML SUSPENSION, CARBOPLATIN, CINACALCET HCL, CISPLATIN 100 MG/100ML SOLUTION, CISPLATIN 200 MG/200ML SOLUTION, CISPLATIN 50 MG/50ML SOLUTION, CLINIMIX/DEXTROSE (4.25/10), CLINIMIX/DEXTROSE (4.25/5), CLINIMIX/DEXTROSE (5/15), CLINIMIX/DEXTROSE (5/20), CLINISOL SF, CLINOLIPID, CROMOLYN SODIUM 20 MG/2ML NEBU SOLN, CYCLOPHOSPHAMIDE 25 MG CAP, CYCLOPHOSPHAMIDE 25 MG TAB, CYCLOPHOSPHAMIDE 50 MG CAP, CYCLOPHOSPHAMIDE 50 MG TAB, CYCLOSPORINE 100 MG CAP, CYCLOSPORINE 25 MG CAP, CYCLOSPORINE 50 MG/ML SOLUTION, CYCLOSPORINE MODIFIED, DOCETAXEL, ELIGARD, ENGERIX-B, ENVARBUS XR, EVEROLIMUS 0.25 MG TAB, EVEROLIMUS 0.5 MG TAB, EVEROLIMUS 0.75 MG TAB, EVEROLIMUS 1 MG TAB, FIRMAGON, FIRMAGON (240 MG DOSE), FLUOROURACIL 1 GM/20ML SOLUTION, FLUOROURACIL 2.5 GM/50ML SOLUTION, FLUOROURACIL 5 GM/100ML SOLUTION, FLUOROURACIL 500 MG/10ML SOLUTION, FORMOTEROL FUMARATE 20 MCG/2ML NEBU SOLN, FREAMINE III, FULVESTRANT, GENGRAF, GRANISETRON HCL 1 MG TAB, HEPLISAV-B, HERCEPTIN HYLECTA, INFLECTRA, INTRALIPID, IPRATROPIUM BROMIDE 0.02 % SOLUTION, IPRATROPIUM-ALBUTEROL, IRINOTECAN HCL, JYNNEOS, KADCYLA, KANJINTI, KEYTRUDA, LEUPROLIDE ACETATE 1 MG/0.2ML KIT, LEUPROLIDE ACETATE (3 MONTH), LEVALBUTEROL HCL 0.31 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 0.63 MG/3ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/0.5ML NEBU SOLN, LEVALBUTEROL HCL 1.25 MG/3ML NEBU SOLN, LUPRON DEPOT (1-MONTH), LUPRON DEPOT (3-MONTH), LUPRON DEPOT (4-MONTH), LUPRON DEPOT (6-MONTH), LUPRON DEPOT-PED (1-MONTH), LUPRON DEPOT-PED (3-MONTH), LUPRON DEPOT-PED (6-MONTH), MVASI, MYCOPHENOLATE MOFETIL 200 MG/ML RECON SUSP, MYCOPHENOLATE MOFETIL 250 MG CAP, MYCOPHENOLATE MOFETIL 500 MG RECON SOLN, MYCOPHENOLATE MOFETIL 500 MG TAB, MYCOPHENOLATE MOFETIL HCL, MYCOPHENOLATE SODIUM, MYCOPHENOLIC ACID, NULOJIX, NUTRILIPID, OGIVRI, ONDANSETRON 4 MG TAB DISP, ONDANSETRON 8 MG TAB DISP, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 8 MG TAB, ONDANSETRON HCL ORAL SOLN 4 MG/5ML,

OXALIPLATIN 100 MG RECON SOLN, OXALIPLATIN 100 MG/20ML SOLUTION, OXALIPLATIN 50 MG RECON SOLN, OXALIPLATIN 50 MG/10ML SOLUTION, PACLITAXEL, PACLITAXEL PROTEIN-BOUND PART, PARAPLATIN, PENTAMIDINE ISETHIONATE FOR NEBULIZATION SOLN 300 MG, PLENAMINE, PREHEVBRIO, PREMASOL, PROCRT, PROGRAF 0.2 MG PACKET, PROGRAF 1 MG PACKET, PROSOL, PULMOZYME, RECOMBIVAX HB, RENFLEXIS, RETACRIT, RUXIENCE, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG TAB, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TAB, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TOBRAMYCIN 300 MG/5ML NEBU SOLN, TPN ELECTROLYTES, TRAVASOL, TRAZIMERA, TRELSTAR MIXJECT, TROPHAMINE, TRUXIMA, YUPELRI, ZIRABEV, ZOLEDRONIC ACID 4 MG/5ML CONC, ZOLEDRONIC ACID 5 MG/100ML SOLUTION

## **DETAILS**

This drug may be covered under Medicare Part B or D depending on the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

## **PEGFILGRASTIM AGENTS**

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### **MEDICATION(S)**

FULPHILA

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

For primary prophylaxis of febrile neutropenia: Documentation that shows that patient is receiving myelosuppressive chemotherapy. Documentation that shows that patient is at increased risk for febrile neutropenia. Documentation that shows that patient is receiving dose-dense or high-dose chemotherapy. For secondary prophylaxis of febrile neutropenia: documentation that shows the patient is receiving myelosuppressive chemotherapy with a history of febrile neutropenia during previous course of chemotherapy (for which primary prophylaxis was not received). For all diagnoses, confirmation that lab work (complete blood count with differential including ANC) is being monitored.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **PHOSPHODIESTERASE 5 INHIBITORS**

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### **MEDICATION(S)**

ALYQ, SILDENAFIL CITRATE 20 MG TAB, TADALAFIL (PAH)

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant organic nitrates. Concomitant Guanylate Cyclase (GC) Stimulators.

### **REQUIRED MEDICAL INFORMATION**

Confirmation of diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1. Diagnosis confirmed by a complete right heart catheterization (RHC). PAH defined as a resting mean pulmonary artery pressure (mPAP) of greater than 20 mmHg, pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg, and pulmonary vascular resistance (PVR) of greater than 3 Wood units (RHC results must be provided). For Raynaud's phenomenon: Confirmation of an inadequate response or intolerance to one calcium channel blocker.

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a cardiologist, pulmonologist, practitioner at a Pulmonary Hypertension Association-Accredited center, or rheumatologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **PIRFENIDONE**

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## **MEDICATION(S)**

PIRFENIDONE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity, Hermansky-Pudlak syndrome, familial idiopathic pulmonary fibrosis, and chronic hypersensitivity pneumonitis).

## **REQUIRED MEDICAL INFORMATION**

Initial request: Documented diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by usual interstitial pneumonia (UIP) pattern present on high resolution computed tomography (HRCT) in patients without lung biopsy, or the combination of HRCT and biopsy pattern in patients with lung biopsy. Documented forced vital capacity (FVC) greater than or equal to 50%. Documented baseline liver function tests (ALT, AST, and bilirubin) and documentation that liver function tests (ALT, AST, and bilirubin) will be monitored periodically throughout the course of treatment as clinically necessary. For ongoing therapy: Documentation of rationale for continued IPF therapy (e.g., stability or improvement in the rate of decline for FVC, IPF symptoms, or other prescriber-assessed benefit of therapy). Confirmation that liver function tests (ALT, AST, and bilirubin) are being monitored periodically throughout the course of treatment as clinically indicated.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a pulmonologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**



N/A

**PART B PREREQUISITE**

N/A

# POSACONAZOLE

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## MEDICATION(S)

POSACONAZOLE 100 MG TAB DR, POSACONAZOLE 40 MG/ML SUSPENSION

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Patients with known hypersensitivity to posaconazole or other azole antifungal agents. Concurrent use with sirolimus, CYP3A4 substrates (pimozide, quinidine), HMG-CoA reductase inhibitors primarily metabolized through CYP3A4, ergot alkaloids, or venetoclax.

## REQUIRED MEDICAL INFORMATION

Documentation of use for treatment of invasive Aspergillosis OR prophylaxis of invasive Aspergillus and Candida infections in severely immunocompromised patients (hematopoietic stem cell transplant (HSCT) recipients with graft-versus host-disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy) OR diagnosis of oropharyngeal candidiasis.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

6 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **PREGABALIN ER**

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### **MEDICATION(S)**

PREGABALIN ER

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation to confirm the diagnosis of pain associated with post-herpetic neuralgia (PHN) or diabetic peripheral neuropathy (DPN). Documentation of an inadequate response or inability to tolerate gabapentin and immediate release Lyrica. Dosage prescribed within package insert requirements (maximum of 330 mg per day for DPN, maximum of 660 mg per day for PHN).

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# PREVYMIS

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## MEDICATION(S)

PREVYMIS 240 MG TAB, PREVYMIS 480 MG TAB

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For prophylaxis of cytomegalovirus (CMV) infection or disease in hematopoietic stem cell transplant (HSCT): 1) the patient is CMV-seropositive, AND 2) the patient is a recipient of an allogeneic HSCT. For prophylaxis of CMV disease in kidney transplant: 1) the patient is CMV-seronegative, AND 2) the patient is a high-risk recipient of kidney transplant where donor is CMV seropositive.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

7 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# **PYRIMETHAMINE**

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## **MEDICATION(S)**

PYRIMETHAMINE 25 MG TAB

## **PA INDICATION INDICATOR**

4 - All FDA-Approved Indications, Some Medically-Accepted Indications

## **OFF LABEL USES**

Primary and secondary prophylaxis of toxoplasmosis in patients with HIV, Prophylaxis of pneumocystis jirovecii pneumonia in patients with HIV.

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For all diagnoses: Documentation of an inadequate response, intolerance, or contraindication to trimethoprim-sulfamethoxazole. For acute treatment of toxoplasmosis: Confirmation of severe or prolonged symptoms that warrants treatment. For primary prophylaxis of toxoplasmosis gondii (T. gondii) infection all of the following: (1) Confirmed diagnosis of HIV, (2) Documentation of CD4 count less than 100 cells/mm<sup>3</sup>, AND (3) T. gondii IgG positive. For secondary prophylaxis of toxoplasmosis gondii infection all of the following: (1) Confirmed diagnosis of HIV, (2) CD4 count less than 200 cells/mm<sup>3</sup>. For primary prophylaxis of Pneumocystis jirovecii pneumonia: (1) Confirmed diagnosis of HIV, (2) CD4 count less than 200 cells/mm<sup>3</sup>.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with infectious disease specialist.

## **COVERAGE DURATION**

For acute treatment of toxoplasmosis: 1 month. For all other diagnoses: 12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **QUININE**

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### **MEDICATION(S)**

QUININE SULFATE 324 MG CAP

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Treatment or prevention of leg cramps.

### **REQUIRED MEDICAL INFORMATION**

One of the following: Documentation of diagnosis of uncomplicated Plasmodium falciparum malaria with confirmation of chloroquine resistance. Or, documentation of diagnosis of babesiosis and quinine will be used in combination with clindamycin.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

1 month.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **RAVICTI**

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## **MEDICATION(S)**

RAVICTI

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Not indicated for the treatment of acute hyperammonemia in patients with UCDs nor for the treatment of N-acetylglutamate synthase (NAGS) deficiency. Concomitant use with another phenylbutyrate product (like sodium phenylbutyrate).

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis by enzymatic, biochemical, or genetic testing attached. Documentation of inadequate response, intolerance, or contraindication to sodium phenylbutyrate. Confirmation that ammonia concentration and serum amino acids are and will continue to be monitored to ensure positive clinical treatment response.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a metabolic or medical genetic specialist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A



## **RECORLEV**

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### **MEDICATION(S)**

RECORLEV

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis of Cushing's Syndrome. Notes showing the member is being treated for endogenous hypercortisolemia (e.g., pituitary tumor, ectopic tumor, adrenal adenoma, or carcinoma). Notes showing that the member is not a candidate for surgery OR has recurrent hypercortisolism after initial surgery. Documentation showing a trial of, intolerance to, or contraindication to ketoconazole.

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an endocrinologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

For reauthorization: confirmation of positive clinical response.

### **PART B PREREQUISITE**

N/A

# REGRANEX

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## MEDICATION(S)

REGRANEX

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documentation to confirm the diagnosis for use on lower extremity diabetic neuropathic ulcers.

## AGE RESTRICTION

16 years of age and older.

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

5 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# REPATHA

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## **MEDICATION(S)**

REPATHA, REPATHA PUSHTRONEX SYSTEM, REPATHA SURECLICK

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# REZUROCK

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## MEDICATION(S)

REZUROCK

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Pregnancy.

## REQUIRED MEDICAL INFORMATION

If female of childbearing age or male with female partners of reproductive potential, confirmation that effective contraception will be used during treatment. Confirmation of a trial and failure of at least 2 conventional systemic treatments for chronic graft-versus-host disease.

## AGE RESTRICTION

12 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with an oncologist, hematologist, or bone marrow transplant specialist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# RINVOQ

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## MEDICATION(S)

RINVOQ

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Severe hepatic impairment. Active, serious infection. Live vaccines. Concomitant use with Janus kinase (JAK) inhibitor, biologic disease modifying anti-rheumatic drugs (DMARDs), potent immunosuppressant drugs, strong cytochrome P450 3A4 (CYP3A4) inducers, biologic immunomodulators, or biological therapies for ulcerative colitis.

## REQUIRED MEDICAL INFORMATION

For a documented diagnosis of moderately to severely active rheumatoid arthritis (RA), active psoriatic arthritis (PsA), moderately to severely active ulcerative colitis (UC), active ankylosing spondylitis (AS), active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, moderately to severely active Crohn's disease (CD), or polyarticular juvenile idiopathic arthritis (pJIA): attach documentation of inadequate response or intolerance to at least one TNF blocker. For a documented diagnosis of refractory, moderate to severe atopic dermatitis (AD), attach a documented history of inadequate control with at least one other systemic drug (including biologics) used to treat refractory, moderate to severe atopic dermatitis OR documentation explaining why these drugs are inadvisable. For all diagnoses: confirmation that recent tuberculin testing is negative for latent tuberculosis infection or positive for latent tuberculosis with confirmation that treatment is completed or is receiving treatment for latent tuberculosis. Confirmation that liver function will be monitored with focus on elevated liver enzymes (ALT or AST). Confirmation that a complete blood count with differential does not show an absolute lymphocyte count less than 500 cells/mm<sup>3</sup>, absolute neutrophil count less than 1000 cells/mm<sup>3</sup>, or hemoglobin level less than 8g/dL.

## AGE RESTRICTION

RINVOQ - 12 years of age and older for AD and 18 years and older for AS, CD, RA, UC and nr-axSpA.  
RINVOQ / RINVOQ LQ – 2 years of age and older for pJIA and PsA.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with the appropriate specialist based on diagnosis: a gastroenterologist, rheumatologist, or dermatologist.

**COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

For reauthorization: Confirmation of positive clinical response.

**PART B PREREQUISITE**

N/A

# RUFINAMIDE

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## MEDICATION(S)

RUFINAMIDE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of Lennox-Gastaut Syndrome (LGS). Documentation showing rufinamide will be used as adjunctive therapy. Documentation of an inadequate response, intolerance, or contraindication to at least one of the following: valproic acid derivatives, lamotrigine, clobazam, topiramate, cannabidiol (pharmaceutical). Applies to new starts only.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with neurologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **SAPROPTERIN**

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### **MEDICATION(S)**

JAVYGTOR, SAPROPTERIN DIHYDROCHLORIDE

**PENDING CMS APPROVAL**



# **SIGNIFOR**

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## **MEDICATION(S)**

SIGNIFOR

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis of Cushing's disease and ONE of the following: patient is not a candidate for pituitary surgery OR pituitary surgery has not been curative.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an endocrinologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: confirmation of decrease in urinary free cortisol levels from baseline.

## **PART B PREREQUISITE**

N/A

# **SIRTURO**

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## **MEDICATION(S)**

SIRTURO

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB). Documentation that Sirturo is being used in combination with at least 3 other medications to which the patient's MDR-TB isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, Sirturo is being used in combination with at least 4 other medications to which the patient's MDR-TB isolate is likely to be susceptible.

## **AGE RESTRICTION**

5 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an infectious disease specialist.

## **COVERAGE DURATION**

24 weeks.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# SIVEXTRO

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## MEDICATION(S)

SIVEXTRO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of an acute bacterial skin and skin structure infection (ABSSSI) and ONE of the following: (1) documentation of an inadequate response, intolerance, or contraindication to two antibiotics to which the organism is susceptible, (2) Sivextro is the only antibiotic to which the organism is susceptible, or (3) Therapy with Sivextro was initiated in an inpatient setting.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with infectious disease specialist.

## COVERAGE DURATION

6 days.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# SKYRIZI

---

## MEDICATION(S)

SKYRIZI, SKYRIZI PEN

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Active, serious infection. Live vaccines.

## REQUIRED MEDICAL INFORMATION

For plaque psoriasis: Confirmed diagnosis of moderately to severely active plaque psoriasis supported by clinical documentation. Documentation of inadequate response, intolerance, or contraindication to methotrexate or UVB therapy (alone or in combination with other medications) or acitretin. For psoriatic arthritis: Confirmed diagnosis of active psoriatic arthritis supported by clinical documentation. Documentation of inadequate response, intolerance, or contraindication to at least one DMARD. For moderately to severely active Crohn's disease: Confirmed diagnosis of moderately to severely active Crohn's disease supported by clinical documentation. Documentation of inadequate response, intolerance, or contraindication to one of the following: corticosteroids, methotrexate, or azathioprine. For all diagnoses: Documentation of tuberculin testing that is negative for latent tuberculosis infection or positive for latent tuberculosis with documentation that treatment is completed or is receiving treatment for latent tuberculosis.

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

For reauthorization: Confirmation of positive clinical response.

**PART B PREREQUISITE**

N/A

## **SODIUM OXYBATE**

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### **MEDICATION(S)**

SODIUM OXYBATE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant use with sedative hypnotics. Succinic semialdehyde dehydrogenase deficiency.

### **REQUIRED MEDICAL INFORMATION**

Documentation showing a diagnosis of excessive daytime sleepiness or cataplexy with narcolepsy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Neurologist or sleep specialist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **SODIUM PHENYLBUTYRATE**

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## **MEDICATION(S)**

SODIUM PHENYLBUTYRATE 3 GM/TSP POWDER, SODIUM PHENYLBUTYRATE 500 MG TAB

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Treatment of acute hyperammonemia in urea cycle disorders.

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis of urea cycle disorder involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS) confirmed by enzymatic, biochemical, or genetic testing. Confirmation showing sodium phenylbutyrate will be used for chronic management.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with prescriber experienced in metabolic disorders.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **SOFOSBUVIR/VELPATASVIR**

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### **MEDICATION(S)**

EPCLUSA, SOFOSBUVIR-VELPATASVIR

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

### **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis of chronic Hepatitis C (CHC). Lab results must be attached: Hepatitis C virus (HCV) genotype, quantitative HCV RNA, complete blood count (CBC), international normalized ratio (INR), hepatic function panel (albumin, total and direct bilirubin, alanine aminotransferase, aspartate aminotransferase, and alkaline phosphatase levels), transient elastography (such as FibroScan) or noninvasive serologic tests (such as FibroSure or calculate FIB-4 score), Hepatitis B surface antigen (HBsAg), and HIV antigen/antibody test. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 to 24 weeks. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

### **OTHER CRITERIA**

Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

### **PART B PREREQUISITE**

N/A



# SOMAVERT

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## MEDICATION(S)

SOMAVERT

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of acromegaly. Baseline insulin-like growth factor-1 (IGF-1) level for age and/or gender is above the upper limit of normal based on laboratory reference range. The patient has had an inadequate response to surgery or radiation therapy OR there is a clinical reason why the patient has not had surgery or radiation therapy. Documentation of an inadequate response, intolerance, or contraindication to octreotide.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with an endocrinologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

For reauthorization: the patient has had a positive clinical response.

## PART B PREREQUISITE

N/A

## **STELARA**

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### **MEDICATION(S)**

STELARA

**PENDING CMS APPROVAL**

# **SYMPAZAN**

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## **MEDICATION(S)**

SYMPAZAN

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of an inadequate response or inability to tolerate generic clobazam. Documentation showing that Sympazan will be used as adjunctive therapy to other antiepileptic drugs. Applies to new starts only.

## **AGE RESTRICTION**

2 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

## **TADALAFIL BPH**

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### **MEDICATION(S)**

TADALAFIL 2.5 MG TAB, TADALAFIL 5 MG TAB

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concomitant organic nitrates. Concomitant Guanylate Cyclase (GC) Stimulators. Treatment of erectile dysfunction (ED) in the absence of benign prostatic hyperplasia (BPH).

### **REQUIRED MEDICAL INFORMATION**

Documentation showing a diagnosis of benign prostatic hyperplasia (BPH). Confirmation of an inadequate response or inability to tolerate at least one alpha blocker (such as tamsulosin, silodosin, alfuzosin) AND confirmation of an inadequate response or inability to tolerate at least one 5-alpha-reductase inhibitor (such as dutasteride, finasteride).

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# TALTZ

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## MEDICATION(S)

TALTZ

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Concurrent therapy with biologic DMARDs or tumor necrosis factor antagonists.

## REQUIRED MEDICAL INFORMATION

Confirmation of diagnosis of moderate-to-severe plaque psoriasis (PsO), active psoriatic arthritis (PsA), active ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. For PsO: in pediatric patients ages 6-17 years, documentation of an inadequate response, intolerance, or contraindication to Enbrel and in adults with PsO documentation of inadequate response, intolerance, or contraindication to Enbrel, Humira, Otezla, or Skyrizi. For PsA: documentation of inadequate response, intolerance, or contraindication to Enbrel, Humira, Otezla, Rinvoq, Skyrizi, or Xeljanz/Xeljanz XR. For AS: documentation of inadequate response, intolerance, or contraindication: Enbrel, Humira, Rinvoq, or Xeljanz/Xeljanz XR. For nr-axSpA: documentation of inadequate response, intolerance, or contraindication to Rinvoq. For all indications: Confirmation of tuberculosis (TB) screening results and treatment plan for active or latent infection.

## AGE RESTRICTION

For moderate-to-severe PsO: 6 years of age or older. For active PsA, active AS and nr-axSpA: 18 years of age or older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a rheumatologist or dermatologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

For reauthorization: Confirmation of positive clinical response.

**PART B PREREQUISITE**

N/A

# **TASIMELTEON**

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## **MEDICATION(S)**

HETLIOZ LQ, TASIMELTEON

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

For Non-24-Hour Sleep-Wake Disorder (Non-24): Documentation of diagnosis of complete blindness. Documentation of diagnosis of Non-24 indicated by actigraphy or sleep log or diary. Documentation of baseline nighttime sleep time and daytime naptime per sleep log or diary. For nighttime sleep disturbances in Smith-Magens Syndrome (SMS): Documentation of diagnosis confirmed by genetic testing. Documentation of sleep disturbances.

## **AGE RESTRICTION**

Capsules: 16 years of age and older. Oral suspension: 3 to 15 years of age.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a sleep specialist, psychiatrist, or neurologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization for Non-24: Documentation of response indicated by improvement in nighttime sleep time or reduction in daytime naptime compared to baseline per sleep log or diary. For renewal for nighttime sleep disturbances in Smith-Magens Syndrome (SMS): Documentation of response indicated by improvement in sleep disturbances including difficulty falling asleep, problems staying asleep, and frequent awakenings at night as documented per chart notes.

## **PART B PREREQUISITE**

N/A



# TAVNEOS

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## MEDICATION(S)

TAVNEOS

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]). Used as adjunct to standard therapy OR in combination with standard therapy (e.g., rituximab, cyclophosphamide, mycophenolate, azathioprine, and/or glucocorticoids).

## AGE RESTRICTION

18 years of age or older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist.

## COVERAGE DURATION

6 months initial. 12 months reauthorization.

## OTHER CRITERIA

For reauthorization: confirmation of disease stability or improvement.

## PART B PREREQUISITE

N/A

# **TERIPARATIDE**

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## **MEDICATION(S)**

TERIPARATIDE (RECOMBINANT) 620 MCG/2.48ML SOLN PEN

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis of osteoporosis (primary or hypogonadal in men, glucocorticoid-induced or postmenopausal in women). Baseline labs (T-score). Documentation of an inadequate response or inability to tolerate at least one of the following: bisphosphonates, hormone replacement therapy, selective-estrogen receptor modulators (SERMs) or Denosumab (Prolia).

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization, one of the following: Cumulative lifetime therapy does not exceed 2 years OR member remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones.

## **PART B PREREQUISITE**

N/A

# **TETRABENAZINE**

---

## **MEDICATION(S)**

TETRABENAZINE

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Congenital long QT syndrome. History of cardiac arrhythmias. Hepatic impairment. Concurrent use of MAO inhibitors. Concurrent use of reserpine, deutetrabenazine, or valbenazine. Actively suicidal patients and patients with untreated or inadequately treated depression.

## **REQUIRED MEDICAL INFORMATION**

Documentation showing that other movement disorders (such as Tardive Dyskinesia or Parkinsons disease) have been excluded with documentation attached. Documentation showing confirmation of a diagnosis of Chorea associated with Huntingtons Disease with documentation attached.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist or psychiatrist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: Documented improvement in symptoms of Chorea with medical records attached.

## **PART B PREREQUISITE**

N/A

## **TOPICAL RETINOIDS**

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### **MEDICATION(S)**

TAZAROTENE 0.05 % GEL, TAZAROTENE 0.1 % CREAM, TAZAROTENE 0.1 % GEL, TAZORAC 0.05 % CREAM, TRETINOIN 0.01 % GEL, TRETINOIN 0.025 % CREAM, TRETINOIN 0.025 % GEL, TRETINOIN 0.05 % CREAM, TRETINOIN 0.1 % CREAM

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **TOPICAL TESTOSTERONE PRODUCTS**

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### **MEDICATION(S)**

TESTOSTERONE 12.5 MG/ACT (1%) GEL, TESTOSTERONE 20.25 MG/ACT (1.62%) GEL, TESTOSTERONE 25 MG/2.5GM (1%) GEL, TESTOSTERONE 50 MG/5GM (1%) GEL, TESTOSTERONE TD GEL PUMP 20.25 MG/ACT (1.62%)

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Men with carcinoma of the breast or known or suspected prostate cancer. Women who are pregnant.

### **REQUIRED MEDICAL INFORMATION**

Documentation confirming diagnosis. For hypogonadism: Confirmed low testosterone levels in comparison to lab reference values on two separate occasions. Explanation of symptoms experienced as a result of testosterone deficiency.

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

For reauthorization: Evaluation of response to testosterone therapy.

### **PART B PREREQUISITE**

N/A

## UPTRAVI

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### **MEDICATION(S)**

UPTRAVI 1000 MCG TAB, UPTRAVI 1200 MCG TAB, UPTRAVI 1400 MCG TAB, UPTRAVI 1600 MCG TAB, UPTRAVI 200 & 800 MCG TAB THPK, UPTRAVI 200 MCG TAB, UPTRAVI 400 MCG TAB, UPTRAVI 600 MCG TAB, UPTRAVI 800 MCG TAB

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Concurrent use with strong inhibitors of CYP2C8 (e.g., gemfibrozil).

### **REQUIRED MEDICAL INFORMATION**

Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH) WHO Group 1 with New York Heart Association (NYHA) Functional Class II-III by complete right catheterization (RHC) with results attached. Mean pulmonary artery pressure (mPAP) greater than 20 mmHg, pulmonary vascular resistance (PVR) greater than 3 wood units, and a pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg. Pharmacy records or chart notes documenting trial of or inadequate response to two alternatives (used alone or in combination) from the following list of medications: endothelin receptor antagonists (bosentan, ambrisentan, macitentan), phosphodiesterase-5 inhibitors (sildenafil, tadalafil), guanylate cyclase stimulators (riociguat). Clarify there is a treatment plan. Chart notes that document required lab monitoring [hepatic impairment status (Child Pugh Class)] and dosing adjustments as needed.

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a cardiologist, pulmonologist, or practitioner at a Pulmonary Hypertension Association-Accredited center.

### **COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

# VALCHLOR

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## MEDICATION(S)

VALCHLOR

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma. Documentation of an inadequate response, intolerance, or contraindication to at least one prior skin-directed therapy (e.g. topical corticosteroids, topical retinoids, topical imiquimod). Applies to new starts only.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A



# VERQUVO

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## MEDICATION(S)

VERQUVO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documentation of symptomatic chronic heart failure with NYHA Class II to IV. The patient has a left ventricular ejection fraction (LVEF) less than 45 percent. For initial therapy, the patient meets ONE of the following: (1) hospitalization for heart failure within the past 6 months OR (2) use of outpatient intravenous diuretics for heart failure within the past 3 months.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

For reauthorization: patient has had a positive clinical response to therapy.

## PART B PREREQUISITE

N/A

# VIGABATRIN

---

## MEDICATION(S)

VIGABATRIN, VIGADRONE, VIGPODER

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of refractory complex partial seizures or infantile spasms. For refractory complex partial seizures: documentation that vigabatrin is being used as adjunctive therapy AND documentation of an inadequate response, intolerance, or contraindication to two antiepileptic agents such as: carbamazepine, divalproex, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, topiramate, zonisamide. Applies to new starts only.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a neurologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

# VORICONAZOLE

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## **MEDICATION(S)**

VORICONAZOLE 200 MG RECON SOLN

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

N/A

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

6 months.

## **OTHER CRITERIA**

N/A

## **PART B PREREQUISITE**

N/A

# VOWST

---

## MEDICATION(S)

VOWST

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Active *Clostridioides difficile* infection (CDI).

## REQUIRED MEDICAL INFORMATION

Documentation to confirm Vowst is being used to prevent the recurrence of CDI. The patient has experienced at least 2 recurrent CDIs. The patient has or will complete CDI standard of care treatment (defined as 10-21 days of treatment with vancomycin and/or fidaxomicin) 2-4 days prior to initiating treatment with Vowst. The patient has or will complete a bowel prep and will not eat or drink for at least 8 hours prior to the first dose.

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a gastroenterologist or infectious disease specialist.

## COVERAGE DURATION

30 days.

## OTHER CRITERIA

N/A

## PART B PREREQUISITE

N/A

## **WAKEFULNESS-PROMOTING AGENTS**

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### **MEDICATION(S)**

ARMODAFINIL, MODAFINIL 100 MG TAB, MODAFINIL 200 MG TAB

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

A confirmed diagnosis of either narcolepsy (with sleep study attached), obstructive sleep apnea (with sleep study attached), or shift work disorder.

### **AGE RESTRICTION**

17 years of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **XCOPRI**

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### **MEDICATION(S)**

XCOPRI, XCOPRI (250 MG DAILY DOSE) 100 & 150 MG TAB THPK, XCOPRI (350 MG DAILY DOSE)

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of partial-onset seizures. Documentation of an inadequate response, intolerance, or contraindication to two of the following drugs: carbamazepine, divalproex, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, topiramate. Applies to new starts only.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a neurologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

## **XDEMZY**

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### **MEDICATION(S)**

XDEMZY

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

6 weeks.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A

# **XELJANZ**

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## **MEDICATION(S)**

XELJANZ, XELJANZ XR

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Concomitant use with other biologic Disease Modifying Anti-Rheumatic Drugs (DMARDs) or potent immunosuppressants.

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. Documentation of tuberculosis screening results and treatment plan for active or latent infection. For all diagnoses, RA, PsA, AS, UC, pcJIA, documentation of an inadequate response or intolerance to at least one TNF blocker indicated to treat the diagnosis.

## **AGE RESTRICTION**

2 years and older for polyarticular course juvenile idiopathic arthritis. 18 years and older for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a rheumatologist or gastroenterologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

For reauthorization: Confirmation of positive clinical response.

## **PART B PREREQUISITE**

N/A



## **XERMELO**

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### **MEDICATION(S)**

XERMELO

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis of carcinoid syndrome diarrhea (CSD). Notes showing diarrhea is inadequately controlled by at least a 3-month trial of somatostatin analog therapy (SSA). Must provide documentation showing average of at least 4 bowel movements per day despite use of SSA therapy (e.g. Sandostatin LAR Depot). Must have records confirming concurrent SSA therapy.

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist.

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

For reauthorization: Confirmation of positive clinical response to therapy.

### **PART B PREREQUISITE**

N/A

# **XGEVA**

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## **MEDICATION(S)**

XGEVA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Patients currently being treated with Prolia.

## **REQUIRED MEDICAL INFORMATION**

Subject to Part B vs Part D review. INITIAL: Documentation Xgeva will be used for one the following: prevention of skeletal-related events in patients with multiple myeloma and patients with bone metastases from solid tumors, treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity or hypercalcemia of malignancy refractory to bisphosphonates. For the prevention of skeletal-related events in patients with multiple myeloma and patients with bone metastases from solid tumors: documentation showing a trial of, intolerance to, or contraindication to zoledronic acid. For a diagnosis hypercalcemia of malignancy that is refractory to bisphosphonates: documentation of albumin-corrected calcium greater than 12.5 mg/dL. Documentation must be attached. Documentation of a trial of, intolerance to, or contraindication to IV bisphosphonates. For all diagnoses: documentation showing calcium levels were checked and will be monitored. Documentation showing calcium levels were corrected prior to therapy. Documentation showing the patient will be receiving supplementation with calcium and vitamin D. Documentation showing that an oral exam was done, and appropriate preventive dentistry was done prior to starting. Documentation showing that the patient is not pregnant or planning to become pregnant while on Xgeva if applicable. Documentation showing the patient will be using highly effective contraception during treatment and for at least 5 months after the last dose of Xgeva if applicable. RENEWALS: diagnosis of hypercalcemia of malignancy that is refractory to bisphosphonates: documentation that the corrected serum calcium is less than 11.5 mg/dL. Documentation must be attached. All diagnoses: documentation showing improvement or stabilization of disease.

## **AGE RESTRICTION**

N/A

**PRESCRIBER RESTRICTION**

Hematologist or oncologist.

**COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

# **XIFAXAN**

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## **MEDICATION(S)**

XIFAXAN

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Hypersensitivity to rifaximin, any of the rifamycin antimicrobial agents, or any component of the formulation.

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis of Traveler's Diarrhea (TD) caused by noninvasive strains of *Escherichia coli*, Hepatic Encephalopathy (HE), or Irritable Bowel Syndrome (IBS) with diarrhea. For TD: Documentation of inadequate response, intolerance, or contraindication to azithromycin or a fluoroquinolone (e.g., ciprofloxacin, levofloxacin). Documentation of dosing as 200 mg tablet 3 times a day. For HE: Documentation of inadequate response, intolerance, or contraindication to lactulose. Documentation of dosing as 550 mg tablet 2 times a day. For IBS with diarrhea: Documentation of inadequate response, intolerance, or contraindication to one antispasmodic agent (e.g., dicyclomine) or one anti-diarrheal agent (e.g., diphenoxylate/atropine, loperamide). Documentation of dosing as 550 mg tablet 3 times a day.

## **AGE RESTRICTION**

12 years of age and older for TD. 18 years of age and older for IBS with diarrhea or HE.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist.

## **COVERAGE DURATION**

TD: 3 days. HE: 12 months. IBS with diarrhea: 3 treatments (14 days per treatment) per 1 year.

## **OTHER CRITERIA**

N/A

**PART B PREREQUISITE**

N/A

# XOLAIR

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## MEDICATION(S)

XOLAIR

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

For moderate to severe persistent asthma: Chart notes that show patient had at least a 3 month trial of OR intolerance to oral corticosteroids and/or combination therapies (inhaled steroids, long acting beta-agonists, antileukotrienes, theophylline). Chart notes that show patient has daily asthma symptoms (coughing, wheezing, dyspnea), daily use of rescue inhalers (such as short acting beta2-agonist), asthma attacks/exacerbations two or more times per week, multiple emergency room visits within the past 12 months, or one or more nights of nocturnal asthma causing awakening. Chart notes that show patient's FEV1 is greater than 40% and less than 80% of predicted normal pre-inhaled steroids. Chart notes that show positive skin test, RAST, or in vitro reactivity to at least one perennial aeroallergen AND IgE levels between 30-700 IU/mL for patients 12 years of age and older or IgE levels between 30-1,300 IU/mL for patients between the ages of 6 to less than 12 years. For chronic spontaneous urticaria (CSU): Chart notes that show patient remained symptomatic despite H1 antihistamine treatment or has an intolerance or contraindication to H1 antihistamine treatment. For nasal polyps: Documentation of a diagnosis of nasal polyps. Documentation showing a trial of, intolerance to, or contraindication to at least one intranasal corticosteroid and at least one systemic corticosteroid. Documentation showing the patient will be treated with Xolair in combination with intranasal corticosteroids. For IgE mediated food allergy: Documentation of a diagnosis of IgE mediated food allergy. Documentation of IgE levels between 30 and 1850 IU/ml.

## AGE RESTRICTION

1 year of age and older.

## PRESCRIBER RESTRICTION

Pulmonologist, allergist, immunologist, dermatologist, otolaryngologist.

**COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

For reauthorization: Confirmation of positive clinical response.

**PART B PREREQUISITE**

N/A

## ZTALMY

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### MEDICATION(S)

ZTALMY

### PA INDICATION INDICATOR

1 - All FDA-Approved Indications

### OFF LABEL USES

N/A

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

Documented diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD). Applies to new starts only.

### AGE RESTRICTION

N/A

### PRESCRIBER RESTRICTION

Prescribed by or in consultation with a neurologist.

### COVERAGE DURATION

12 months.

### OTHER CRITERIA

N/A

### PART B PREREQUISITE

N/A



## ZURZUVAE

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### **MEDICATION(S)**

ZURZUVAE

### **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

Current pregnancy.

### **REQUIRED MEDICAL INFORMATION**

Documentation of a diagnosis of postpartum depression. Medical records must be attached. Applies to new starts only.

### **AGE RESTRICTION**

18 years of age or older.

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with a psychiatrist or obstetrician/gynecologist.

### **COVERAGE DURATION**

30 days.

### **OTHER CRITERIA**

N/A

### **PART B PREREQUISITE**

N/A