

# ABILIFY MYCITE

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## MEDICATION(S)

ABILIFY MYCITE, ABILIFY MYCITE MAINTENANCE KIT, ABILIFY MYCITE STARTER KIT

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Dementia-related psychosis. Concurrent use with other aripiprazole-containing medications.

## REQUIRED MEDICAL INFORMATION

Chart notes documenting an inadequate response or inability to tolerate generic aripiprazole (solution, tablets, or orally-disintegrating tablets).

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

# 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.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

# **ACTHAR GEL**

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## **MEDICATION(S)**

ACTHAR, CORTROPHIN

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, sensitivity to proteins of porcine origin, congenital infections suspected in children under 2 years old, or administration of a live or live attenuated vaccine in a patient receiving immunosuppressive doses of corticotropin gel.

## **REQUIRED MEDICAL INFORMATION**

Documented diagnosis of an FDA-approved indication not otherwise excluded from Part D. Cover under Medicare Part B, if the medication will be furnished by the prescriber/office, administered in the prescriber's office or ambulatory setting, and will be billed by the prescriber/office. Cover under Medicare Part D, if the prescriber wants to have the medication provided by a pharmacy.

## **AGE RESTRICTION**

Infantile Spasms: Less than 2 years of age. Multiple Sclerosis: Greater than or equal to 18 years of age. Other FDA-approved indications not otherwise excluded from Part D: Greater than 2 years of age.

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

Infantile Spasms: 12 months. Other FDA-approved indications: 1 month.

## **OTHER CRITERIA**

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

# 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

Confirmed diagnosis of Pulmonary Arterial Hypertension WHO Group 1 with New York Heart Association (NYHA) Functional Class II-III by catheterization or echocardiography. Report 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: Clarify there is a treatment plan.

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

Cardiologist, pulmonologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

# AMBRISENTAN

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## MEDICATION(S)

AMBRISENTAN

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Pregnancy. Idiopathic pulmonary fibrosis.

## REQUIRED MEDICAL INFORMATION

If female of child bearing age, confirmation that she will use reliable forms of contraception and that she will have monthly pregnancy tests performed during therapy. 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 report must be attached). Confirmation that hemoglobin and hematocrit are being monitored (baseline, at 1 month, and periodically thereafter).

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

Cardiologist, pulmonologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

# ARMODAFINIL

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## MEDICATION(S)

ARMODAFINIL

## 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

Sleep specialist or neurologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

# AUSTEDO

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## MEDICATION(S)

AUSTEDO

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Congenital long QT syndrome. Arrhythmias associated with prolonged QT interval. Concurrent use of MAO inhibitors. 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 with assessment attached. 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) with documentation attached. 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. For renewals: For Tardive Dyskinesia: Improvement in symptoms of Tardive Dyskinesia with both medical records and an updated AIMS assessment with assessment attached. For Chorea associated with Huntington's Disease: Improvement in symptoms of Chorea with medical records 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



N/A

# **BOSENTAN**

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## **MEDICATION(S)**

BOSENTAN, TRACLEER 32 MG TAB SOL

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Pregnancy. Use with cyclosporine A and/or glyburide.

## **REQUIRED MEDICAL INFORMATION**

If female of child bearing age, documentation that she will use reliable forms of contraception and that she will have monthly pregnancy tests performed during therapy. For pediatric patient aged 3 to 15 years, confirmation of diagnosis of idiopathic or congenital pulmonary arterial hypertension (PAH), confirmed by mean pulmonary artery pressure (mPAP) of greater than 20 mmHg. For patients 15 years or older, confirmation of diagnosis of PAH WHO Group 1 with New York Heart Association (NYHA) Functional Class II, III or IV symptoms. Diagnosis confirmed by a complete right heart catheterization (RHC), PAH defined as a resting 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 report must be attached). Documentation that serum transaminases (AST/ALT) and bilirubin are being monitored (prior to initiation of treatment and then monthly).

## **AGE RESTRICTION**

3 years of age and older.

## **PRESCRIBER RESTRICTION**

Cardiologist, pulmonologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

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: 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

## **CGRP ANTAGONISTS**

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### **MEDICATION(S)**

AIMOVIG, AJOVY, 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**

Confirmation the diagnosis was based on the most current criteria from the International Headache Society Classification of Headache Disorders. IN ADDITION: (1) For migraine: Confirmation of intolerance or inadequate response to a 4-week minimum trial with at least one preventive medication from two of the following classes: beta blockers, antidepressants, anticonvulsants. (2) For episodic cluster headaches (Emgality only): Confirmation of a history of inadequate response, inability to tolerate 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**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

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).

## **AGE RESTRICTION**

6 years of age and older.

## **PRESCRIBER RESTRICTION**

Allergist or immunologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

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

# 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

Creatinine clearance 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

Hematologist, oncologist, hepatologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

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 (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.

## 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, inability to tolerate or contraindication to two generic triptans (such as sumatriptan, zolmitriptan, rizatriptan) OR an inadequate response, inability to tolerate or contraindication to one generic triptan AND Ubrovelvy (ubrogepant).

## 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

# 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

# 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: Documentation showing a trial of, intolerance to, or contraindication to at least one topical corticosteroid and at least one topical calcineurin inhibitor (such as tacrolimus ointment). 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 a 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 chronic rhinosinusitis with nasal polyposis. 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.

## AGE RESTRICTION

6 years of age and older for atopic dermatitis, eosinophilic phenotype or oral corticosteroid dependent asthma. 18 years of age and older for CRSwNP. 12 years of age and older for EOE.

## PRESCRIBER RESTRICTION

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

**COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

N/A

# EMFLAZA

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## MEDICATION(S)

EMFLAZA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of Duchenne Muscular Dystrophy confirmed by genetic testing. Confirmation of an inadequate response or inability to tolerate prednisone.

## 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

# 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), plaque psoriasis (PsO), polyarticular juvenile idiopathic arthritis (JIA), or ankylosing spondylitis (AS). For RA or PsA: Documentation of inadequate response, intolerance or contraindication to at least one or more DMARDs. 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. 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 JIA: Documentation of inadequate response, intolerance or contraindication to one or more DMARDs. For AS: Documentation of inadequate response, intolerance or contraindication to at least two non-steroidal anti-inflammatory drugs OR is intolerant to non-steroidal anti-inflammatory drugs.

## AGE RESTRICTION

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

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a rheumatologist or dermatologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A



# ENDARI

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## MEDICATION(S)

ENDARI

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documentation of diagnosis of sickle cell disease confirmed by chart notes (must be attached).

Documentation that request is to reduce acute complications of sickle cell disease. Documentation of inadequate response to maximum tolerated dose of hydroxyurea therapy OR documented intolerance or contraindication to hydroxyurea therapy. Request is within the FDA labeled dose.

## AGE RESTRICTION

5 years of age and older.

## PRESCRIBER RESTRICTION

Hematologist or oncologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

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 adequate trials of at least 2 antiepileptic drugs (include the drugs tried, dates, and duration of trial). Confirmation that Epidiolex is adjunctive therapy with documentation of antiepileptic drug(s) with which Epidiolex will be used.

## AGE RESTRICTION

1 year of age and older.

## PRESCRIBER RESTRICTION

Neurologist or epileptologist.

## 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.

# ESBRIET

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## MEDICATION(S)

ESBRIET, 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 REQUESTS:** 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). Documentation that liver function tests (ALT, AST, and bilirubin) are being monitored periodically throughout the course of treatment as clinically necessary.

## 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

# 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

12 years of age and older.

## PRESCRIBER RESTRICTION

Pulmonologist, allergist, immunologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

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

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Prescribers and patients not enrolled in TIRF REMs Access Program. Must not be used in opioid non-tolerant patients.

## **REQUIRED MEDICAL INFORMATION**

For use in the management of breakthrough pain in cancer patients (documentation must be attached) who are already receiving and have become tolerant to around-the-clock opioid therapy for persistent cancer pain. Opioid tolerant is defined as patients taking at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily or an equianalgesic dose of another opioid daily for 1 week or longer. Patients must remain on around-the-clock opioids when taking fentanyl citrate transmucosal lozenges. For renewal: assessment of pain severity and functional ability, progress towards achieving therapeutic goals, presence of adverse effects, plan of care including duration of treatment. Chart notes that assess the patient for possible aberrant drug-related behaviors, substance use, and psychological issues. Patients remain on around-the-clock opioids when taking fentanyl citrate transmucosal lozenges.

## **AGE RESTRICTION**

16 years of age and older.

## **PRESCRIBER RESTRICTION**

Pain management specialist or oncologist.

## **COVERAGE DURATION**

6 months.

## **OTHER CRITERIA**

N/A



## **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**

6 months.

### **OTHER CRITERIA**

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**

Documented diagnosis of Dravet syndrome (DS). Confirmation that the patient will have required echocardiogram monitoring.

Documentation showing an inadequate response or intolerance to at least two of the following: clobazam, valproic acid derivatives, topiramate, cannabidiol, or stiripentol (include dates, duration, and outcome).

## **AGE RESTRICTION**

2 years of age and older.

## **PRESCRIBER RESTRICTION**

Neurologist or epileptologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

# FORTEO

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## MEDICATION(S)

FORTEO

## 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 [DXA scan, serum calcium, phosphorus, creatinine, alkaline phosphatase, albumin, 25-hydroxyvitamin D (25[OH]D)]. Documentation of an inadequate response or inability to tolerate at least one of the following: bisphosphonates, hormone replacement therapy, or selective-estrogen receptor modulators (SERMs).

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with an endocrinologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

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

# 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 and subtype, 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), serum creatinine/calculated glomerular filtration rate, transient elastography (such as FibroScan) or noninvasive serologic tests (such as FibroSure), Hepatitis B surface antigen (HBsAg), Hepatitis B core antibody (anti-HBc), Hepatitis B surface antibody (anti-HBs), and HIV antigen/antibody test. Criteria will be applied consistent with current AASLD-IDSA HCV guidance.

## AGE RESTRICTION

3 years of age and older.

## 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.

# HETLIOZ

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## **MEDICATION(S)**

HETLIOZ, HETLIOZ LQ

## **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 renewal 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.

## **HIGH RISK MEDICATION**

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### **MEDICATION(S)**

DIPYRIDAMOLE 25 MG TAB, DIPYRIDAMOLE 50 MG TAB, DIPYRIDAMOLE 75 MG TAB, DISOPYRAMIDE PHOSPHATE, ERGOLOID MESYLATES 1 MG TAB, GUANFACINE HCL, METHYLDOPA, NIFEDIPINE 10 MG CAP, NIFEDIPINE 20 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. Confirmation that the patient has been counseled on the potential side effects and risks 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 the elderly population. Patients under 65 years of age are not subject to the prior authorization requirements.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

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

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### **MEDICATION(S)**

BAC, BUTALBITAL-APAP-CAFF-COD 50-325-40-30 MG CAP, BUTALBITAL-APAP-CAFFEINE 50-325-40 MG CAP, BUTALBITAL-APAP-CAFFEINE 50-325-40 MG TAB, BUTALBITAL-ASPIRIN-CAFFEINE 50-325-40 MG CAP, ESGIC 50-325-40 MG CAP, ZEBUTAL

### **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 there is specific benefit established and that the benefit outweighs the potential risk. Confirmation that the patient has been counseled on the potential side effects and risks 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 the elderly population. Patients under 65 years of age are not subject to the prior authorization requirements.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

## **HIGH RISK MEDICATION - FIRST GENERATION ANTIHISTAMINES**

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### **MEDICATION(S)**

PROMETHAZINE HCL 12.5 MG TAB, PROMETHAZINE HCL 25 MG TAB, PROMETHAZINE HCL 50 MG TAB, PROMETHAZINE HCL 6.25 MG/5ML SOLUTION, PROMETHAZINE HCL 6.25 MG/5ML SYRUP

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

Confirmation of 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 of the specific benefit established and that the benefit outweighs the potential risk. Confirmation that the patient has been counseled on the potential side effects and risks of the High Risk Medication. For allergic conditions, confirmation of an inadequate response or inability to tolerate two (2) safer formulary alternatives, such as levocetirizine, desloratadine, azelastine nasal spray, fluticasone propionate nasal spray, or mometasone nasal spray.

### **AGE RESTRICTION**

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

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

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

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### **MEDICATION(S)**

ESZOPICLONE, ZALEPLON, ZOLPIDEM TARTRATE 10 MG TAB, ZOLPIDEM TARTRATE ER

### **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. Confirmation that the patient has been counseled on the potential side effects and risks of the High Risk Medication. Confirmation of an inadequate response or inability to tolerate two (2) safer formulary alternatives, such as temazepam, 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 the elderly population. Patients under 65 years of age are not subject to the prior authorization requirements.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

## **HIGH RISK MEDICATION - NON-COX-SELECTIVE NSAIDS**

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### **MEDICATION(S)**

INDOMETHACIN 25 MG CAP, INDOMETHACIN 50 MG CAP, INDOMETHACIN ER

### **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. Confirmation that the patient has been counseled on the potential side effects and risks of the High Risk Medication. Confirmation of an inadequate response or inability to tolerate two (2) safer formulary alternatives, such as ibuprofen, naproxen, nabumetone, etodolac, diclofenac, meloxicam, or topical diclofenac 1% gel.

### **AGE RESTRICTION**

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

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A



## **HIGH RISK MEDICATION - SKELETAL MUSCLE RELAXANTS**

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### **MEDICATION(S)**

CARISOPRODOL 350 MG TAB, CYCLOBENZAPRINE HCL 10 MG TAB, CYCLOBENZAPRINE HCL 5 MG TAB, METAXALONE, METHOCARBAMOL 500 MG TAB, METHOCARBAMOL 750 MG TAB, VANADOM

### **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. Confirmation that the patient has been counseled on the potential side effects and risks 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 the elderly population. Patients under 65 years of age are not subject to the prior authorization requirements.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

# HUMIRA

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## MEDICATION(S)

HUMIRA 10 MG/0.1ML PREF SY KT, HUMIRA 20 MG/0.2ML PREF SY KT, HUMIRA 40 MG/0.4ML PREF SY KT, HUMIRA 40 MG/0.8ML PREF SY KT, HUMIRA PEDIATRIC CROHNS START, HUMIRA PEN, HUMIRA PEN-CD/UC/HS STARTER, HUMIRA PEN-PEDIATRIC UC START, HUMIRA PEN-PS/UV/ADOL HS START, HUMIRA PEN-PSOR/UVEIT STARTER

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

N/A

## REQUIRED MEDICAL INFORMATION

Documentation of PPD test results and treatment plan for active or latent infection. Confirmation of diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA), plaque psoriasis (PsO), polyarticular juvenile idiopathic arthritis (JIA), ankylosing spondylitis (AS), Crohn's disease (CD), ulcerative colitis (UC), hidradenitis suppurativa (HS), uveitis. For RA, PsA: Documentation of inadequate response, intolerance or contraindication to at least 1 DMARD (e.g. methotrexate, hydroxychloroquine, sulfasalazine). For JIA: Documentation of inadequate response, intolerance or contraindication to 1 or more DMARDs (e.g. NSAIDs, methotrexate). For AS: Documentation of inadequate response, intolerance or contraindication to at least 2 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. 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 corticosteroids and methotrexate or azathioprine, or lost response to or intolerant to infliximab. For active UC: Documentation of inadequate response, intolerance or contraindication to corticosteroids, azathioprine, OR 6-MP. For HS: Documentation of inadequate response, intolerance or contraindication to 2 of the following: topical antibiotics (e.g. clindamycin), oral antibiotics (e.g. doxycycline, minocycline, amoxicillin-clavulanic acid, clindamycin, rifampin, dapsone), intralesional triamcinolone injections. For Uveitis: Documentation of inadequate response, intolerance or contraindication to 1 or more oral or topical glucocorticoids (e.g. prednisone), immunosuppressant agent, or periocular or intraocular injection (e.g. triamcinolone).

## AGE RESTRICTION

RA, PsA, AS, PsO, adult CD: 18 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. Pediatric CD: 6 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**

N/A

# INGREZZA

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## MEDICATION(S)

INGREZZA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Congenital long QT syndrome, Arrhythmias associated with prolonged QT interval, Pregnancy, Concurrent use of MAO inhibitors or strong CYP3A4 inducers.

## REQUIRED MEDICAL INFORMATION

Documented diagnosis of Tardive Dyskinesia including copy of Abnormal Involuntary Movement Scale (AIMS) assessment with assessment attached. 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) 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 renewal: Improvement in symptoms of Tardive Dyskinesia with an updated AIMS assessment attached.

## **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. For continuation: Evaluation of response to testosterone therapy.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

N/A

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

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### **MEDICATION(S)**

BIVIGAM 5 GM/50ML SOLUTION, FLEBOGAMMA DIF, GAMMAGARD, GAMMAGARD S/D LESS IGA, GAMMAKED, GAMMAPLEX, GAMUNEX-C, OCTAGAM, PANZYGA, PRIVIGEN

### **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

### **OFF LABEL USES**

N/A

### **EXCLUSION CRITERIA**

N/A

### **REQUIRED MEDICAL INFORMATION**

N/A

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an allergist, immunologist, hematologist, neurologist, cardiologist, or oncologist.

### **COVERAGE DURATION**

3 months.

### **OTHER CRITERIA**

Subject to Part B vs D review. Documentation showing confirmation of one of the following is present (1) autoimmune mucocutaneous blistering disease pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatrical) pemphigoid, benign mucous membrane pemphigoid, epidermolysis bullosa acquisita and one of the following: (a) inadequate response or inability to tolerate conventional therapy (ie steroids, immunosuppressants) OR (b) rapidly progressive disease in conjunction with conventional therapy (such as steroids, immunosuppressants) (2) erythema multiforme major (SJS, TEN) and SCORTEN level 3 or greater (3) scleromyxedema (4) acute idiopathic thrombocytopenia purpura (ITP) and ONE of the following (a) management of acute bleeding (b) used to increase platelet count prior to surgical procedures (c) severe thrombocytopenia (platelets less than 20,000 per uL) OR (d) high risk for intracerebral hemorrhage (5) chronic ITP and ALL of the following (a) inadequate response or inability to tolerate corticosteroids (b) duration of illness greater than 6 months (c) platelets persistently less than

20,000 per uL (6) chronic B-cell lymphocytic leukemia with IgG less than 600 mg/dL and recurrent, serious bacterial infections requiring antibiotic therapy (7) hematopoietic stem cell transplant and IgG less than 400 mg/dL (8) HIV and all of the following (a) less than 14 years of age (b) evidence of qualitative or quantitative humoral immunologic defects and (c) current bacterial infection despite antimicrobial prophylaxis (9) solid organ transplant (10) chronic inflammatory demyelinating polyneuropathy confirmed by electrodiagnostic testing or nerve biopsy and an inadequate response or inability to tolerate corticosteroids (11) dermatomyositis or polymyositis diagnosed by laboratory testing (antinuclear or myositis specific antibodies, biopsy, EMG, or MRI) and inadequate response or inability to tolerate steroids or immunosuppressants (12) Guillain Barre syndrome with impaired function (ie unable to stand or walk without aid) (13) Lambert Eaton myasthenic syndrome refractory to steroids, immunosuppressants, or cholinesterase inhibitors (14) multifocal motor neuropathy diagnosed by electrodiagnostic studies (15) acute exacerbations of multiple sclerosis unresponsive to steroids (16) myasthenia gravis refractory to at least 8 weeks of standard therapy (steroids, immunosuppressants, cholinesterase inhibitors) (17) myasthenic crisis (18) stiff person syndrome refractory to standard therapy (muscle relaxants, benzodiazepines, gabapentin) (19) severe, active SLE unresponsive to steroids (20) Kawasaki disease. CONTINUATION OF THERAPY CRITERIA: Documentation of clinical improvement using objective monitoring as appropriate to the diagnosis such as, but not limited to, Rankin score and Activities of Daily Living (ADL) scores.

# JUXTAPID

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## MEDICATION(S)

JUXTAPID 10 MG CAP, JUXTAPID 20 MG CAP, JUXTAPID 30 MG CAP, JUXTAPID 5 MG CAP

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Pregnancy, moderate or severe hepatic impairment (Child-Pugh category B or C), active liver disease including unexplained persistent abnormal liver function tests, and use of Juxtapid in combination with moderate or strong CYP3A4 inhibitors.

## REQUIRED MEDICAL INFORMATION

Initial: Chart notes that document a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) with genetic testing and lipid profile attached. Documentation of inadequate response, intolerance or contraindication to standard lipid-lowering regimen containing high potency statins. Documentation of inadequate response or medical reason for not utilizing a PCSK9 inhibitor (Repatha) to manage condition. Documentation that Juxtapid therapy will be used in combination with other lipid-lowering treatments such as statins, fenofibrates, ezetimibe, or niacin. For renewal: Documentation of post treatment liver function test and lipid profile. Documentation that Juxtapid therapy will be used in combination with other lipid-lowering treatments such as statins, fenofibrates, ezetimibe, or niacin.

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist.

## COVERAGE DURATION

6 months.

## OTHER CRITERIA

N/A



# KALYDECO

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## MEDICATION(S)

KALYDECO

## 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 (confirmation of one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data). Chart notes showing that lab work (baseline liver function, including alanine aminotransferase and asparatate aminotransferase) has been assessed prior to initiation of treatment.

## AGE RESTRICTION

For oral granules: 4 months to less than 6 years of age. For oral tablets: 6 years of age and older.

## PRESCRIBER RESTRICTION

Pulmonologist, endocrinologist, pediatrician.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

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 multiple sclerosis.

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

Neurologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

# LIDOCAINE PATCHES

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## **MEDICATION(S)**

LIDOCAINE 5 % PATCH

## **PA INDICATION INDICATOR**

3 - All Medically-Accepted Indications

## **OFF LABEL USES**

N/A

## **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 or diabetic peripheral neuropathy.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

N/A

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

# **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 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

# MAVENCLAD

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## MEDICATION(S)

MAVENCLAD (10 TABS), MAVENCLAD (4 TABS), MAVENCLAD (5 TABS), MAVENCLAD (6 TABS), MAVENCLAD (7 TABS), MAVENCLAD (8 TABS), MAVENCLAD (9 TABS)

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Presence of current malignancy. Pregnancy. Women and men of reproductive potential who do not plan to use effective contraception during treatment with Mavenclad and for 6 months after last dose. HIV infection and any active chronic infections (hepatitis, tuberculosis). Hypersensitivity to cladribine. Women intending to breastfeed on a Mavenclad treatment day and for 10 days after the last dose. Clinically isolated syndrome.

## REQUIRED MEDICAL INFORMATION

Diagnosis of relapsing form of multiple sclerosis, including relapsing-remitting disease and active secondary progressive disease. Documentation showing patient has tried and failed or experienced intolerance to at least one alternative drug indicated for treatment of multiple sclerosis.

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a neurologist.

## COVERAGE DURATION

12 months. Max 2 treatment courses not to exceed 2 years of treatment.

## OTHER CRITERIA

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 and subtype, 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), serum creatinine/calculated glomerular filtration rate, transient elastography (such as FibroScan) or noninvasive serologic tests (such as FibroSure), Hepatitis B surface antigen (HBsAg), Hepatitis B core antibody (anti-HBc), Hepatitis B surface antibody (anti-HBs), 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.

# 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 hemoglobin A1C, glucose, and triglycerides. For members who have been previously approved, chart notes documenting updated hemoglobin A1C, glucose, and triglycerides.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with an endocrinologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

# **NATPARA**

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## **MEDICATION(S)**

NATPARA

## **PA INDICATION INDICATOR**

1 - All FDA-Approved Indications

## **OFF LABEL USES**

N/A

## **EXCLUSION CRITERIA**

Patients with a documented risk for osteosarcoma (including Paget's disease or unexplained elevation of alkaline phosphatase, open epiphyses, hereditary disorders predisposed to osteosarcoma, or a history of external beam or implant radiation therapy).

## **REQUIRED MEDICAL INFORMATION**

Confirmation of diagnosis. Documentation showing uncontrolled hypocalcemia despite treatment with calcium supplements and active forms of vitamin D. Labs showing serum calcium is above 7.5 mg/dL and serum 25-hydroxyvitamin D level is within normal range prior to starting Natpara. Confirmation Natpara will be used along with calcium supplementation or active forms of vitamin D.

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

Prescribed by or in consultation with an endocrinologist or parathyroid specialist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A



# NAYZILAM

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## **MEDICATION(S)**

NAYZILAM

## **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.

## **AGE RESTRICTION**

12 years of age and older.

## **PRESCRIBER RESTRICTION**

Neurologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

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.

# NUCALA

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## MEDICATION(S)

NUCALA 100 MG RECON SOLN, NUCALA 100 MG/ML SOLN A-INJ, NUCALA 100 MG/ML SOLN PRSYR

## 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: (1) 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. (2)

Documented diagnosis of relapsing or refractory eosinophilic granulomatosis with polyangiitis (EGPA). (3)

Documented diagnosis of hypereosinophilic syndrome for greater than or equal to 6 months without an identifiable non-hematologic secondary cause. (4) Documented diagnosis of rhinosinusitis with nasal polyps (CRSwNP) with inadequate response to nasal corticosteroids.

## AGE RESTRICTION

6 years of age and older.

## PRESCRIBER RESTRICTION

Pulmonologist, allergist, immunologist, rheumatologist, hematologist, otolaryngologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

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. Patients with known hypersensitivity to dextromethorphan. Use with an MAOI or within 14 days of stopping an MAOI. Prolonged QT interval, congenital long QT syndrome, history suggestive of torsades de pointes, or heart failure. Complete atrioventricular (AV) block without implanted pacemaker, or patients at high risk of complete AV block. 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. For patients at risk of QT prolongation and torsades de pointes, baseline EKG and an EKG 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

# 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

N/A

## PRESCRIBER RESTRICTION

Hepatologist or gastroenterologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

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

# OPSUMIT

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## MEDICATION(S)

OPSUMIT

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Pregnancy.

## REQUIRED MEDICAL INFORMATION

For a woman of childbearing potential, documentation that she will use reliable forms of contraception and that she will have pregnancy tests performed prior to initiation of therapy, monthly during therapy and 1 month after stopping treatment. Confirmation of diagnosis of pulmonary arterial hypertension (PAH) WHO Group 1 with New York Heart Association (NYHA) Functional Class II or III symptoms. 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 report must be attached). Documentation should be submitted showing that liver enzymes, hemoglobin and hematocrit were measured at baseline prior to initiation, after the first month and repeated as clinically necessary.

## AGE RESTRICTION

18 years of age and older.

## PRESCRIBER RESTRICTION

Cardiologist, pulmonologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A



## ORAL ONCOLOGY AGENTS

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### MEDICATION(S)

ABIRATERONE ACETATE, AFINITOR 10 MG TAB, AFINITOR DISPERZ, ALECENSA, ALUNBRIG, 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, ERLEADA, 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, EXKIVITY, FARYDAK, FOTIVDA, GAVRETO, GILOTRIF, IBRANCE, ICLUSIG, IDHIFA, IMATINIB MESYLATE, IMBRUVICA, INLYTA, INQOVI, INREBIC, IRESSA, JAKAFI, KISQALI (200 MG DOSE), KISQALI (400 MG DOSE), KISQALI (600 MG DOSE), KISQALI FEMARA (400 MG DOSE), KISQALI FEMARA (600 MG DOSE), KISQALI FEMARA(200 MG DOSE), KOSELUGO, 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 100 MG TAB, LYNPARZA 150 MG TAB, MEKINIST, MEKTOVI, NERLYNX, NEXAVAR, NINLARO, NUBEQA, ODOMZO, ONUREG, ORGOVYX, PEMAZYRE, PIQRAY (200 MG DAILY DOSE), PIQRAY (250 MG DAILY DOSE), PIQRAY (300 MG DAILY DOSE), POMALYST, QINLOCK, RETEVMO, REVLIMID, ROZLYTREK, RUBRACA, RYDAPT, SCEMBLIX, SPRYCEL, STIVARGA, SUNITINIB MALATE, SUTENT, TABRECTA, TAFINLAR, TAGRISSO, TALZENNA, TASIGNA, TAZVERIK, TEPMETKO, THALOMID, TIBSOVO, TRUSELTIQ (100MG DAILY DOSE), TRUSELTIQ (125MG DAILY DOSE), TRUSELTIQ (50MG DAILY DOSE), TRUSELTIQ (75MG DAILY DOSE), TUKYSA, TURALIO, UKONIQ, VENCLEXTA, VENCLEXTA STARTING PACK, VERZENIO, VITRAKVI, VIZIMPRO, VOTRIENT, WELIREG, XALKORI, XOSPATA, XPOVIO (100 MG ONCE WEEKLY), XPOVIO (40 MG ONCE WEEKLY), XPOVIO (40 MG TWICE WEEKLY), XPOVIO (60 MG ONCE WEEKLY), XPOVIO (60 MG TWICE WEEKLY), XPOVIO (80 MG ONCE WEEKLY), XPOVIO (80 MG TWICE WEEKLY), XTANDI, YONSA, ZEJULA, ZELBORAF, ZOLINZA, ZYDELIG, ZYKADIA 150 MG TAB, ZYTIGA 500 MG TAB

### 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

# ORKAMBI

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## MEDICATION(S)

ORKAMBI

## 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 (homozygous for the F508del mutation in the CFTR gene). 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.

## AGE RESTRICTION

For lumacaftor 100 mg/ivacaftor 125 mg granules and lumacaftor 150 mg/ivacaftor 188 mg granules: Ages 2-5 years. For lumacaftor 100 mg/ivacaftor 125 mg tablets: Ages 6-11 years. For lumacaftor 200 mg/ivacaftor 125 mg tablets: Ages 12 and older.

## PRESCRIBER RESTRICTION

Pulmonologist, endocrinologist or pediatrician.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

# OXERVATE

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## MEDICATION(S)

OXERVATE

## 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

Ophthalmologist.

## COVERAGE DURATION

8 weeks.

## OTHER CRITERIA

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.

## AGE RESTRICTION

N/A

## PRESCRIBER RESTRICTION

Dermatologist, oncologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

## PART D VS PART B

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### MEDICATION(S)

ABELCET, ABRAXANE, ACETYLCYSTEINE 10 % SOLUTION, ACETYLCYSTEINE 20 % SOLUTION, ACYCLOVIR SODIUM, ADRIAMYCIN 2 MG/ML SOLUTION, 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, ALIMTA, ALIQOPA, AMBISOME, AMINOSYN-PF 7 % SOLUTION, AMPHOTERICIN B 50 MG RECON SOLN, AMPHOTERICIN B LIPOSOME, APREPITANT, ARFORMOTEROL TARTRATE, ARSENIC TRIOXIDE 10 MG/10ML SOLUTION, ASTAGRAF XL, ATGAM, AVASTIN, AVSOLA, AZACITIDINE, AZASAN, AZATHIOPRINE 100 MG TAB, AZATHIOPRINE 50 MG TAB, AZATHIOPRINE 75 MG TAB, AZATHIOPRINE SODIUM, BAVENCIO, BLEOMYCIN SULFATE, 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, CLADRIBINE, CLINIMIX E/DEXTROSE (2.75/5), CLINIMIX E/DEXTROSE (4.25/10), CLINIMIX E/DEXTROSE (4.25/5), CLINIMIX E/DEXTROSE (5/15), CLINIMIX E/DEXTROSE (5/20), CLINIMIX/DEXTROSE (4.25/10), CLINIMIX/DEXTROSE (4.25/5), CLINIMIX/DEXTROSE (5/15), CLINIMIX/DEXTROSE (5/20), CLINISOL SF, CLINOLIPID, CLOFARABINE, 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, CYRAMZA, CYTARABINE, CYTARABINE (PF), DACTINOMYCIN, DARZALEX, DAUNORUBICIN HCL, DECITABINE, DOCETAXEL 160 MG/16ML SOLUTION, DOCETAXEL 160 MG/8ML CONC, DOCETAXEL 20 MG/2ML SOLUTION, DOCETAXEL 20 MG/ML CONC, DOCETAXEL 80 MG/4ML CONC, DOCETAXEL 80 MG/8ML SOLUTION, DOXORUBICIN HCL 2 MG/ML SOLUTION, DOXORUBICIN HCL LIPOSOMAL, ELIGARD, EMEND 125 MG/5ML RECON SUSP, EMPliciti, ENGERIX-B 10 MCG/0.5ML SUSPENSION, ENGERIX-B 20 MCG/ML SUSPENSION, ENVARUSUS XR, EPIRUBICIN HCL, 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, FOLOTYN 40 MG/2ML SOLUTION, FORMOTEROL FUMARATE 20 MCG/2ML NEBU SOLN, FREAMINE III, FULVESTRANT, GEMCITABINE HCL 1 GM RECON SOLN, GENGRAF, GRANISETRON HCL 1 MG TAB, HERCEPTIN HYLECTA, HERZUMA, IDARUBICIN HCL, IMFINZI, INFLECTRA, INTRALIPID, IPRATROPIUM BROMIDE 0.02 % SOLUTION, IPRATROPIUM-ALBUTEROL, IRINOTECAN HCL, KADCYLA, KANJINTI, KEYTRUDA, KYPROLIS, LEUPROLIDE ACETATE 1 MG/0.2ML KIT, 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), MELPHALAN, MELPHALAN HCL, 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, MYLOTARG, NIPENT, NULOJIX, NUTRILIPID, OGIVRI, ONDANSETRON, ONDANSETRON HCL 24 MG TAB, ONDANSETRON HCL 4 MG TAB, ONDANSETRON HCL 4 MG/5ML SOLUTION, ONDANSETRON HCL 8 MG TAB, ONTRUZANT, OPDIVO 100 MG/10ML SOLUTION, OPDIVO 240 MG/24ML SOLUTION, OPDIVO 40 MG/4ML SOLUTION, 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, PEMETREXED DISODIUM 100 MG RECON SOLN, PEMETREXED DISODIUM 1000 MG RECON SOLN, PEMETREXED DISODIUM 500 MG RECON SOLN, PEMETREXED DISODIUM 750 MG RECON SOLN, PENTAMIDINE ISETHIONATE, PLENAMINE, PREMASOL 10 % SOLUTION, PROCIT, PROGRAF 0.2 MG PACKET, PROGRAF 1 MG PACKET, PROSOL, PULMOZYME, RECOMBIVAX HB, RENFLEXIS, RETACRIT, RIABNI, RITUXAN HYCELA, RUXIENCE, SANDIMMUNE 100 MG/ML SOLUTION, SIMULECT 20 MG RECON SOLN, SIROLIMUS 0.5 MG TAB, SIROLIMUS 1 MG TAB, SIROLIMUS 1 MG/ML SOLUTION, SIROLIMUS 2 MG TAB, SYLVANT, SYNRIPO, TACROLIMUS 0.5 MG CAP, TACROLIMUS 1 MG CAP, TACROLIMUS 5 MG CAP, TECENTRIQ, THYMOGLOBULIN, TOBRAMYCIN 300 MG/5ML NEBU SOLN, TOPOTECAN HCL 4 MG RECON SOLN, TPN ELECTROLYTES, TRAVASOL, TRAZIMERA, TREANDA, TRELSTAR MIXJECT, TROPHAMINE 10 % SOLUTION, TRUXIMA, VECTIBIX 100 MG/5ML SOLUTION, VELCADE, VINBLASTINE SULFATE, VINCASAR PFS, VINCRISTINE SULFATE, VYXEOS, YUPELRI, ZANOSAR, ZIRABEV, ZOLEDRONIC ACID 4 MG/5ML CONC, ZOLEDRONIC ACID 5 MG/100ML SOLUTION, ZORTRESS 1 MG TAB

## **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)**

NYVEPRIA, ZIEXTENZO

### **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 there is a treatment plan and that lab work (complete blood count with differential including ANC) is being monitored.

### **AGE RESTRICTION**

N/A

### **PRESCRIBER RESTRICTION**

Oncologist or hematologist.

### **COVERAGE DURATION**

6 months.

### **OTHER CRITERIA**

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

# PROMACTA

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## MEDICATION(S)

PROMACTA

## 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 of inadequate response, intolerance or contraindication to glucocorticoids (prednisone, high-dose dexamethasone or methylprednisolone), immunoglobulins, or splenectomy. For chronic hepatitis C: Documentation of patient's degree of thrombocytopenia that prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. For severe aplastic anemia: Documentation of inadequate response, intolerance or contraindication to immunosuppressive therapy or being used in combination with standard immunosuppressive therapy.

## AGE RESTRICTION

For ITP: 1 year or older. For thrombocytopenia in patients with chronic hepatitis C: 18 years or older. For severe aplastic anemia: 2 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

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

N/A

## REQUIRED MEDICAL INFORMATION

Documentation of diagnosis by enzymatic, biochemical, or genetic testing and labs including electrolytes, pre-albumin and albumin measurement, (fasting) plasma ammonia concentration and amino acids.

Documentation of trial, contraindication, or inadequate response to sodium phenylbutyrate.

## 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

# 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

# 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

For Homozygous Familial Hypercholesterolemia (HoFH): Genetic confirmation of 2 mutant alleles in the LDL receptor, Apo B-100 PCSK9 gene OR untreated LDL-C greater than 500 mg/dL OR treated LDL-C greater than or equal to 300 mg/dL with cutaneous or tendonous xanthoma before the age of 10 OR untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia (HeFH) in both parents with documentation attached. Dosing as 420 mg once a month. For HeFH: Documentation of either genetic confirmation OR Dutch Lipid Network Criteria score greater than 6 with documentation attached. For patients with clinical atherosclerotic cardiovascular disease (ASCVD) or primary hyperlipidemia: Documentation of diagnosis. For all diagnoses: Documentation of prior treatment of at least one high intensity statin therapy (such as atorvastatin 40 mg or 80 mg or rosuvastatin 20 mg or 40 mg) for at least 3 continuous months with failure to reach target LDL-C levels. 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. Either baseline or post-treatment labs (lipid profile) required for all indications.

## AGE RESTRICTION

HoFH: 13 years of age and older. HeFH and ASCVD: 18 years of age and older.

## PRESCRIBER RESTRICTION

Prescribed by or in consultation with a cardiologist, endocrinologist, or lipidologist.

## COVERAGE DURATION

Initial: 6 months. Renewal: 12 months.

## OTHER CRITERIA

N/A



## **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 confirmed diagnosis of moderately to severely active rheumatoid arthritis, active psoriatic arthritis, moderately to severely active ulcerative colitis, or active ankylosing spondylitis, attached documentation of inadequate response or intolerance to at least one TNF blocker. For a confirmed diagnosis of refractory, moderate to severe atopic dermatitis, 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 showing 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**

18 years of age and older for rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis. 12 years of age and older for atopic dermatitis.

## **PRESCRIBER RESTRICTION**

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

## **COVERAGE DURATION**

12 months.

**OTHER CRITERIA**

N/A



# SILDENAFIL

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## MEDICATION(S)

SILDENAFIL CITRATE 20 MG TAB

## 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

For pulmonary arterial hypertension (PAH): Confirmation of diagnosis of 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 report must be attached). 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

Cardiologist, pulmonologist or rheumatologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

# SKYRIZI

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## MEDICATION(S)

SKYRIZI, SKYRIZI (150 MG DOSE), 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 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 or rheumatologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

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 and subtype, 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), serum creatinine/calculated glomerular filtration rate, transient elastography (such as FibroScan) or noninvasive serologic tests (such as FibroSure), Hepatitis B surface antigen (HBsAg), Hepatitis B core antibody (anti-HBc), Hepatitis B surface antibody (anti-HBs), 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.

# STELARA

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## MEDICATION(S)

STELARA

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Active, serious infection. Live vaccines.

## REQUIRED MEDICAL INFORMATION

Subject to Part B vs Part D review. INITIAL REQUESTS: Confirmation of diagnosis of moderate to severe plaque psoriasis who is a candidate for phototherapy or systemic therapy, active psoriatic arthritis, moderately to severely active Crohn's disease, moderately to severely active ulcerative colitis. For plaque psoriasis: (1) patient 6 to 17 years of age: documentation of an inadequate response, intolerance, or contraindication to Enbrel, (2) patient 18 years of age or older: documentation of an inadequate response, intolerance, or contraindication to two of the following: Enbrel, Humira, Skyrizi. For psoriatic arthritis: documentation of an inadequate response, intolerance, or contraindication to two of the following: Enbrel, Humira, Xeljanz/Xeljanz XR. For Crohn's Disease: documentation of an inadequate response, intolerance, or contraindication to Humira. For ulcerative colitis: inadequate response, intolerance, or contraindication to Humira AND Xeljanz/Xeljanz XR. For all indications: Documentation of tuberculosis (TB) 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. FOR RENEWAL REQUESTS: documentation of improvement in symptoms.

## AGE RESTRICTION

For moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy: 6 years or older. For active psoriatic arthritis, moderately to severely active Crohn's disease, or moderately to severely active Ulcerative Colitis: 18 years of age or older.

## PRESCRIBER RESTRICTION

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

## COVERAGE DURATION

12 months.

**OTHER CRITERIA**

N/A

# 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.

## AGE RESTRICTION

2 years of age and older.

## PRESCRIBER RESTRICTION

N/A

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

# TADALAFIL

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## **MEDICATION(S)**

ALYQ, TADALAFIL (PAH)

## **PA INDICATION INDICATOR**

1 - All FDA-Approved 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 report must be attached).

## **AGE RESTRICTION**

18 years of age and older.

## **PRESCRIBER RESTRICTION**

Cardiologist, pulmonologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

**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: documentation of inadequate response, intolerance or contraindication to Enbrel, Humira or Skyrizi. For PsA: documentation of inadequate response, intolerance or contraindication to Enbrel, Humira or Xeljanz/Xeljanz XR. For active AS and nr-axSpA: documentation of inadequate response, intolerance or contraindication to one tumor necrosis factor antagonist (Enbrel or Humira). 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**

N/A



# TARGRETIN GEL

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## **MEDICATION(S)**

BEXAROTENE 1 % GEL, TARGRETIN 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.

## **AGE RESTRICTION**

N/A

## **PRESCRIBER RESTRICTION**

Dermatologist, hematologist, oncologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

N/A

# TETRABENAZINE

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## MEDICATION(S)

TETRABENAZINE

## PA INDICATION INDICATOR

1 - All FDA-Approved Indications

## OFF LABEL USES

N/A

## EXCLUSION CRITERIA

Congenital long QT syndrome. Arrhythmias associated with prolonged QT interval. Concurrent use of MAO inhibitors. 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 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 renewal: Documented improvement in symptoms of Chorea with medical records attached.

## **TOPICAL RETINOIDS**

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### **MEDICATION(S)**

AVITA, TRETINOIN 0.01 % GEL, TRETINOIN 0.025 % CREAM, TRETINOIN 0.025 % GEL, TRETINOIN 0.05 % CREAM, TRETINOIN 0.05 % GEL, 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

## **TOPICAL TESTOSTERONE PRODUCTS**

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### **MEDICATION(S)**

TESTOSTERONE 1.62 % GEL, 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

### **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. For renewal: Evaluation of response to testosterone therapy.

### **AGE RESTRICTION**

18 years of age and older.

### **PRESCRIBER RESTRICTION**

N/A

### **COVERAGE DURATION**

12 months.

### **OTHER CRITERIA**

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 catheterization or echocardiography with report 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. 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

Cardiologist, pulmonologist.

## COVERAGE DURATION

12 months.

## OTHER CRITERIA

N/A

# VALTOCO

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## **MEDICATION(S)**

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.

## **AGE RESTRICTION**

6 years of age and older.

## **PRESCRIBER RESTRICTION**

Neurologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

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

# 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 (such as azathioprine or cyclosporine).

## **REQUIRED MEDICAL INFORMATION**

Documentation of diagnosis. Documentation of tuberculosis screening results and treatment plan for active or latent infection. For rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis: Documentation of inadequate response or intolerance to at least one TNF blocker. For ulcerative colitis: Documentation of inadequate response, intolerance or contraindication to at least one previous treatments tried (such as TNF blockers, oral or intravenous corticosteroids, azathioprine, 6-MP). For active polyarticular course juvenile idiopathic arthritis: documentation of inadequate response, intolerance or contraindication to at least one first-line therapy (including full-dose NSAIDs).

## **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, dermatologist or gastroenterologist.

## **COVERAGE DURATION**

12 months.

## **OTHER CRITERIA**

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. For renewal requests: Documentation of positive clinical response to 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**

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 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 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**

Part B before Part D Step Therapy.

# 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

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

# 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 an adequate 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 6 and 12 years of age. For chronic idiopathic urticaria: 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 renewal for moderate to severe persistent asthma: chart notes that show that the patient has improvement in FEV1. Chart notes showing documentation of decreased steroid dose requirements and documented decrease of rescue medications.

## AGE RESTRICTION

6 years of age and older.

## PRESCRIBER RESTRICTION

Pulmonologist, allergist, immunologist, dermatologist, otolaryngologist.

## COVERAGE DURATION

12 months.

**OTHER CRITERIA**

N/A

# **XYREM**

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## **MEDICATION(S)**

XYREM

## **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