# **PRIOR AUTHORIZATION PROTOCOLS**

### How do I request an exception to the Ultimate Health Plans' Formulary?

You can ask Ultimate Health Plans to make an exception to our coverage rules. There are several types of exceptions that you can ask us to make.

- You can ask us to cover your drug even if it is not on our formulary. If approved, this drug will be covered at a pre-determined cost-sharing level, and you would not be able to ask us to provide the drug at a lower cost-sharing level.
- You can ask us to cover a formulary drug at a lower cost-sharing level if this drug is not on the specialty tier. If approved this would lower the amount you must pay for your drug.
- You can ask us to waive coverage restrictions or limits on your drug. For example, for certain drugs, Ultimate Health Plans limits the amount of the drug that we will cover. If your drug has a quantity limit, you can ask us to waive the limit and cover a greater amount.

Generally, Ultimate Health Plans will only approve your request for an exception if the alternative drugs included on the plan's formulary, the lower cost-sharing drug or additional utilization restrictions would not be as effective in treating your condition and/or would cause you to have adverse medical effects.

You should contact us to ask us for an initial coverage decision for a formulary, or utilization restriction exception. When you request a formulary or utilization restriction exception you should submit a statement from your prescriber or physician supporting your request. Generally, we must make our decision within 72 hours of getting your prescriber's supporting statement. You can request an expedited (fast) exception if you or your doctor believe that your health could be seriously harmed by waiting up to 72 hours for a decision. If your request to expedite is granted, we must give you a decision no later than 24 hours after we get a supporting statement from your doctor or other prescriber.

Your prescriber must submit a statement supporting your coverage determination or exception request. In order to help us make a decision more quickly, you should include supporting medical information from your prescriber when you submit your exception request.

#### What if I have additional questions?

You can call us at: 1-800-311-7517 (seven days a week, 24 hours a day) if you have any additional questions. If you have a hearing or speech impairment, please call us at TTY 1-866-706-4757.

### accutane

#### **Products Affected**

- accutane
- amnesteem
- claravis

- isotretinoin oral
- myorisan
- zenatane

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

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• ACTEMRA ACTPEN

### • ACTEMRA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to tocilizumab. RA: Diagnosis of moderately to severely active RA AND documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, D-penicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds, cyclosporine.
Age Restrictions	
Prescriber Restrictions	Arthritis and giant cell arteritis: prescribed by or in consult with a rheumatologist.
Coverage Duration	End of plan year
Other Criteria	Must have documentation of baseline liver function (AST, ALT) tests prior to initiation of therapy. Therapy should not be started if baseline ALT or AST are greater than 1.5 x the upper limit of normal (ULN). Patient is not receiving in combination with biologic DMARDs such as TNF antagonists, IL-1R antagonists, anti-CD20 monoclonal antibodies and selective co- stimulation modulators.
Indications	All Medically-accepted Indications.
Off Label Uses	

## acthar

#### **Products Affected**

• ACTHAR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

fentanyl citrate buccal lozenge on a handle

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	16 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# ADAKVEO

#### **Products Affected**

• ADAKVEO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• alyq

• tadalafil (pah)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with organic nitrates (i.e. isosorbide mononitrate, isosorbide dinitrate, nitroglycerin).
Required Medical Information	Pulmonary arterial hypertension: WHO group 1. The patient has had baseline liver function tests (ALT, AST) performed prior to the initiation of therapy. Not recommended in patients with severe hepatic impairment (Child Pugh class C).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a cardiologist or pulmonologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# adempas

#### **Products Affected**

• ADEMPAS

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy in females of reproductive potential. Concurrent use with nitrates or nitric oxide donors in any form. Concurrent use with PDE inhibitors. Pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP).
Required Medical Information	Pulmonary arterial hypertension: WHO group 1. The patient has had baseline liver function tests (ALT, AST) performed prior to the initiation of therapy. Not recommended in patients with severe hepatic impairment (Child Pugh class C).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a cardiologist or pulmonologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• AJOVY

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another CGRP inhibitor.
Required Medical Information	One of the following: 1) Patient has tried and failed at least TWO conventional migraine prophylaxis agents from two different pharmacological classes (e.g., anticonvulsants, beta blockers, antidepressants) for two months each or 2) Patient has a documented contraindication to TWO conventional migraine prophylaxis agents from two different pharmacological classes (e.g., anticonvulsants, beta blockers, antidepressants).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist, headache specialist, or pain specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• dalfampridine er

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe renal impairment (CrCl less than or equal to 50mL per min). History of seizures or a seizure disorder.
Required Medical Information	1) MS: patient must be ambulatory. 2) All indications: a baseline serum creatinine must be obtained prior to initiation of medication.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist or MS specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• ANADROL-50

PA Criteria	Criteria Details
Exclusion Criteria	Nephrosis or the nephrotic phase of nephritis. Severe hepatic dysfunction. Carcinoma of the prostate or breast in male patients. Carcinoma of the breast in females with hypercalcemia. Pregnancy in females of reproductive potential.
Required Medical Information	Anadrol-50 will not be used as replacement of other supportive measures, e.g., correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, etc., if any.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• APOKYN

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a serotonin 5-HT3 antagonist (ondansetron, granisetron, dolasetron, palonosetron, alosetron).
Required Medical Information	Parkinson's Disease: 1. Patient must have a diagnosis of advanced Parkinson's disease. 2. Patient is experiencing an acute hypomobility off episode (i.e. muscle stiffness, slow movements, or difficulty starting movements) AND 3. Evidence of a claim that the patient is receiving concurrent therapy for Parkinson's disease (e.g. levodopa, dopamine agonist, or monoamine oxidase B inhibitor) within the past 30 days.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Apomorphine will not be approved for the prevention of off episodes.
Indications	All Medically-accepted Indications.
Off Label Uses	

ARALAST NP INTRAVENOUS
 SOLUTION RECONSTITUTED 1000 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of emphysema and an alpha-1-antitrypsin (AAT) deficiency with PiZ, PiZ (null), or Pi (null, null) phenotype
Age Restrictions	AAT deficiency: 18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• ARANESP (ALBUMIN FREE)

PA Criteria	Criteria Details
Exclusion Criteria	Patients with cancer receiving hormonal agents, biologics, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. Patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure or in whom the anemia can be managed by transfusion. As a substitute for RBC transfusions in pts who require immediate correction of severe anemia.
Required Medical Information	1. Anemia associated with chronic kidney disease (CKD) in including patients on dialysis (end-stage renal disease) and patients not on dialysis: dx of CKD, anemia by lab value within 30 days of request (Hgb less than 10 g/dL or Hct less than 30 percent). 2. Symptomatic anemia in cancer patients receiving chemotherapy: cancer is a non-myeloid malignancy, anemia is caused in part by the effect of administered chemotherapy, patient must be on chemotherapy concurrently for a minimum of 2 months, anemia by lab value within 30 days of request (Hgb less than 10 g/dL or Hct less than 30 percent). 3. Anemia in MDS: dx of MDS, serum erythropoietin level 500 mU/mL or less or dx of transfusion-dependent MDS.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	Patients will be provided an exception if administration of prerequisite blood products conflicts with religious beliefs. Reauth for CKD and anemia caused by chemo: Most recent or average Hct over 3-month period is 30 percent or less or Hgb over same period 11 g/dL or less. MDS: most recent or average Hct over 3-month period is 36 percent or less or most recent or average Hgb over same period 12 g/dL or less.
Indications	All Medically-accepted Indications.
Off Label Uses	

# arcalyst

#### **Products Affected**

• ARCALYST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	12 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a rheumatologist or immunologist.
Coverage Duration	End of plan year
Other Criteria	Patient is not receiving in combination with biologic DMARDs such as TNF antagonists or IL-1R antagonists,
Indications	All Medically-accepted Indications.
Off Label Uses	

• AUBAGIO

PA Criteria	Criteria Details
Exclusion Criteria	Use in combination with leflunomide. Severe hepatic impairment.
Required Medical Information	Baseline liver function tests or clinical notes documenting patient does not have severe hepatic impairment. For female patient's of childbearing potential only: a) patient must have a negative pregnancy test result within 2 weeks prior to start of therapy and b) documentation must be provided that patient is using reliable contraception.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist or MS specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

## austedo

#### **Products Affected**

 AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with tetrabenazine, valbenazine, reserpine, or monoamine oxidase inhibitors (e.g., selegiline, isocarboxazid, phenelzine, tranylcypromine). Patients with hepatic impairment. For Huntington's disease only, patients who have suicidal ideations, or have untreated or inadequately treated depression.
Required Medical Information	Patient has a documented failure of, intolerance to, or contraindication to tetrabenazine.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or psychiatrist.
Coverage Duration	End of plan year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• AVASTIN

PA Criteria	Criteria Details
Exclusion Criteria	Non-Small Cell Lung Cancer: Excluded if squamous cell histology.
Required Medical Information	Colorectal Cancer: Diagnosis of metastatic colorectal cancer. One of the following: 1) Both of the following: a) used as first- or second-line treatment and b) used in combination with an intravenous 5-fluorouracil- based chemotherapy, OR 2) All of the following: a) used as second-line treatment, b) used in combination with fluoropyrimidine-irinotecan-based chemotherapy or fluoropyrimidine-oxaliplatin-based chemotherapy, and c) patient has progressed on a first-line bevacizumab-containing regimen. Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is unresectable, locally advanced, recurrent, or metastatic. Used as first-line treatment. Used in combination with paclitaxel and carboplatin. Renal Cell Cancer: Diagnosis of metastatic renal cell cancer. Used in combination with interferon-alpha. Cervical Cancer: Diagnosis of recurrent glioblastoma. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) All of the following: a) disease is platinum-resistant recurrent, b) patient has received no more than 2 prior chemotherapy regimens, and c) used in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, OR 3) All of the following: a) disease is platinum-sensitive recurrent, b) patient has been treated with bevacizumab as a single agent, c) treatment is collowing suggical resection, or 3) All of the following: a) disease is platinum-sensitive recurrent, b) patient has been treated with bevacizumab as a single agent, c) treatment and paclitaxel, or topotecan, OR 3) All of the following: a) disease is platinum-sensitive recurrent, b) patient has been treated with bevacizumab as a single agent, and c) used in combination with an a paclitaxel or ii) carboplatin and gemcitabine.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

PA Criteria	Criteria Details
Indications	All Medically-accepted Indications.
Off Label Uses	

• AVONEX PEN

### AVONEX PREFILLED

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours, and proceeded by stability or improvement for at least 30 days. The patient must have a diagnosis of relapsing forms of Multiple Sclerosis (MS), to include Clinically Isolated Syndrome, Relapsing-Remitting disease, and Active Secondary Progressive Disease.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist or MS specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• BENLYSTA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	Severe active lupus nephritis, Severe active central nervous system lupus, In combination with other biologic products (including B-cell targeted therapies) or intravenous cyclophosphamide
Required Medical Information	Currently receiving at least one standard of care treatment for active SLE (e.g., antimalarials (e.g., hydroxychloroquine), corticosteroids (e.g., prednisone), or immunosuppressants (e.g., methotrexate, azathioprine).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a rheumatologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# BEOVU

#### **Products Affected**

• BEOVU

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

## berinert

#### **Products Affected**

• BERINERT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (e.g., Firazyr, Ruconest).
Age Restrictions	5 years of age or older
Prescriber Restrictions	Prescribed by or in consult with an allergist, immunologist, or other prescriber that specialized in the treatment of HAE.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• BETASERON

### • EXTAVIA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Have had at least two acute exacerbations during the previous two years, which consisting of new symptoms or aggravation of old symptoms lasting at least 24 hours, and preceded by stability or improvement for at least 30 days. The patient must have a diagnosis of relapsing forms of Multiple Sclerosis (MS), to include Clinically Isolated Syndrome, Relapsing-Remitting disease, and Active Secondary Progressive Disease
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist or MS specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# cablivi

#### **Products Affected**

CABLIVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient is currently receiving at least one immunosuppressive therapy agent.
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	3 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• CAYSTON

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation must be provided with evidence of Pseudomonas aeruginosa lung infection.
Age Restrictions	7 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a pulmonologist, endocrinologist, or infectious disease specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• CERDELGA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Gaucher's disease (Initial): Diagnosis of Gaucher's disease type 1. Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Gaucher's disease (Reauth): Patient's condition has not progressed, as defined by ALL of the following: A) Hemoglobin level decreased greater than 1.5 g/dL from baseline, AND B) Platelet count decreased greater than 25% from baseline, AND C) Spleen volume
Indications	All Medically-accepted Indications.
Off Label Uses	

## cholbam

#### **Products Affected**

• CHOLBAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 2) patient has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g., rickets).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• tadalafil oral tablet 2.5 mg, 5 mg

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with a nitrate or riociguat.
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Approval will not be granted for the treatment of erectile dysfunction
Indications	All Medically-accepted Indications.
Off Label Uses	

# CICLODAN

#### **Products Affected**

• ciclodan

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

CIMZIA

### • CIMZIA PREFILLED KIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to certolizumab. CD: a documented trial and inadequate response or intolerance to one of the following: a salicylate (mesalamine, sulfasalazine), an oral corticosteroid, or an immunomodulator (e.g., azathioprine, mercaptopurine, methotrexate). RA and PsA: a documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, D-penicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds, cyclosporine. For PsA, if patient has documented axial PsA or enthesitis the above trial can be overridden AND instead patient must have a documented trial and inadequate response or intolerance to a prescription NSAID. AS: documented trial and inadequate response or intolerance to one of the following: NSAIDs, sulfasalazine, intra-articular glucocorticoids. Plaque psoriasis: documented trial and inadequate response or intolerance to methotrexate and one of the following: topical corticosteroid, calcipotriene, calcitriol, tazarotene, anthralin, acetretin, cyclosporine, tacrolimus ointment, or pimecrolimus cream.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Plaque psoriasis: prescribed by or in consult with a dermatologist or rheumatologist. RA, PsA, AS, non-radiographic axial spondyloarthritis: prescribed by or in consult with a rheumatologist. CD prescribed by or in consult with a gastroenterologist.
Coverage Duration	End of plan year
Other Criteria	Patient is not receiving in combination with biologic DMARDs or other TNF antagonists.
Indications	All Medically-accepted Indications.
Off Label Uses	

• CINRYZE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (e.g., Firazyr, Ruconest). HAE Prophylaxis: Diagnosis of HAE. Prescribed for prophylaxis against HAE attacks.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Prescribed by or in consult with an allergist, immunologist, or other prescriber that specialized in the treatment of HAE.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

### copaxone

#### **Products Affected**

- glatiramer acetate subcutaneous solution glatopa subcutaneous solution prefilled prefilled syringe 20 mg/ml, 40 mg/ml
  - syringe 20 mg/ml, 40 mg/ml

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist or MS specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

CORLANOR ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	Acute decompensated heart failure, blood pressure less than 90/50 mmHG, sick sinus syndrome, sinoatrial block or 3rd degree AV block (unless a functioning demand pacemaker is present), severe hepatic impairment, pacemaker dependence (heart rate maintained exclusively by the pacemaker).
Required Medical Information	Chronic heart failure (CHF) in Adults: ALL of the following: 1) Patient has stable, symptomatic chronic heart failure (e.g. NYHA Class II, III, IV, ACCF/AHA Class C, D) AND 2) Patient has a baseline OR current left ventricular ejection fraction of less than or equal to 35% AND 3) Patient is in sinus rhythm with a resting heart rate of greater than or equal to 70 beats per minute AND 4) ONE of the following: A) Patient is on a maximally tolerated dose of beta blocker (e.g. atenolol, bisoprolol, carvedilol, metoprolol) OR B) Patient has a history of a documented intolerance, FDA labeled contraindication, or hypersensitivity to a beta blocker.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a cardiologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• COSENTYX (300 MG DOSE)

### • COSENTYX SENSOREADY (300 MG)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to secukinumab. Plaque psoriasis: documented trial and inadequate response or intolerance to methotrexate and one of the following: topical corticosteroid, calcipotriene, calcitriol, tazarotene, anthralin, acetretin, cyclosporine, tacrolimus ointment, or pimecrolimus cream. PsA: a documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, D-penicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds, or cyclosporine. For PsA, if patient has documented axial PsA or enthesitis the above trial can be overridden AND instead patient must have a documented trial and inadequate response or intolerance to a prescription NSAID. AS: documented trial and inadequate response or intolerance to one of the following: NSAIDs, sulfasalazine, intra-articular glucocorticoids.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Plaque psoriasis: prescribed by or in consult with a dermatologist or rheumatologist. PsA, AS: prescribed by or in consult with a rheumatologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

CRINONE

PA Criteria	Criteria Details
Exclusion Criteria	Use in patients to supplement or replace progesterone as part of an Assisted Reproductive Technology (ART) treatment for infertile women with progesterone deficiency.
Required Medical Information	Secondary Amenorrhea: Patient must have trial and failure with Crinone 4% vaginal gel.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

## cystaran

## **Products Affected**

• CYSTARAN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystinosis: Diagnosis of cystinosis, confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation AND Patient is concomitantly receiving treatment with oral cysteamine.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• DALIRESP

PA Criteria	Criteria Details
Exclusion Criteria	Moderate to severe hepatic impairment. Patient is experiencing acute bronchospasms.
Required Medical Information	Baseline liver function tests should be obtained prior to treatment initiation. Patient must have moderate to severe COPD (FEV1 between 30 and 80 percent of normal). One of the following: A) Patient has had an inadequate response to an agent from two of the following categories: i. long-acting beta-2 agonist ii. long-acting antimuscarinic antagonist/anticholinergic iii. inhaled corticosteroid OR B) patient has a documented intolerance or contraindication two an agent from two of the following categories: i. long-acting beta-2 agonist ii. long-acting antimuscarinic antagonist/anticholinergic iii. inhaled corticosteroid
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# daraprim

## **Products Affected**

• pyrimethamine oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Toxoplasmosis: 1) Patient is using pyrimethamine for the treatment of toxoplasmic encephalitis, toxoplasmosis chorioretinitis, or congenital toxoplasmosis OR 2) Patient is using pyrimethamine for the primary prophylaxis of toxoplasmosis following a hematopoietic stem cell transplant, or secondary prophylaxis of toxoplasmosis encephalitis.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with an infectious disease specialist.
Coverage Duration	End of plan year
Other Criteria	Toxoplasmosis only: Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

## dextroamphet

### Products Affected

- amphetamine-dextroamphetamine er
- dexmethylphenidate hcl
- dexmethylphenidate hcl er oral capsule extended release 24 hour 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 5 mg
- dextroamphetamine sulfate er oral capsule extended release 24 hour 10 mg, 15 mg, 5 mg
- dextroamphetamine sulfate oral tablet 10
  mg, 5 mg
- metadate er
- methylphenidate hcl er (cd)

- methylphenidate hcl er (la) oral capsule extended release 24 hour 10 mg, 60 mg
- methylphenidate hcl er oral tablet extended release 10 mg, 18 mg, 20 mg, 27 mg, 36 mg, 54 mg
- methylphenidate hcl er oral tablet extended release 24 hour 18 mg, 27 mg, 36 mg, 54 mg
- methylphenidate hcl oral solution
- methylphenidate hcl oral tablet
- methylphenidate hcl oral tablet chewable 10 mg, 2.5 mg, 5 mg
- zenzedi oral tablet 10 mg, 15 mg, 2.5 mg, 20 mg, 30 mg, 5 mg, 7.5 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

## diacomit

## **Products Affected**

• DIACOMIT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with clobazam.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

## diclofenac

## **Products Affected**

• diclofenac sodium external solution

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Osteoarthritis: 1) Must be used for signs and symptoms of osteoarthritis of joints amenable to topical treatment such as the knee(s) and those of the hands AND 2) Must have therapeutic failure with a one-week trial of an NSAID OR pt has had intolerable side effects or contraindications to NSAIDs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# differin

## **Products Affected**

- adapalene external cream
- adapalene external gel
- adapalene external solution
- adapalene-benzoyl peroxide external gel
- AVITA

- clindamycin-tretinoin
- EPIDUÓ FORTE
- tretinoin external
- tretinoin microsphere

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	9 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

 EGRIFTA SUBCUTANEOUS SOLUTION RECONSTITUTED 1 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	HIV-associated lipodystrophy (initial): All of the following: 1) diagnosis of HIV-associated lipodystrophy, 2) one of the following: a) waist- circumference of at least 95 cm (37.4 inches) AND waist-to-hip ratio of at least 0.94 in men, OR b) waist-circumference of at least 94 cm (37 inches) AND waist-to-hip ratio of at least 0.88 in women.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	(Reauth): documentation of clinical improvement (e.g., improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance, etc.) while on Egrifta therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

• EMGALITY

## • EMGALITY (300 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	Concurrent use with another CGRP inhibitor.
Required Medical Information	Cluster headache: Patient has been diagnosed with episodic cluster headaches. For all other indications One of the following: 1) Patient has tried and failed at least TWO conventional migraine prophylaxis agents from two different pharmacological classes (e.g., anticonvulsants, beta blockers, antidepressants) for two months each or 2) Patient has a documented contraindication to TWO conventional migraine prophylaxis agents from two different pharmacological classes (e.g., anticonvulsants, beta blockers, antidepressants).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist, headache specialist, or pain specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• ENBREL

## • ENBREL SURECLICK

ENBREL MINI

PA Criteria	Criteria Details
Exclusion Criteria	Shall not be granted for use Wegener¿s granulomatosis.
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to etanercept. Plaque psoriasis: documented trial and inadequate response or intolerance to methotrexate and one of the following: topical corticosteroid, calcipotriene, calcitriol, tazarotene, anthralin, cyclosporine, tacrolimus ointment, or pimecrolimus cream. RA/jRA/PsA: documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, D- penicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds. For PsA, if patient has documented axial PsA or enthesitis the above trial can be overridden must have a documented trial and inadequate response or intolerance to a prescription NSAID. AS: documented trial and inadequate response or intolerance to one of the following: NSAIDs, sulfasalazine, intra-articular glucocorticoids.
Age Restrictions	2 years of age or older
Prescriber Restrictions	Plaque psoriasis: prescribed by or in consult with a dermatologist or rheumatologist. PsA, RA, jRA, AS: prescribed by or in consult with a rheumatologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• ENTRESTO

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment. Concomitant use with ACE inhibitors or ARBs. Concomitant use with aliskiren (Tekturna) in diabetic patients. Concomitant use with aliskiren (Tekturna) in renal impairment (eGFR less than 60).
Required Medical Information	Adult CHF patients: 1) Documentation of CHF diagnosis. 2) NYHA classification II, III, or IV AND 3) Documentation of left ventricular ejection fraction less than or equal to 40%.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a cardiologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• sofosbuvir-velpatasvir

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of chronic hepatitis C infection and genotype. Documentation of quantitative baseline HCV RNA load performed within the prior 6 months. Documentation of testing for evidence of current or prior HBV infection. Prior tx history (if tx experienced, known dates and drugs(s) of prior HCV tx). Hepatic fibrosis stage as confirmed by one of the following: liver biopsy, transient elastography (FibroScan) score, fibrotest score (such as FibroSure), APRI score, FIB-4 score, severe extrahepatic manifestations/sx per radiology report. Presence or absence of cirrhosis (if cirrhosis is present, compensated vs. decompensated). HIV coinfection status. Liver and kidney transplant status if applicable.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a hepatologist, gastroenterologist, infectious disease or liver disease specialist.
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# epidiolex

## **Products Affected**

• EPIDIOLEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Lennox-Gastaut syndrome (LGS): Diagnosis of seizures associated with LGS. Trial of, contraindication, or intolerance to two formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate). Dravet syndrome (DS): Diagnosis of seizures associated with DS.
Age Restrictions	
Prescriber Restrictions	LGS, DS: Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# erthyropoietin

## **Products Affected**

• PROCRIT

## • RETACRIT

PA Criteria	Criteria Details
Exclusion Criteria	As a substitute for RBC transfusions in pts who require immediate correction of severe anemia.
Required Medical Information	1. Anemia associated with chronic kidney disease (CKD) in including patients on dialysis (end-stage renal disease) and patients not on dialysis: dx of CKD, anemia by lab value within 30 days of request (Hgb less than 10 g/dL or Hct less than 30 percent). 2. Anemia in HIV infection: anemia by lab value within 30 days of request (Hgb less than 12 g/dL or Hct less than 36 percent) and serum erythropoietin level 500 mU/mL or less, and patient is receiving zidovudine therapy. 3. Symptomatic anemia in cancer patients receiving chemotherapy: cancer is a non-myeloid malignancy, anemia is caused in part by the effect of administered chemotherapy, patient must be on chemotherapy concurrently for a minimum of 2 months, anemia by lab value within 30 days of request (Hgb less than 10 g/dL or Hct less than 30 percent). 4. Anemia in surgery: patient is scheduled to undergo elective, noncardiac, nonvascular surgery and pretreatment Hgb is greater than 10 g/dL and less than or equal to 13 g/dL.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Surgical prophylaxis: 1 month. All other indications: 3 months.
Other Criteria	Patients will be provided an exception if administration of prerequisite blood products conflicts with religious beliefs. Reauth for CKD and anemia caused by chemo: Most recent or average Hct over 3-month period is 30 percent or less or Hgb over same period 11 g/dL or less. MDS: most recent or average Hct over 3-month period is 36 percent or less or most recent or average Hgb over same period 12 g/dL or less.
Indications	All Medically-accepted Indications.
Off Label Uses	

• ESBRIET ORAL CAPSULE

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh Category C). End stage renal disease on dialysis.
Required Medical Information	A clear diagnosis of idiopathic pulmonary fibrosis has been made excluding other known causes of interstitial lung disease (e.g. domestic and occupational environmental exposures, connective tissue disease, drug toxicity).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a pulmonologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• EVENITY

PA Criteria	Criteria Details
Exclusion Criteria	Hypocalcemia
Required Medical Information	Postmenopausal osteoporosis: patient should meet National Osteoporosis Foundation guidelines for treatment and have one of the following: 1. Bone mineral density (BMD) 2.5 or more standard deviations below mean value (i.e., T-score less than 2.5) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) with no risk factors 2. BMD T-score below 1.5 with one or more risk factors 3. History of low- trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm.
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Must have a trial and failure to a bisphosphonate agent or denosumab unless patient has a contraindication to both. Treatment duration with romosozumab-aqqg has not exceeded a total of 12 months during the patient's lifetime.
Indications	All Medically-accepted Indications.
Off Label Uses	

• deferasirox

PA Criteria	Criteria Details
Exclusion Criteria	Serum creatinine is greater than 2 times the age-appropriate upper limit of normal (ULN). Estimated GFR less than 40 mL/min. Patient has poor performance status, patient has high-risk myelodysplastic syndrome (MDS), patient has advanced malignancy, or patient has a platelet count less than 50 x 10^9/L.
Required Medical Information	Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Chronic Iron Overload Due to Non-Transfusion Dependent Thalassemia (NTDT)(Initial): Diagnosis of NTDT. Patient has serum ferritin level greater than 300 mcg/L AND liver iron concentration of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw).
Age Restrictions	Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a hematologist, oncologist, hepatologist, or infectious disease specialist.
Coverage Duration	End of plan year
Other Criteria	Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin lev
Indications	All Medically-accepted Indications.
Off Label Uses	

• FASENRA

## • FASENRA PEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: 1) Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months, OR 2) Any prior intubation for an asthma exacerbation, OR 3) Prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)].
Age Restrictions	Asthma (Initial): Patient is 12 years of age or older
Prescriber Restrictions	Asthma (Initial/Reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist
Coverage Duration	Asthma (init): 6 months. Asthma (reauth): 12 months
Other Criteria	Asthma (Reauth): Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications). Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)].
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	

## FENTANYL

#### **Products Affected**

ABSTRAL SUBLINGUAL TABLET
 SUBLINGUAL 400 MCG, 600 MCG, 800
 MCG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• deferiprone

## • FERRIPROX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) Serum iron studies confirming iron overload. 2) Patient has tried Exjade with inadequate response.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# fintepla

## **Products Affected**

• FINTEPLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of seizures associated with Dravet syndrome
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

• icatibant acetate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (e.g., Berinert, Ruconest).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with an allergist, immunologist, or other prescriber that specialized in the treatment of HAE.
Coverage Duration	End of Plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• FIRDAPSE

PA Criteria	Criteria Details
Exclusion Criteria	History of seizures.
Required Medical Information	Diagnosis of LEMS as confirmed by neurophysiology study or a positive anti-P/Q Type voltage-gated calcium channel antibody test.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	Prescribed by or in consult with a neurologist.
Coverage Duration	End of plan year.
Other Criteria	Reauthorization: documentation of a positive clinical response to Firdapse therapy (e.g., improvement in Quantitative Myasthenia Gravis (QMD) score, Subject Global Impression (SGI) score, clinical global impression improvement (CGI-I) score).
Indications	All Medically-accepted Indications.
Off Label Uses	

## **FLEBOGAMMA DIF**

## **Products Affected**

 FLEBOGAMMA DIF INTRAVENOUS SOLUTION 10 GM/200ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• FORTEO

PA Criteria	Criteria Details
Exclusion Criteria	Children or adolescents with open epiphyses, Paget¿s disease of the bone, hypercalcemia, patients with bone cancer or other cancers that have metastasized to the bones
Required Medical Information	1. A baseline calcium level must be obtained prior to treatment initiation. 2. Patient should also meet National Osteoporosis Foundation guidelines for treatment and have one of the following: a) Bone Mineral Density (BMD) 2.5 or more standard deviations below the mean value (i.e. T- score less than 2.5) with no risk factors OR b) BMD T-score below 1.5 (1.5 or more standard deviations below the mean value) with one or more of the following risk factors: history of low trauma (non-collision) osteoporotic fracture as and adult, family history of fracture, low body weight (less than 127 lb) or low mass index, rheumatoid arthritis, vitamin D deficiency, use of oral glucocorticoids for at least 3 months at a dose of prednisone of 5 mg daily or more (or equivalent dose of other glucocorticoids), vitamin D deficiency, anticonvulsants, or loop diuretics, increased fall risk (poor vision, dementia, neuromuscular disorder), age greater than or equal to 65 years of age, current smoker, or alcohol intake greater than or equal to 3 drinks per day. 3. Patient must have a prior trial and failure to at least one oral bisphosphonate agent unless patient has a clinical reason to avoid treatment with oral bisphosphonates.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Treatment duration of all parathyroid hormones combined (i.e. , teriparatide and abaloparatide) must not exceed a total of 24 months during the patient's lifetime.
Indications	All Medically-accepted Indications.
Off Label Uses	

## fortesta

## **Products Affected**

- ANDRODERM
- depo-testosterone
- STRIANT BUCCAL 30 MG
- testosterone cypionate intramuscular
- testosterone enanthate intramuscular
- testosterone transdermal gel 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 40.5 mg/2.5gm (1.62%)

PA Criteria	Criteria Details
Exclusion Criteria	Female patients except for those with advancing inoperable metastatic (skeletal) mammary cancer. Patients with testosterone levels greater than 300 ng per dL.
Required Medical Information	A baseline testosterone level must be obtained prior to treatment initiation (baseline level must be less than 300 ng per dL). A level will not be required for women with advancing inoperable metastatic (skeletal) mammary cancer.
Age Restrictions	12 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• FULPHILA

PA Criteria	Criteria Details
Exclusion Criteria	Chemotherapy associated with delayed myelosuppression. Mobilization of peripheral blood progenitor cells for HSCT.
Required Medical Information	Primary prophylaxis of febrile neutropenia (FN): One of the following: 1) patient is receiving chemotherapy regimen associated with a greater than 20% incidence of FN, OR 2) patient is receiving National Cancer Institute's Breast Intergroup, INT c9741 dose dense chemotherapy protocol for primary breast cancer. 3) Both of the following: a) patient receiving chemotherapy regimen associated with 10- 20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (AND less than or equal to 500 cells/mm3), AND 2) patients with a history of FN during a previous course of chemotherapy.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a hematologist or oncologist.
Coverage Duration	FN treatment: 1 month. All other medically-accepted indications: 3 months.
Other Criteria	Reauth: appropriate lab tests - CBC and platelet count, must be conducted to necessitate the continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# galafold

## **Products Affected**

• GALAFOLD

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Galafold will not be used in combination with Fabrazyme (agalsidase beta).
Indications	All Medically-accepted Indications.
Off Label Uses	

• GATTEX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Short bowel syndrome: 1) Patient is dependent on parenteral support. 2) Colonoscopy of the entire colon has been performed with any polyps removed, if present, within 6 months prior to initiating treatment if patient is 18 years or older OR if patient is between 1 and 17 years of age and has unexplained blood in the stool.
Age Restrictions	1 year of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	SBS (Reauth): Documentation of positive clinical response.
Indications	All Medically-accepted Indications.
Off Label Uses	

• GAVRETO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Presence of rearranged during transfection (RET) gene fusion-positive tumor(s).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy
Indications	All Medically-accepted Indications.
Off Label Uses	

• GILENYA ORAL CAPSULE 0.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Active infection. Recent MI, unstable angina, stroke, transient ischemic attack, decompensated heart failure w/ hospitalization, or Class III/IV heart failure. Cardiac arrhythmias requiring treatment with Class Ia or Class III anti-arrhythmic drugs.
Required Medical Information	A baseline ophthalmologic evaluation and liver function tests should be performed prior to the initiation of treatment. Varicella zoster virus (VZV) antibody test should be performed. If VZV negative, prescriber must attest that patient has received or will receive VZV vaccine AND fingolimod will be postponed for at least one month following administration to allow immunity to develop.
Age Restrictions	10 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist or MS specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

## GIVLAARI

## **Products Affected**

• GIVLAARI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• GRANIX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, 2) patient is receiving chemotherapy regimen following bone marrow transplant, OR 2) both of the following: a) patient receiving chemotherapy regimen with 10-20% risk of FN AND b) patient has any of the following FN risk factors: 1) 65 years of age or older 2) prior chemo or radiation therapy 3) persistent neutropenia 4) HIV 5) CrCl below 50 mL/min 5) bilirubin level greater than 2 mg/dL 6) recent surgery or open wounds 7) bone marrow involvement by tumor
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a hematologist, oncologist, or infectious disease specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE
- NORDITROPIN FLEXPRO
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 20

- NUTROPIN AQ NUSPIN 5
- OMNITROPE SUBCUTANEOUS
  SOLUTION CARTRIDGE
- SAIZEN
- SAIZENPREP
- SEROSTIM

PA Criteria	Criteria Details
Exclusion Criteria	Closed epiphyses in pediatric patients. Active malignancy. Prader-Willi syndrome patients with any of the following: severe obesity, severe respiratory impairment, hx upper airway obstruction, hx sleep apnea.
Required Medical Information	Long-term tx of GF in children: 1. Ht is more than 2 SD below mean for chron. age. 2. Ht velocity is more than 2 SD below the age mean. 4. One of the following: a) IGF-1 levels are less than 84 ng/L or more than 2 SD below the mean level. b) If IGF-1 levels are only moderately reduced, two GH stim tests (e.g., insulin, arginine, clonidine, levodopa/carbidopa, glucagon) must be less than 10 ng/nL. Replacement therapy in adult onset GHD: 1. One of the following: a) Clinical manifestations consistent with GHD (e.g., dyslipidemia, cardiovascular disease, impaired psychological function, change in body composition such as increase in fat mass w/ decrease in lean body mass, decreased QOL, reduced exercise tolerance, decreased bone mineral density). b) Documented pituitary or hypothalamic disease evidenced by panhypopituitarism, surgery, prior tx such as cranial irradiation, hx of head injury, or radiographic imaging such as MRI. 2. One of the following: a) IGF-1 levels are less than 84 ng/L or more than 2 SD below the mean level. b) If IGF-1 levels are only moderately reduced, two GH stim tests (e.g., insulin, arginine, clonidine, levodopa/carbidopa, glucagon) must be less than 10 ng/nL. Replacement therapy in adults with childhood onset GHD: 1. One of the following: a) Documented pituitary or hypothalamic disease evidenced by panhypopituitarism, surgery, prior tx such as cranial irradiation, history of head injury, or radiographic imaging such as MRI. b) Documented idiopathic GHD in childhood w/ evidence of GH tx during childhood. 2. One of the following: a) IGF-1 levels are only moderately reduced, two GH stim tests (e.g., insulin, arginine, clonidine, levol. b) If IGF-1 levels are only moderately reduced, two GH stim tests (e.g., insulin, arginine, clonidine, levodopa/carbidopa, glucagon) must be less than 84 ng/L or more than 2 SD below the mean level. b) If IGF-1 levels are only moderately reduced, two GH stim tests (e.g., insulin, arginine, clonidine, levodopa/carbidopa, glucagon) must be less than 10 ng/nL. Tu
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consult with an endocrinologist, infectious disease specialist, or gastroenterologist. GF due to chronic renal insufficiency: prescribed by or in consult with an endocrinologist or nephrologist.
Coverage Duration	End of plan year
Other Criteria	For patients with AIDS related wasting with involuntary weight loss, patient is currently on antiretroviral therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

- HARVONI ORAL PACKET 33.75-150 MG, 45-200 MG
- HARVONI ORAL TABLET 45-200 MG
- ledipasvir-sofosbuvir

PA Criteria	Criteria Details
Exclusion Criteria	Coadministration with sofosbuvir.
Required Medical Information	Documentation of chronic hepatitis C infection and genotype. Documentation of quantitative baseline HCV RNA load performed within the prior 6 months. Documentation of testing for evidence of current or prior HBV infection. Prior tx history (if tx experienced, known dates and drugs(s) of prior HCV tx). Hepatic fibrosis stage as confirmed by one of the following: liver biopsy, transient elastography (FibroScan) score, fibrotest score (such as FibroSure), APRI score, FIB-4 score, severe extrahepatic manifestations/sx per radiology report. Presence or absence of cirrhosis (if cirrhosis is present, compensated vs. decompensated). HIV coinfection status. Liver and kidney transplant status if applicable.
Age Restrictions	3 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a hepatologist, gastroenterologist, infectious disease or liver disease specialist.
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• HETLIOZ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Non-24-hour Sleep-Wake-Disorder both of the following: patient has diagnosis of Non-24-hour Sleep-Wake-Disorder AND patient is totally blind (i.e. no light perception).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a neurologist or sleep specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

- carisoprodol oral tablet 350 mg
- menest

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For patients less than or equal to 64 years, claim will automatically pay. For patients greater than or equal to 65 years, coverage determination is approved for medically accepted indications not otherwise excluded from Part D, AND prescriber must acknowledge that medication benefits outweighs potential risks.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# humira

# **Products Affected**

- HUMIRA
- HUMIRA PEDIATRIC CROHNS START
- HUMIRA PEN

- HUMIRA PEN-CD/UC/HS STARTER
- HUMIRA PEN-PS/UV/ADOL HS START
- HUMIRA PEN-PSOR/UVEIT STARTER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to adalimumab. RA/jRA/ PsA: documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, D-penicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds. For PsA, if patient has documented axial PsA or enthesitis the above trial can be overridden AND instead patient must have a documented trial and inadequate response or intolerance to a prescription NSAID. Plaque psoriasis: documented trial and inadequate response or intolerance to methotrexate and one of the following: topical corticosteroid, calcipotriene, calcitriol, tazarotene, anthralin, cyclosporine, tacrolimus ointment, or pimecrolimus cream. AS: documented trial and inadequate response or intolerance to one of the following: NSAIDs, sulfasalazine, intra-articular glucocorticoids. UC/CD: a documented trial and inadequate response or intolerance to one of the following: a salicylate (e.g., balsalazide, mesalamine, sulfasalazine), an oral corticosteroid, azathioprine, or mercaptopurine. HS: patient has documented hidradenitis suppurativa with Hurley Stage II or III disease and with at least 3 abscesses or inflammatory nodules.
Age Restrictions	2 years of age or older
Prescriber Restrictions	Plaque psoriasis: prescribed by or in consult with a dermatologist or rheumatologist. PsA, RA, jRA, AS: prescribed by or in consult with a rheumatologist. CD/UC: prescribed by or in consult with a gastroenterologist. HS: prescribed by or in consult with a dermatologist. Uveitis: Prescribed by or in consultation with an ophthalmologist or rheumatologist.
Coverage Duration	End of plan year
Other Criteria	Patient is not receiving in combination with biologic DMARDs or other TNF antagonists.
Indications	All Medically-accepted Indications.

PA Criteria	Criteria Details
Off Label Uses	

• ILUMYA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Plaque Psoriasis (initial): Diagnosis of moderate-to-severe plaque psoriasis. One of the following: set A) Both of the following: 1) Trial and failure, contraindication, or intolerance to one of the following: Enbrel (etanercept), Humira (adalimumab), Skyrizi (risankizumab), AND 2) Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab), or set B) For continuation of prior therapy.
Age Restrictions	
Prescriber Restrictions	Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Plaque Psoriasis (Reauth): Documentation of positive clinical response to therapy as evidenced by one of the following: reduction in the body surface area (BSA) involvement from baseline, OR improvement in symptoms (eg, pruritus, inflammation) from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	

# immunizing agents, passive

# Products Affected

- FLEBOGAMMA DIF INTRAVENOUS SOLUTION 5 GM/50ML
- GAMMAGARD INJECTION SOLUTION
  2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMMAKED INJECTION SOLUTION 1
  GM/10ML
- GAMMAPLEX INTRAVENOUS
  SOLUTION 10 GM/200ML
- GAMUNEX-C INJECTION SOLUTION 1
  GM/10ML
- OCTAGAM INTRAVENOUS SOLUTION
  1 GM/20ML, 2 GM/20ML
- PRIVIGEN INTRAVENOUS SOLUTION
  20 GM/200ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• INBRIJA

PA Criteria	Criteria Details
Exclusion Criteria	Prevention of off episodes. Asthma, COPD, or other chronic underlying lung disease. Currently taking a MAO inhibitor or has taken one within the last two weeks.
Required Medical Information	Patient is experiencing an off episode. Patient must currently be receiving and will continue to receive concomitant carbidopa/levodopa therapy.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	
Coverage Duration	End of plan year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• INQOVI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome. Patient has ONE of the following French- American-British subtypes: a) refractory anemia, b) refractory anemia with ringed sideroblasts, c) refractory anemia with excess blasts, or d) chronic myelomonocytic leukemia (CMML).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

• deferasirox

• JADENU SPRINKLE

• deferasirox granules

PA Criteria	Criteria Details
Exclusion Criteria	Serum creatinine is greater than 2 times the age-appropriate upper limit of normal (ULN). Estimated GFR less than 40 mL/min. Patient has poor performance status, patient has high-risk myelodysplastic syndrome (MDS), patient has advanced malignancy, or patient has a platelet count less than 50 x 10^9/L.
Required Medical Information	Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Chronic Iron Overload Due to Non-Transfusion Dependent Thalassemia (NTDT)(Initial): Diagnosis of NTDT. Patient has serum ferritin level greater than 300 mcg/L AND liver iron concentration of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw).
Age Restrictions	Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a hematologist, oncologist, hepatologist, or infectious disease specialist.
Coverage Duration	End of plan year
Other Criteria	Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin lev
Indications	All Medically-accepted Indications.
Off Label Uses	

• JUXTAPID

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment (Child-Pugh category B or C) or active hepatic disease. Pregnancy in females of reproductive potential.
Required Medical Information	1) Patient has a clinical or laboratory diagnosis consistent with homozygous familial hypercholesterolemia defined as a) documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality OR b) skin fibroblast LDL receptor activity less than 20% normal, OR c) untreated TC greater than 500 mg/dL and TG less than 300 mg/dL and both parents with documented untreated TC greater 250 mg/dL. 2) Baseline liver function tests. 3) One of the following: a. Patient is on a maximally tolerated lipid-lowering regimen in the last 90 days (i.e. rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe) OR b. Patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a maximally tolerated lipid-lowering regimen (i.e. rosuvastatin in combination with ezetimibe OR atorvastatin in combination with ezetimibe).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# kalydeco

# **Products Affected**

• KALYDECO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient has an ivacaftor-responsive mutation in the CFTR gene. Patient is not homozygous for the F508del mutation in the CFTR gene. Patient has a pre-therapeutic/baseline FEV1 level measurement.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a pulmonologist or prescriber who specializes in CF.
Coverage Duration	End of plan year
Other Criteria	Reauthorization requires documentation of a positive clinical response (e.g., improvement/stabilization in FEV1 from pretreatment levels or decreased number of pulmonary exacerbations).
Indications	All Medically-accepted Indications.
Off Label Uses	

• KEVEYIS

PA Criteria	Criteria Details
Exclusion Criteria	Severe pulmonary disease, hepatic insufficiency, concomitant use of high-dose aspirin (greater than 100 mg per day).
Required Medical Information	Documented trial and failure or contraindication to acetazolamide. For primary HYPOkalemic periodic paralysis: 1) The diagnosis was supported by genetic test results, OR 2) patient has a family history of primary hypokalemic periodic paralysis, OR 3) patients attacks are associated with hypokalemia AND both Andersen-Tawil syndrome and thyrotoxic periodic paralysis have been ruled out. For primary HYPERkalemic periodic paralysis: 1) The diagnosis was supported by genetic test results, OR 2) patient has a family history of primary hyperkalemic periodic paralysis, OR 3) patients attacks are associated with hyperkalemia AND Andersen-Tawil syndrome has been ruled out.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a neurologist.
Coverage Duration	Initial: 2 months. Renewal: end of plan year
Other Criteria	Keveyis is used as maintenance therapy to prevent attacks. For continuation of therapy, patient is demonstrating a response to Keveyis therapy as demonstrated by a decrease in the number of attacks.
Indications	All Medically-accepted Indications.
Off Label Uses	

• KINERET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to anakinra. RA: patent must have a diagnosis of moderately to severely active rheumatoid arthritis as defined by the American College of Rheumatology AND a documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, D-penicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds, cyclosporine.
Age Restrictions	RA: 18 years of age or older
Prescriber Restrictions	RA: prescribed by or in consult with a rheumatologist.
Coverage Duration	End of plan year
Other Criteria	Patient is not receiving in combination with TNF antagonists.
Indications	All Medically-accepted Indications.
Off Label Uses	

• KORLYM

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy in females of reproductive potential.
Required Medical Information	Cushing's syndrome: 1) Diagnosis of endogenous Cushing's syndrome. 2) Diagnosis of type 2 diabetes mellitus or diagnosis of glucose intolerance. 3) Patient has failed surgical resection or is not a candidate for surgical resection.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with an endocrinologist.
Coverage Duration	End of plan year
Other Criteria	Limitation of use: mifepristone will not be approved for the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome.
Indications	All Medically-accepted Indications.
Off Label Uses	

# koselugo

# **Products Affected**

• KOSELUGO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Neurofibromatosis Type 1 (NF1): Diagnosis of NF1. Patient has plexiform neurofibromas that are both of the following: inoperable and causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment). Patient is able to swallow a capsule whole.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with one of the following: oncologist or neurologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

• KUVAN

• sapropterin dihydrochloride

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Phenylketonuria (PKU): 1) Diagnosis of PKU AND 2) A baseline phenylalanine level must be obtained prior to treatment initiation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	PKU (Reauth): Phenylalanine (Phe) level must demonstrate patient has had an objective response to sapropterin (i.e. a 30 percent or greater reduction in Phe blood levels from baseline).
Indications	All Medically-accepted Indications.
Off Label Uses	

• ambrisentan

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy in females of reproductive potential. Idiopathic pulmonary fibrosis.
Required Medical Information	Pulmonary arterial hypertension: WHO group 1. The patient has had baseline liver function tests (ALT, AST) performed prior to the initiation of therapy. Not recommended in patients with severe hepatic impairment (Child Pugh class C).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a cardiologist or pulmonologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• LEUKINE

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant chemo- or radiotherapy (or within 24 hours before or after). Excess leukemic myeloid blasts in the blood/bone marrow (greater than10%). Hypersensitivity to GM-CSF or yeast-derived products
Required Medical Information	Patient must have biweekly CBC with differential
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# lidocaine

## **Products Affected**

- lidocaine external ointment
- lidocaine external patch 5 %

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# LIDOCAINE TOPICAL

# **Products Affected**

- glydo
- *lidocaine hcl external solution*
- *lidocaine hcl urethral/mucosal*
- lidocaine-prilocaine external cream

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• alosetron hcl

PA Criteria	Criteria Details
Exclusion Criteria	Male patients. Severe hepatic disease or impairment. Ischemic colitis, constipation, gastrointestinal disease, Crohn's disease, ulcerative colitis, or diverticulitis.
Required Medical Information	Diarrhea-predominant irritable bowel syndrome (IBS) all of the following: 1) diagnoses of IBS with diarrhea being the main problem. 2) Physician has ruled-out anatomic or biochemical abnormalities of the gastrointestinal tract. 3) Patient should be an adult female. 4) Patient has tried and failed at least one conventional treatment for diarrhea.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

 LUPANETA PACK COMBINATION KIT 11.25 & 5 MG, 3.75 & 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence OR trial and failure, contraindication, or intolerance to one NSAID or one oral contraceptive.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months. Renewal: 6 months.
Other Criteria	Reauth: Documentation that symptoms have recurred. Total treatment duration should not exceed 12 months.
Indications	All Medically-accepted Indications.
Off Label Uses	

 hydroxyprogesterone caproate intramuscular oil

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Preterm birth prophylaxis: Patient had a previous singleton (single offspring) spontaneous preterm birth. Patient is having a singleton pregnancy. Therapy will be started between 16 weeks, 0 days and 20 weeks, 6 days of gestation. Therapy will be continued until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.
Age Restrictions	
Prescriber Restrictions	Preterm birth prophylaxis: Prescribed by or in consultation with a specialist in obstetrics and gynecology
Coverage Duration	Preterm birth prophylaxis: 21 weeks
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# mavenclad

## **Products Affected**

- MAVENCLAD (10 TABS)
- MAVENCLAD (4 TABS)
- MAVENCLAD (5 TABS)
- MAVENCLAD (6 TABS)

PA Criteria **Criteria Details** Exclusion Clinically isolated syndrome. Active chronic infection (e.g. hepatitis, tuberculosis). A current malignancy. HIV. Criteria Required Patient must have an inadequate response or failure to tolerate an Medical alternate drug indicated for the treatment of MS. Information Age Restrictions 18 years of age or older. Prescriber Prescribed by or in consult with a neurologist or MS specialist. Restrictions Coverage 2 months. Duration Other Criteria Reauthorization: one renewal will be granted for a second treatment course after a review of therapy and re-screening for HIV infection, active tuberculosis, and hepatitis. Additional approvals beyond a second treatment course will not be granted due to increased risk for malignancy. Indications All Medically-accepted Indications. Off Label Uses

•

MAVENCLAD (7 TABS)

MAVENCLAD (8 TABS)

MAVENCLAD (9 TABS)

# MAVYRET

# **Products Affected**

• MAVYRET

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh Category C).
Required Medical Information	Documentation of chronic hepatitis C infection and genotype. Documentation of quantitative baseline HCV RNA load performed within the prior 6 months. Documentation of testing for evidence of current or prior HBV infection. Prior tx history (if tx experienced, known dates and drugs(s) of prior HCV tx). Hepatic fibrosis stage as confirmed by one of the following: liver biopsy, transient elastography (FibroScan) score, fibrotest score (such as FibroSure), APRI score, FIB-4 score, severe extrahepatic manifestations/sx per radiology report. Presence or absence of cirrhosis (if cirrhosis is present, compensated vs. decompensated). HIV coinfection status. Liver and kidney transplant status if applicable.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a hepatologist, gastroenterologist, infectious disease or liver disease specialist.
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

 MAYZENT ORAL TABLET 0.25 MG, 2 MG

PA Criteria	Criteria Details
Exclusion Criteria	Homozygous for CYP2C9(3) (i.e. CYP2C9(3/3) genotype). Mobitz type II second-degree, third-degree AV block, or sinus syndrome, unless pt has a functioning pacemaker. Any of the following in the past 6 mo: MI, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure.
Required Medical Information	Patient must have a relapsing form of MS such as one of the following: clinically isolated syndrome, relapsing-remitting disease, active secondary progressive disease. Documentation indicating CYP2C9 genotype.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	Prescribed by or in consult with a neurologist or MS specialist.
Coverage Duration	End of plan year.
Other Criteria	Prior to initiation of siponimod in patients with sinus bradycardia (HR less than 55 beats per min), first- or second-degree (Mobitz type I) AV block, or a hx of MI or heart failure which was diagnosed more than 6 mo prior to time of request, prescriber must attest that a first-dose 6 hr monitoring period will be performed.
Indications	All Medically-accepted Indications.
Off Label Uses	

• methitest

• methyltestosterone oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG), and b) one pretreatment calculated free or bioavailable T level less than 5 ng/dL (0.17nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG. Delayed Puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG, and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.
Indications	All Medically-accepted Indications.
Off Label Uses	

# mirvaso

## **Products Affected**

• MIRVASO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of rosacea. Patient has moderate to severe persistent (nontransient) facial erythema.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Documentation of positive clinical response for reauthorization of Mirvaso.
Indications	All Medically-accepted Indications.
Off Label Uses	

# modafinil

# **Products Affected**

• modafinil

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	17 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# mulpleta

# **Products Affected**

• MULPLETA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	All of the following: diagnosis of thrombocytopenia, baseline platelet count is less than 50,000/mcL, patient has chronic liver disease, and patient is scheduled to undergo a procedure.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One month
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• MYALEPT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Lipodystrophy (initial): Diagnosis of congenital or acquired generalized lipodystrophy AND Patient is refractory to at least one current pharmacological agent for lipid management and one for diabetic management AND One or more of the following metabolic abnormalities are present: A) Insulin resistance, B) Hypertriglyceridemia, or C) Diabetes.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with an endocrinologist.
Coverage Duration	End of plan year
Other Criteria	Lipodystrophy (Reauth): Patient has experienced an objective response to therapy, such as A) Sustained reduction in hemoglobin A1c (HbA1c) level from baseline OR B) Sustained reduction in triglyceride (TG) levels from baseline
Indications	All Medically-accepted Indications.
Off Label Uses	

• NATPARA

PA Criteria	Criteria Details
Exclusion Criteria	Increased baseline risk for osteosarcoma (e.g. those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, pediatric and young adult patients with open epiphyses, or prior external beam or implant radiation therapy involving the skeleton). Patient is well-controlled on calcium supplements and vitamin D alone.
Required Medical Information	Hypocalcemia: 1) diagnosis of hypocalcemia due to chronic hypothyroidism. 2) Confirm serum calcium level is above 7.5 mg/dL. 3) Confirm 25-hydroxyvitamin D stores are sufficient (normal levels at least 50 nmol/L to less than 75 nmol/L OR at least 20 ng/ml to less than 30 ng/ml).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with an endocrinologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• NEULASTA

PA Criteria	Criteria Details
Exclusion Criteria	Chemotherapy associated with delayed myelosuppression. Mobilization of peripheral blood progenitor cells for HSCT.
Required Medical Information	Primary prophylaxis of febrile neutropenia (FN): One of the following: 1) patient is receiving chemotherapy regimen associated with a greater than 20% incidence of FN, OR 2) patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer. 3) both of the following: a) patient receiving chemotherapy regimen associated with 10- 20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with a history of FN during a previous course of chemotherapy. Acute radiation syndrome (ARS): Patient was acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a hematologist or oncologist.
Coverage Duration	FN treatment and ARS: 1 month. All other medically-accepted indications: 3 months.
Other Criteria	Reauth: appropriate lab tests - CBC and platelet count, must be conducted to necessitate the continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

• NEUPOGEN

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Primary prophylaxis of febrile neutropenia (FN): One of the following: 1) patient is receiving chemotherapy regimen associated with a greater than 20% incidence of FN, OR 2) patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer. 3) both of the following: a) patient receiving chemotherapy regimen associated with 10- 20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with a history of FN during a previous course of chemotherapy. Acute radiation syndrome (ARS): Patient was acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). Harvesting of peripheral blood stem cells: mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a hematologist, oncologist, or infectious disease specialist.
Coverage Duration	FN treatment and ARS: 1 month. All other medically-accepted indications: 3 months.
Other Criteria	Reauth: appropriate lab tests - CBC and platelet count, must be conducted to necessitate the continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

• NORTHERA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Neurogenic orthostatic hypotension is caused by primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, or pure autonomic failure), dopamine beta-hydroxylase deficiency, or non- diabetic autonomic neuropathy. Trial and failure to midodrine or fludrocortisone unless patient has a contraindication to both agents.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a cardiologist or neurologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

### nourianz

#### **Products Affected**

NOURIANZ ORAL TABLET 20 MG, 40 MG

PA Criteria	Criteria Details
Exclusion Criteria	Prevention of off episodes. Used in combination with strong CYP3 A4 inducers (e.g. carbamazepine, rifampin, phenytoin, St. John's wort).
Required Medical Information	Patient must be currently receiving and will continue to receive concomitant levodopa/carbidopa therapy. Trial and failure, contraindication, or intolerance to two of the following: MAO-B inhibitor (e.g., rasagiline, selegiline), dopamine agonist (e.g., pramipexole, ropinirole), COMT inhibitor (e.g., entacapone).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• NUEDEXTA

PA Criteria	Criteria Details
Exclusion Criteria	Heart failure. Complete atrioventricular (AV) block without an implanted pacemaker.
Required Medical Information	Pseudobulbar affect: 1) Patient has a diagnosis of psuedobulbar affect. 2) Patient has had a baseline electrocardiographic (ECG) evaluation to rule out QT prolongation or prescriber indicates that patient is not at risk for QT prolongation.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# nuvigil

#### **Products Affected**

• armodafinil oral tablet 150 mg, 200 mg, 250 mg, 50 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

OCALIVA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Primary Biliary Cholangitis (PBC) (initial): Diagnosis of PBC (aka primary biliary cirrhosis). One of the following: a) patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after at least 12 months of treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) AND used in combination with UDCA, OR b) contraindication or intolerance to UDCA. Patients with moderate to severe hepatic impairment (Child-Pugh class B or C) will be subject to a quantity limit of 5 mg or 10 mg twice weekly (MDD = 0.34).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a hepatologist or gastroenterologist.
Coverage Duration	End of plan year
Other Criteria	PBC (reauthorization): Submission of medical records (e.g., laboratory values) documenting a reduction in ALP level from pretreatment baseline (i.e., prior to Ocaliva therapy).
Indications	All Medically-accepted Indications.
Off Label Uses	

## OCTAGAM

#### **Products Affected**

OCTAGAM INTRAVENOUS SOLUTION
 10 GM/200ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• OFEV

PA Criteria	Criteria Details
Exclusion Criteria	Moderate or severe hepatic impairment (Child-Pugh category B or C).
Required Medical Information	IPF: A clear diagnosis of idiopathic pulmonary fibrosis has been made excluding other known causes of interstitial lung disease (e.g. domestic and occupational environmental exposures, connective tissue disease, drug toxicity).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a pulmonologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• ONUREG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia (AML). Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin, etc.). Patient has achieved one of the following: a) first complete remission (CR) or b) complete remission with incomplete blood count recovery (CRi). Patient is not able to complete intensive curative therapy.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

## opsumit

#### **Products Affected**

• OPSUMIT

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy in females of reproductive potential.
Required Medical Information	Pulmonary arterial hypertension: WHO group 1. The patient has had baseline liver function tests (ALT, AST) performed prior to the initiation of therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a cardiologist or pulmonologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• ORENCIA CLICKJECT

### ORENCIA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to abatacept. RA/jRA/PsA: documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, D-penicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds, cyclosporine. For PsA, if patient has documented axial PsA or enthesitis the above trial can be overridden AND instead patient must have a documented trial and inadequate response or intolerance to a prescription NSAID.
Age Restrictions	2 years of age or older
Prescriber Restrictions	RA/jRA/PsA: prescribed by or in consult with a rheumatologist.
Coverage Duration	End of plan year
Other Criteria	Patient is not receiving in combination with TNF antagonists or other biologic RA therapy (e.g. anakinra).
Indications	All Medically-accepted Indications.
Off Label Uses	

### orenitram

#### **Products Affected**

• ORENITRAM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary arterial hypertension: WHO group 1. The patient has had baseline liver function tests (ALT, AST) performed prior to the initiation of therapy. Not recommended in patients with severe hepatic impairment (Child Pugh class C).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a cardiologist or pulmonologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

ORILISSA ORAL TABLET 150 MG, 200
 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of moderate to severe pain associated with endometriosis AND one of the following: A) History of inadequate pain control response following a trial of at least one month, or history of intolerance to one of the following unless member has a medical contraindication: Danazol, combination (estrogen/progesterone) oral contraceptives, progestins B) Patient has had surgical ablation to prevent recurrence.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Reauthorization will not be granted for Orilissa 200mg. Orilissa 150mg reauthorization: Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and non-menstrual pelvic pain) AND treatment duration has not exceeded
Indications	All Medically-accepted Indications.
Off Label Uses	

### orkambi

#### **Products Affected**

ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) Patient has cystic fibrosis and 2) patient is homozygous for the F508del mutation in the CFTR gene as detected by an FDA-cleared CF mutation test showing the presence of the F508del mutation on both alleles of the CFTR gene and 3) Patient has a pre-therapeutic/baseline FEV1 level measurement.
Age Restrictions	2 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a pulmonologist or prescriber who specializes in CF.
Coverage Duration	End of plan year
Other Criteria	Reauthorization requires documentation of a positive clinical response (e.g., improvement/stabilization in FEV1 from pretreatment levels or decreased number of pulmonary exacerbations).
Indications	All Medically-accepted Indications.
Off Label Uses	

• OTEZLA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	PsA: documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, Dpenicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds, cyclosporine. For PsA, if patient has documented axial PsA or enthesitis the above trial can be overridden AND instead patient must have a documented trial and inadequate response or intolerance to a prescription NSAID. Plaque psoriasis: documented trial and inadequate response or intolerance to methotrexate and of the following: topical corticosteroid, calcipotriene, calcitriol, tazarotene, anthralin, acitretin, cyclosporine, tacrolimus ointment, or pimecrolimus cream. Behcet's disease: documented trial and inadequate response or intolerance to at least one nonbiologic medication indicated for the treatment of oral ulcers associated with Behcet's disease (e.g. colchicine, thalidomide).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Plaque psoriasis: prescribed by or in consult with a dermatologist or rheumatologist. PsA: prescribed by or in consult with a rheumatologist. Behcet's: prescribed by or in consultation with a rheumatologist, dermatologist, gastroenterologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

### oxandrolone

#### **Products Affected**

• oxandrolone oral tablet 10 mg, 2.5 mg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Promote weight gain (initial): Medication will be used as an adjunct therapy to promote weight gain AND One of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons. Counterbalance protein catabolism (initial): Medication will be used to counterbalance protein catabolism associated with chronic corticosteroid administration. Bone pain (initial): Diagnosis of bone pain associated with osteoporosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	All diagnoses (Reauth): patient has experienced an objective improvement (i.e. weight gain, increase in lead body mass, reduction in muscle pain/weakness, or decrease in bone pain)
Indications	All Medically-accepted Indications.
Off Label Uses	

# **OXBRYTA**

#### **Products Affected**

• OXBRYTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient has experienced at least one vasoocclusive crisis within the last year. Anemia by lab value within 30 days of request (Hgb less than or equal to 10.5 g/dL). Patient must have a trial and failure or intolerance to hydroxyurea unless contraindicated.
Age Restrictions	12 years of age and older
Prescriber Restrictions	Prescribed by or in consult with a hematologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

### PADCEV

#### **Products Affected**

 PADCEV INTRAVENOUS SOLUTION RECONSTITUTED 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Urothelial Cancer: Diagnosis of locally advanced or metastatic urothelial cancer. Both of the following: 1) Patient has received prior treatment with one immune checkpoint inhibitor (CPI) in the neoadjuvant/adjuvant, locally advanced or metastatic setting, unless contraindicated: a) Programmed death receptor-1 (PD-1) inhibitor [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab)] or b) Programmed death-ligand 1 (PD-L1) inhibitor [e.g., Tecentriq (atezolizumab), Imfinzi (durvalumab), Bavencio (avelumab)] and 2) Patient has received prior treatment with a platinumbased chemotherapy (e.g., carboplatin, cisplatin) in the neoadjuvant/adjuvant, locally advanced or metastatic setting.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

## palynziq

#### **Products Affected**

 PALYNZIQ SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 10 MG/0.5ML, 2.5 MG/0.5ML, 20 MG/ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Phenylketonuria (PKU) all of the following: 1) Diagnosis of PKU 2) Baseline blood phenylalanine concentration greater than 600 micromol/L prior to initiation AND 3) One of the following: a) Patient is not also receiving sapropterin OR b) Patient has been receiving sapropterin and will discontinue at least 14 days prior to receiving Palynziq.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	PKU (Reauth): Phenylalanine (Phe) level must demonstrate patient has had an objective response to pegvaliase (i.e. a 20 percent or greater reduction in Phe blood levels from baseline or a blood Phe level less than or equal to 600 micromol/L).
Indications	All Medically-accepted Indications.
Off Label Uses	

# peg intron and pegasys

#### **Products Affected**

• PEGASYS

 PEGASYS PROCLICK SUBCUTANEOUS SOLUTION 180 MCG/0.5ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Hepatitis C: Criteria will be applied consistent with current AASLD/IDSA guidance.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

### pemazyre

#### **Products Affected**

• PEMAZYRE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of cholangiocarcinoma. Disease is one of the following: unresectable locally advanced or metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement. Patient has been previously treated.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a hepatologist or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

## penlac

#### **Products Affected**

• ciclopirox external solution

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

PLEGRIDY

#### PLEGRIDY STARTER PACK SUBCUTANEOUS SOLUTION PEN-INJECTOR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist or MS specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• PRALUENT

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant therapy with another PCSK9 inhibitor
Required Medical Information	Most recent cholesterol laboratory report. Heterozygous Familial Hypercholesterolemia: medical records supporting clinical or laboratory confirmation of diagnosis: A) genetic confirmation of a mutation in LDL receptor, ApoB, or PCSK9, B) score of 6 or higher on the Dutch Lipid Network criteria for HeFH, C) presence of xanthomas with pretreatment LDL greater than 190 mg/dL. Hyperlipidemia: a diagnosis of primary hyperlipidemia. Prevention of cardiovascular events in patients with established cardiovascular disease: documented history of clinical atherosclerotic cardiovascular disease (defined as acute coronary syndrome, history of myocardial infarction, stable or unstable angina, stroke, transient ischemic attack, coronary or other revascularization, clinically significant coronary heart disease, or peripheral arterial disease of atherosclerotic origin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	Initial: 3 months. Renewal: End of plan year
Other Criteria	For statin tolerant patients: 1) Must have a therapeutic failure to a 3 month trial of maximally tolerated dose of high intensity statin therapy with at least two different statin medications (i.e. atorvastatin 40mg or 80mg, simvastatin 40mg or 80mg, rosuvastatin 20mg or 40mg) with failure to achieve LDL-C less than 70 mg/dL (with ASCVD) or less than 100 mg/dL (without ASCVD) AND 2) patient must continue statin therapy unless unable to tolerate statins. Intolerance to statins or contraindication to statins: 1) Patient has an intolerance to statin therapy including severe and intolerable adverse effects with at least two previous statins such as increased liver function tests, rhabdomyolysis, intolerable myalgia, myopathy or myositis or patient has a contraindication to statin therapy. Reauthorization requests require 1) documentation of continued statin use if applicable and 2) documented LDL reduction from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	

# PRETOMANID

### **Products Affected**

• PRETOMANID

PA Criteria	Criteria Details
Exclusion Criteria	Any of the following: drug-sensitive tuberculosis, latent infection or extra- pulmonary infection due to Mycobacterium tuberculosis, multi-drug resistant tuberculosis that is not treatment-intolerant or nonresponsive to standard therapy.
Required Medical Information	Pretomanid must be prescribed in combination with bedaquiline and linezolid.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consult with an infectious disease specialist
Coverage Duration	26 weeks
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# prolastin

#### **Products Affected**

- GLASSIA
- PROLASTIN-C INTRAVENOUS
  SOLUTION RECONSTITUTED

• ZEMAIRA

SOLUTION REC	SOLUTION RECONSTITUTED	
PA Criteria	Criteria Details	
Exclusion Criteria		
Required Medical Information	Diagnosis of emphysema and an alpha-1-antitrypsin (AAT) deficiency with PiZ, PiZ (null), or Pi (null, null) phenotype	
Age Restrictions	AAT deficiency: 18 years of age or older	
Prescriber Restrictions		
Coverage Duration	End of plan year	
Other Criteria		
Indications	All Medically-accepted Indications.	
Off Label Uses		

• PROLIA

PA Criteria	Criteria Details
Exclusion Criteria	Hypocalcemia.
Required Medical Information	1. A baseline calcium level must be obtained prior to treatment initiation. 2. When using Prolia for osteoporosis in men and women at high risk for bones fractures with nonmetastatic prostate cancer or breast cancer, must provide evidence that men have been receiving androgen deprivation therapy (surgical castration or medical castration with GnRH agonist, GnRH antagonists, or anti-androgens) and women have been receiving adjuvant aromatase inhibitor therapy. 3. Patient should meet National Osteoporosis Foundation guidelines for treatment and have one of the following: a) Bone Mineral Density (BMD) 2.5 or more standard deviations below the mean value (i.e. T-score less than 2.5) with no risk factors OR b) BMD T-score below 1.5 (1.5 or more standard deviations below the mean value) with one or more of the following risk factors: history of low trauma (non-collision) osteoporotic fracture as an adult, family history of fracture, low body weight (less than 127 lb) or low mass index, rheumatoid arthritis, vitamin D deficiency, use of oral glucocorticoids for at least 3 months at a dose of prednisone of 5 mg daily or more (or equivalent dose of other glucocorticoids), anticonvulsants, or loop diuretics, increased fall risk (poor vision, dementia, neuromuscular disorder), age greater than or equal to 65 years of age, current smoker, or alcohol intake greater than or equal to 3 drinks per day.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

### promacta

#### **Products Affected**

PROMACTA ORAL PACKET 12.5 MG, 25
 PROMACTA ORAL TABLET
 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chronic immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of relapsed/refractory chronic ITP for greater than 6 months. Baseline platelet count is less than 50,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. Trial and failure, intolerance, contraindication to corticosteroids or immunoglobulins or splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C-associated thrombocytpenia. One of the following: 1) Planning to initiate and maintain interferon-based treatment, or 2) currently receiving interferon-based treatment. Severe aplastic anemia (initial): Diagnosis of severe aplastic anemia. Patient has a platelet count less than 30,000/mcL. Given in combination with immunosuppressive therapy (antithymocyte globulin and cyclosporine) as first line treatment OR given alone if patient has a trial and failure, intolerance, or contraindication to immunosuppressive therapy.
Age Restrictions	1 year of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# pulmozyme

### **Products Affected**

• PULMOZYME

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Management of cystic fibrosis in conjunction with standard therapies, to improve pulmonary function.
Age Restrictions	5 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a pulmonologist or prescriber who specializes in CF.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• QINLOCK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Gastrointestinal Stromal Tumor (GIST): Diagnosis of gastrointestinal stromal tumor (GIST). Disease is advanced. Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# quinine

### **Products Affected**

• quinine sulfate oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Quinine will not be approved for prophylaxis or treatment of nocturnal leg cramps.
Indications	All Medically-accepted Indications.
Off Label Uses	

• RAVICTI

PA Criteria	Criteria Details
Exclusion Criteria	Treatment of acutely elevated ammonia concentrations in a patient with urea cycle disorders. Treatment of N-acetylglutamate synthase (GAGS) deficiency.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

- REBIF
- REBIF REBIDOSE

- REBIF REBIDOSE TITRATION PACK
- REBIF TITRATION PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist or MS specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

## REBLOZYL

### **Products Affected**

REBLOZYL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• REGRANEX

PA Criteria	Criteria Details
Exclusion Criteria	Prior authorization requests shall not be granted for use in pressure ulcers or venous stasis ulcers.
Required Medical Information	The patient must have a diagnosis of a lower extremity diabetic neuropathic ulcer. The ulcer must extend into the subcutaneous tissue or beyond. (Stage III or IV as defined by the International Association of Enterostomal Therapy for staging chronic wounds). The ulcer must have an adequate blood supply.
Age Restrictions	16 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a wound care specialist or podiatrist.
Coverage Duration	Initial: 3 months. Renewal: 2 months.
Other Criteria	Reauth: the patient's condition has been reassessed by a wound care specialist or podiatrist. Patient has a documented reduction in ulcer size. There are no known neoplasms at application site(s).
Indications	All Medically-accepted Indications.
Off Label Uses	

RELISTOR ORAL

 RELISTOR SUBCUTANEOUS SOLUTION 12 MG/0.6ML, 12 MG/0.6ML (0.6ML SYRINGE), 8 MG/0.4ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) Patient is receiving opioids. 2)Patient has an advanced illness and receiving palliative care OR patient has chronic noncancer pain. 3) For patients with advanced illness receiving palliative care, patient has failed or has an intolerance to one other conventional laxative therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• REPATHA

### • REPATHA SURECLICK

REPATHA PUSHTRONEX SYSTEM

PA Criteria	Criteria Details
Exclusion Criteria	Concomitant therapy with another PCSK9 inhibitor
Required Medical Information	Most recent cholesterol laboratory report. Heterozygous Familial Hypercholesterolemia: medical records supporting clinical or laboratory confirmation of diagnosis: A) genetic confirmation of a mutation in LDL receptor, ApoB, or PCSK9, B) score of 6 or higher on the Dutch Lipid Network criteria for HeFH, C) presence of xanthomas with pretreatment LDL greater than 190 mg/dL for adults or 155 mg/dL in children less than 16 years old. Hyperlipidemia: a diagnosis of primary hyperlipidemia. Prevention of cardiovascular events in patients with established cardiovascular disease : documented history of clinical atherosclerotic cardiovascular disease (defined as acute coronary syndrome, history of myocardial infarction, stable or unstable angina, stroke, transient ischemic attack, coronary or other revascularization, clinically significant coronary heart disease, or peripheral arterial disease of atherosclerotic origin. Homozygous Familial Hypercholesterolemia: A) Pre-treatment LDL greater than 500 mg/dL OR B) genetic testing confirming 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein OR C) treated LDL greater than 300 mg/dL with presence of either xanthomas prior to age 10 years or untreated elevated LDL in both parents consistent with HeFH.
Age Restrictions	Patient is at least 13 years of age for HoFH. Patient is at least 18 years of age for all other indications
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Renewal: End of plan year
Other Criteria	For statin tolerant patients: 1) Must have a therapeutic failure to a 3 month trial of maximally tolerated dose of high intensity statin therapy with at least two different statin medications (i.e. atorvastatin 40mg or 80mg, simvastatin 40mg or 80mg, ros
Indications	All Medically-accepted Indications.
Off Label Uses	

• RETEVMO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Lung Cancer: Diagnosis of metastatic non-small cell lung cancer (NSCLC). Disease has presence of RET gene fusion-positive tumor(s). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or metastatic. Disease has presence of RET gene mutation tumor(s). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is advanced or metastatic. Disease has presence of RET gene fusion- positive tumor(s). Disease requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate.
Age Restrictions	
Prescriber Restrictions	Lung Cancer, MTC: Prescribed by or in consultation with an oncologist. Thyroid Cancer: Prescribed by or in consultation with an endocrinologist or an oncologist.
Coverage Duration	Lung Cancer, MTC, Thyroid Cancer: 12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

sildenafil citrate oral suspension reconstituted

• sildenafil citrate oral tablet 20 mg

PA Criteria	Criteria Details
Exclusion Criteria	Member must not be concurrently taking a nitrate, ritonavir, riociguat, or an alpha adrenergic blocker (i.e. doxazosin, prazosin, terazosin, tamsulosin).
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a cardiologist or pulmonologist.
Coverage Duration	End of plan year
Other Criteria	Approval will not be granted for the treatment of erectile dysfunction
Indications	All Medically-accepted Indications.
Off Label Uses	

• riluzole

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Obtain baseline liver function (AST, ALT, bilirubin) tests prior to initiation of therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• RINVOQ

PA Criteria	Criteria Details
Exclusion Criteria	Use in combination with other JAK inhibitors, biologic DMARDS, or with potent immunosuppressants such as azathioprine and cyclosporine.
Required Medical Information	All of the following: 1) Negative tuberculosis test within six months prior to initiation of therapy. 2) Documented failure or intolerance to methotrexate. 3) Absolute neutrophil count of 1000 cells/m(3) or greater, lymphocyte count 500 cells/mm(3) or greater, and hemoglobin 8 g/dL or greater.
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• RUCONEST

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (e.g., Berinert, Firazyr).
Age Restrictions	13 years of age or older
Prescriber Restrictions	Prescribed by or in consult with an allergist, immunologist, or other prescriber that specialized in the treatment of HAE.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

RUZURGI

PA Criteria	Criteria Details
Exclusion Criteria	History of seizures.
Required Medical Information	Diagnosis of LEMS as confirmed by neurophysiology study or a positive anti-P/Q Type voltage-gated calcium antibody test.
Age Restrictions	6 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist.
Coverage Duration	End of plan year.
Other Criteria	Reauth: documentation of a positive clinical response (e.g., improvement in Quantitative Myasthenia Gravis (QMD) score, Subjective Global Impression (SGI) score, clinical global impression improvement (CGI-I) score).
Indications	All Medically-accepted Indications.
Off Label Uses	

# sandostatin lar depot, sandostatin inj.

# **Products Affected**

• octreotide acetate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acromegaly: documented inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and dopamine agonist (e.g. bromocriptine or cabergoline) at maximally tolerated doses. Baseline growth hormone and insulin like growth factor levels prior to therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Acromegaly (renewal): growth hormone and insulin like growth factor levels demonstrate a positive response.
Indications	All Medically-accepted Indications.
Off Label Uses	

• SIGNIFOR

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh Category C).
Required Medical Information	Cushing's disease - documentation that pituitary surgery is not an option or has not been curative.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Cushing Disease (renewal): patient demonstrates improvement in urinary free cortisol level from baseline
Indications	All Medically-accepted Indications.
Off Label Uses	

• SILIQ

PA Criteria	Criteria Details
Exclusion Criteria	Patients with Crohn's disease.
Required Medical Information	Patient had a negative tuberculosis test result within 6 months of starting therapy. For patients with moderate to severe plaque psoriasis, the patient has failed or lost response to other systemic therapies, AND the patient has demonstrated a failure, intolerance, or has a contraindication to at least one topical therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	End of plan year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# simponi

# **Products Affected**

• SIMPONI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to golimumab. RA/PsA: documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, D-penicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds, cyclosporine. For PsA, if patient has documented axial PsA or enthesitis the above trial can be overridden AND instead patient must have a documented trial and inadequate response or intolerance to a prescription NSAID. AS: documented trial and inadequate response or intolerance to one of the following: NSAIDs, sulfasalazine, intra-articular glucocorticoids. UC: documented trial and inadequate response or intolerance to one of the following: a salicylate (e.g., balsalazide, mesalamine, sulfasalazine), an oral corticosteroid, azathioprine, mercaptopurine.
Age Restrictions	18 years of age or older
Prescriber Restrictions	RA/PsA/AS: prescribed by or in consult with a rheumatologist. UC: prescribed by or in consult with a gastroenterologist.
Coverage Duration	End of plan year
Other Criteria	Patient is not receiving in combination with biologic DMARDs or other TNF antagonists.
Indications	All Medically-accepted Indications.
Off Label Uses	

• SKYRIZI (150 MG DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to risankizumab-rzaa. Plaque psoriasis: patient must demonstrate a documented failure or intolerance, or contraindication to methotrexate and one or more of the following: topical corticosteroid, calcipotriene, calcitriol, tazarotene, anthralin, acitretin, cyclosporine, tacrolimus ointment, or pimecrolimus cream.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	Prescribed by or in consult with a dermatologist or rheumatologist.
Coverage Duration	End of plan year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• SOLIRIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS) (initial): Diagnosis of PNH or aHUS. Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab). Generalized Myasthenia Gravis (gMG) (initial): Diagnosis of gMG. Patient is anti- acetylcholine (AChR) antibody positive. One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus), or 2) TF/C/I to one immunsuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus), and TF/C/I to chronic plasmapheresis/plasma exchange (PE) or intravenous immunoglobulin (IVIG). Neuromyelitis Optica Spectrum Disorder (NMOSD) (initial): Diagnosis of NMOSD. Patient is anti- aquaporin-4 (AQP4) antibody positive.
Age Restrictions	
Prescriber Restrictions	gMG, NMOSD (initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	PNH (reauth): Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy. aHUS (reauth): Documentation of positive clinical response (e.g., increase in mean platelet counts, hematologic normalization) to therapy. gMG, NMOSD (reauth): Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

# somatuline

#### **Products Affected**

 SOMATULINE DEPOT SUBCUTANEOUS SOLUTION 120 MG/0.5ML, 60 MG/0.2ML, 90 MG/0.3ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	A baseline growth hormone level must be obtained prior to treatment initiation. A level will not be required for a cancer diagnosis or carcinoid syndrome. Acromegaly: documented inadequate response to surgery and or radiotherapy unless surgery and/ or radiotherapy is not an option.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Acromegaly (renewal): growth hormone and insulin like growth factor levels demonstrate a positive response.
Indications	All Medically-accepted Indications.
Off Label Uses	

• SOMAVERT

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acromegaly: Baseline growth hormone and insulin like growth factor levels prior to treatment initiation. Documented inadequate response to surgery and/or radiation therapy unless these therapies are not an option. Baseline LFTs (AST and ALT less than 3 times upper limit).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Acromegaly (renewal): growth hormone and insulin like growth factor levels demonstrate a positive response.
Indications	All Medically-accepted Indications.
Off Label Uses	

SOVALDI ORAL PACKET 150 MG, 200
 SOVALDI ORAL TABLET 400 MG MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation of chronic hepatitis C infection and genotype. Documentation of quantitative baseline HCV RNA load performed within the prior 6 months. Documentation of testing for evidence of current or prior HBV infection. Prior tx history (if tx experienced, known dates and drugs(s) of prior HCV tx). Hepatic fibrosis stage as confirmed by one of the following: liver biopsy, transient elastography (FibroScan) score, fibrotest score (such as FibroSure), APRI score, FIB-4 score, severe extrahepatic manifestations/sx per radiology report. Presence or absence of cirrhosis (if cirrhosis is present, compensated vs. decompensated). HIV coinfection status. Liver and kidney transplant status if applicable.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a hepatologist, gastroenterologist, infectious disease or liver disease specialist.
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# sporanox

# **Products Affected**

• itraconazole oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

STELARA SUBCUTANEOUS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to ustekinumab. PsA: documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, D-penicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds, cyclosporine. For PsA, if patient has documented axial PsA or enthesitis the above trial can be overridden AND instead patient must have a documented trial and inadequate response or intolerance to a prescription NSAID. Plaque psoriasis: documented trial and inadequate response or intolerance to methotrexate and one of the following: topical corticosteroid, calcipotriene, calcitriol, tazarotene, anthralin, acetretin, cyclosporine, tacrolimus ointment, or pimecrolimus cream. CD, UC: a documented trial and inadequate response or intolerance to one of the following: a salicylate (e.g., mesalamine, sulfasalazine), an oral corticosteroid, or an immunomodulator (e.g., azathioprine, mercaptopurine, methotrexate).
Age Restrictions	Plaque psoriasis: 6 years of age and older. All other indications: 12 years of age or older
Prescriber Restrictions	Plaque psoriasis: prescribed by or in consult with a dermatologist or rheumatologist. PsA: prescribed by or in consult with a rheumatologist. UC and CD: prescribed by or in consult with a gastroenterologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

SUNOSI

PA Criteria	Criteria Details
Exclusion Criteria	General daytime sleepiness without an identifiable cause. Unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems.
Required Medical Information	Must have a complete evaluation of excessive sleepiness with a sleep study and polysomnogram AND a documented treatment failure or intolerance to one of the following preferred agents unless the patient has a contraindication to both: modafinil or armodafinil.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year.
Other Criteria	Must not be currently taking a monoamine oxidase inhibitor (MAOI) OR prescriber attests that the patient will discontinue use of MAOI at least 14 days prior to initiating treatment with Sunosi.
Indications	All Medically-accepted Indications.
Off Label Uses	

• SYMLINPEN 120

# • SYMLINPEN 60

PA Criteria	Criteria Details
Exclusion Criteria	Gastroparesis. Hemoglobin A1C greater than or equal to 9 percent.
Required Medical Information	1) Treatment must be adjunct to insulin therapy. 2) Must obtain a baseline Hemoglobin A1C prior to treatment initiation.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• TABRECTA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of non-small cell lung cancer (NSCLC). Disease is one of the following: recurrent, advanced, metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

• TAKHZYRO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	HAE Prophylaxis: Diagnosis of HAE. Prescribed for prophylaxis against HAE attacks.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Prescribed by or in consult with an allergist, immunologist, or other prescriber that specialized in the treatment of HAE.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• TALTZ

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to ixekizumab. Plaque psoriasis: documented trial and inadequate response or intolerance to methotrexate and one of the following: topical corticosteroid, calcipotriene, calcitriol, tazarotene, anthralin, acetretin, cyclosporine, tacrolimus ointment, or pimecrolimus cream. PsA: documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, D- penicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds, cyclosporine. For PsA, if patient has documented axial PsA or enthesitis the above trial can be overridden AND instead patient must have a documented trial and inadequate response or intolerance to a prescription NSAID. Ankylosing spondylitis (AS): documented trial and inadequate response or intolerance to one of the following: NSAIDs, sulfasalazine, intra-articular glucocorticoids.
Age Restrictions	Plaque psoriasis: 6 years of age and older. All other indications: 18 years of age or older
Prescriber Restrictions	Plaque psoriasis: prescribed by or in consult with a dermatologist or rheumatologist. AS: prescribed by or in consult with a rheumatologist.
Coverage Duration	End of plan year
Other Criteria	Patient is not receiving in combination with biologic DMARDs or other TNF antagonists.
Indications	All Medically-accepted Indications.
Off Label Uses	

# targretin

# **Products Affected**

• TARGRETIN EXTERNAL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cutaneous T-Cell Lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [eg, corticosteroids {ie, clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}] or systemic therapies [eg, interferons]).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

• TAZORAC EXTERNAL GEL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Acne vulgaris (initial): Diagnosis of acne vulgaris AND History of failure or intolerance to at least two topical acne products (e.g., tretinoin, adapalene, benzoyl peroxide, clindamycin, erythromycin, or azelaic acid) unless all are contraindicated. Plaque psoriasis (initial): Diagnosis of stable moderate to severe plaque psoriasis AND Patient has body surface area (BSA) involvement of less than 20 percent AND History of failure or intolerance to at least two topical psoriasis product (e.g., medium to high potency corticosteroids and/or vitamin D analogs).
Age Restrictions	Acne (initial): 12 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Acne, Plaque psoriasis (Reauth): Documentation of positive clinical response to therapy .
Indications	All Medically-accepted Indications.
Off Label Uses	

# tecfidera

# **Products Affected**

- dimethyl fumarate oral
- •
- dimethyl fumarate starter pack TECFIDERA STARTER PACK •
- TECFIDERA ORAL CAPSULE DELAYED RELEASE

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist or MS specialist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• TEGSEDI

PA Criteria	Criteria Details
Exclusion Criteria	Platelet count less than 100,000/microLiter (normal range: 150,000 - 400,000/microLiter)
Required Medical Information	Patient has a transthyretin (TTR) mutation (e.g., V30M) and ONE of the following: 1) Baseline polyneuropathy disability (PND) score of IIIb or less. 2) Baseline familial amyloidotic polyneuropathy (FAP) stage 1 or 2. 3) Baseline neuropathy impairment score (NIS) between 10 and 130.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• TREMFYA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had a negative tuberculosis test result within 6 months of starting therapy. For patients with moderate to severe plaque psoriasis, the patient has demonstrated a failure, intolerance, or has a contraindication to at least one topical therapy.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	End of plan year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• TRIKAFTA

PA Criteria	Criteria Details
Exclusion Criteria	Severe hepatic impairment (Child-Pugh Class C).
Required Medical Information	Patient has a confirmed CFTR gene mutation as demonstrated by a FDA- cleared CF mutation test. Baseline liver function tests: AST, ALT, total biliribin.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a pulmonologist, gastroenterologist, endocrinologist or other prescriber specializing in the treatment of CF.
Coverage Duration	End of plan year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# triptodur

# **Products Affected**

• TRIPTODUR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range. Trial and failure or intolerance to Lupron Depot-Ped.
Age Restrictions	
Prescriber Restrictions	CPP (initial): Prescribed by or in consultation with a pediatric endocrinologist.
Coverage Duration	CPP (Initial, reauth): 12 months
Other Criteria	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.
Indications	All Medically-accepted Indications.
Off Label Uses	

• TUKYSA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) advanced unresectable or b) metastatic. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Used in combination with trastuzumab and capecitabine. Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

• TYSABRI

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following disease-modifying therapies for MS: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone/Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Mavenclad (cladribine), Mayzent (siponimod), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), 2) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their MS, or 3) for continuation of prior therapy. Not used in combination with another disease-modifying therapy for MS. Crohn's Disease (CD) (initial): Diagnosis of moderate to severe CD with evidence of inflammation (eg, elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes). TF/C/I to one of the following conventional therapies: corticosteroids, 6-mercaptopurine (6MP [Purinethol], azathioprine (Imuran), methotrexate, aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). TF/C/I to a TNF-inhibitor (eg, Cimzia [certolizumab pegol], Humira [adalimumab], Remicade [infliximab]). CD (initial and reauth): Not used in combination with an immunosuppressant (eg, 6-MP, azathioprine, cyclosporine, or methotrexate). Not used in combination with a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or Remicade [infliximab]).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	MS: 12mo. CD (Init): 3 mo. CD (Reauth): 6 mo if not on steroids. Otherwise, 3 mo.
Other Criteria	CD (reauth): Documentation of positive clinical response (eg, improved disease activity index) to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

• UDENYCA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Primary prophylaxis of febrile neutropenia (FN): One of the following: 1) patient is receiving chemotherapy regimen associated with a greater than 20% incidence of FN, OR 2) patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer OR 3) both of the following: a) patient receiving chemotherapy regimen associated with 10- 20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with a history of FN during a previous course of chemotherapy. Acute radiation syndrome (ARS): Patient was acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a hematologist or oncologist.
Coverage Duration	FN treatment and ARS: 1 month. All other medically-accepted indications: 3 months.
Other Criteria	Reauthorization: appropriate lab tests - CBC and platelet count, must be conducted to necessitate the continuation of therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

- JATENZO
- PALFORZIA (12 MG DAILY DOSE)
- PALFORZIA (120 MG DAILY DOSE)
- PALFORZIA (160 MG DAILY DOSE)
- PALFORZIA (20 MG DAILY DOSE)
- PALFORZIA (200 MG DAILY DOSÉ)
- PALFORZIA (240 MG DAILY DOSE)
- PALFORZIA (3 MG DAILY DOSE)
- PALFORZIA (300 MG MAINTENANCE)
- PALFORZIA (300 MG TITRATION)
- PALFORZIA (40 MG DAILY DOSE)
- PALFORZIA (6 MG DAILY DOSE)
- PALFORZIA (80 MG DAILY DOSE)
- PALFORZIA INITIAL ESCALATION

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• UPTRAVI ORAL TABLET

 UPTRAVI ORAL TABLET THERAPY PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary arterial hypertension: WHO group 1. The patient has had baseline liver function tests (ALT, AST) performed prior to the initiation of therapy. Not recommended in patients with severe hepatic impairment (Child Pugh class C).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a cardiologist or pulmonologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• VARIZIG

PA Criteria	Criteria Details
Exclusion Criteria	Presence of contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).
Required Medical Information	Immune globulin is being used intramuscularly. The immune globulin is being used for passive immunization or post exposure-prophylaxis of varicella. Patient is considered a high risk individual (i.e., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months (approve one dose only)
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# ventavis

# **Products Affected**

• VENTAVIS

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Pulmonary arterial hypertension: WHO group 1.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a cardiologist or pulmonologist.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# VUMERITY

# **Products Affected**

• VUMERITY

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age and older
Prescriber Restrictions	Prescribed by or in consult with a neurologist or MS specialist
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# vyndamax

#### **Products Affected**

• VYNDAMAX

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Patient has been diagnosed with wild type or hereditary transthyretin- mediated amyloidosis AND 2. One of the following: A) history of heart failure resulting in at least one prior hospitalization or B) Clinical evidence of cardiac involvement (e.g., increased ventricular wall or interventricular septum thickening) without hospitalization as demonstrated by cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.
Coverage Duration	End of plan year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# vyndaqel

#### **Products Affected**

• VYNDAQEL

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Patient has been diagnosed with wild type or hereditary transthyretin- mediated amyloidosis AND 2. One of the following: A) history of heart failure resulting in at least one prior hospitalization or B) Clinical evidence of cardiac involvement (e.g., increased ventricular wall or interventricular septum thickening) without hospitalization as demonstrated by cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging).
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

# **VYONDYS 53**

#### **Products Affected**

• VYONDYS 53

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• WAKIX

PA Criteria	Criteria Details
Exclusion Criteria	General daytime sleepiness without an identifiable cause. Severe hepatic impairment (Child-Pugh Class C). End stage renal disease (eGFR less than 15 mL/min/1.73m2). Known QT prolongation.
Required Medical Information	Must have a complete evaluation of excessive sleepiness with a sleep study and polysomnogram AND a documented treatment failure or intolerance to one of the following preferred agents unless the patient has a contraindication to both: modafinil or armodafinil.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year.
Other Criteria	Must not be used in combination with drugs known to prolong the QT interval (e.g., quinidine, procainamide, disopyramide, amiodarone, sotalol, ziprasidone, chlorpromazine, thioridazine, moxifloxacin).
Indications	All Medically-accepted Indications.
Off Label Uses	

XCOPRI

- XCOPRI (350 MG DAILY DOSE)
- XCOPRI (250 MG DAILY DOSE)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of partial onset seizures.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	

XELJANZ

## • XELJANZ XR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient had negative tuberculin skin test or CDC recommended equivalent test prior to initiating treatment. Treatment for latent TB infection should be initiated prior to ixekizumab. RA/PsA: documented trial and inadequate response or intolerance to one of the following: methotrexate, hydroxychloroquine, D-penicillamine, sulfasalazine, leflunomide, azathioprine, oral/injectable gold compounds, cyclosporine. For PsA, if patient has documented axial PsA or enthesitis the above trial can be overridden AND instead patient must have a documented trial and inadequate response or intolerance to a prescription NSAID. UC: documented trial and inadequate response or intolerance to one of the following: a salicylate (e.g., balsalazide, mesalamine, sulfasalazine), an oral corticosteroid, or an immunomodulator (e.g., azathioprine, mercaptopurine, methotrexate).
Age Restrictions	18 years of age or older
Prescriber Restrictions	RA/PsA: prescribed by or in consult with a rheumatologist. UC: prescribed by or in consult with a gastroenterologist.
Coverage Duration	End of plan year
Other Criteria	Patient is not receiving tofacitinib in combination with biologic DMARDs or potent immunosuppressant (e.g., azathioprine, tacrolimus, cyclosporine).
Indications	All Medically-accepted Indications.
Off Label Uses	

## xenazine

#### **Products Affected**

• tetrabenazine

PA Criteria	Criteria Details
Exclusion Criteria	Hepatic impairment.
Required Medical Information	Baseline liver function tests should be obtained prior to treatment initiation.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consult with a neurologist or psychologist.
Coverage Duration	End of plan year
Other Criteria	Tetrabenazine will not be approved if patient is currently taking a monoamine oxidase inhibitor (or has taken one within 14 days prior to anticipated treatment start date).
Indications	All Medically-accepted Indications.
Off Label Uses	

• XGEVA

PA Criteria	Criteria Details
Exclusion Criteria	Hypocalcemia. Pregnancy in females of reproductive potential.
Required Medical Information	Baseline serum calcium level. Hypercalcemia of malignancy: Patient is refractory to treatment with one intravenous bisphosphonate therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Patient should not also be receiving Prolia.
Indications	All Medically-accepted Indications.
Off Label Uses	

• XIFAXAN

PA Criteria	Criteria Details
Exclusion Criteria	Known Clostridium Difficile associated diarrhea.
Required Medical Information	Traveler's diarrhea: patient must have an inadequate response to ciprofloxacin unless contraindicated. Hepatic encephalopathy: patient must have an inadequate response to lactulose unless contraindicated. IBS diarrhea: patient must have an inadequate response to an antispasmodic agent unless contraindicated.
Age Restrictions	Traveler's diarrhea: 12 years of age or older. All other indications: 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Traveler's diarrhea and IBS: 1 month. All other indications: end of plan year.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• XIIDRA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial: Diagnosis of dry eye disease. Patient has suppressed tear production due to ocular inflammation as determined by at least one of the following diagnostic tests: Schirmer test (aqueous tear production and clearance), tear break-up time, ocular surface dye staining, tear film osmolarity, or fluorescein clearance test/tear function test.
Age Restrictions	17 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	Reauth: Documentation of positive clinical response to Xiidra therapy (e.g., increased tear production or improvement in dry eye symptoms).
Indications	All Medically-accepted Indications.
Off Label Uses	

• XOLAIR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Asthma (init): Diagnosis of moderate to severe persistent allergic asthma. Positive skin test or in vitro reactivity to a perennial aeroallergen. Pretreatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL for patients 12 years of age and older OR 30 to 1300 IU/mL for patients 6 years to less than 12 years of age. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. Chronic Idiopathic Urticaria (CIU) (init): Diagnosis of CIU. Persistent symptoms (itching and hives) for at least 4 consecutive weeks despite titrating to an optimal dose with a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines. Patient has tried and had an inadequate response or intolerance or contraindication to at least one of the following additional therapies: H2 antagonist (e.g., famotidine, cimetidine), leukotriene receptor antagonist (e.g., montelukast), H1 antihistamine, hydroxyzine, doxepin. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines.
Age Restrictions	
Prescriber Restrictions	Asthma (init/reauth): Prescribed by or in consultation with an allergist/immunologist, or pulmonologist. CIU (init): Prescribed by or in consultation with an allergist/immunologist, or dermatologist
Coverage Duration	Asthma (init): 6 months, Asthma (reauth): 12 months. CIU (init): 3 months, (reauth) 6 months
Other Criteria	Asthma (reauth): Documentation of positive clinical response to therapy (e.g., Reduction in number of asthma exacerbations, improvement in forced expiratory volume in 1 second (FEV1), or decreased use of rescue medications). Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a)

PA Criteria	Criteria Details
	Both of the following: i) inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), tiotropium], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)]. CIU (reauth): Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment. Patient has experienced one or both of the following: Reduction in itching severity from baseline or Reduction in the number of hives from baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	

• XYREM

PA Criteria	Criteria Details
Exclusion Criteria	In combination with sedative hypnotic agents at the time of the prior authorization review. In patients with succinic semialdehyde dehydrogenase deficiency.
Required Medical Information	
Age Restrictions	7 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• ZARXIO

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with a history of Febrile Neutropenia (FN) during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose- dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with FN at high risk for infection-associated complications.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consult with a hematologist, oncologist, or infectious disease specialist.
Coverage Duration	End of plan year
Other Criteria	Documentation of positive clinical response for reauthorization of Zarxio.
Indications	All Medically-accepted Indications.
Off Label Uses	

• miglustat

PA Criteria	Criteria Details
Exclusion Criteria	Severe renal impairment (estimated GFR less than 30ml/min).
Required Medical Information	Gaucher's disease (all of the following): 1) diagnosis is confirmed by genetic testing or enzyme assay demonstrating beta-glucocerebrosidase enzyme deficiency AND 2) a baseline serum creatinine must be obtained prior to treatment initiation AND 3) enzyme replacement therapy is not an option (e.g. allergy, hypersensitivity, poor venous access,).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	End of plan year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• ZEPOSIA

#### • ZEPOSIA STARTER KIT

• ZEPOSIA 7-DAY STARTER PACK

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS: Aubagio (teriflunomide), Gilenya (fingolimod), or Tecfidera (dimethyl fumarate), OR b) for continuation of prior therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	

• ZORBTIVE

PA Criteria	Criteria Details	
Exclusion Criteria	Acute malignancy. Active proliferative or severe non-proliferative diabetic retinopathy.	
Required Medical Information	ient is currently receiving specialized nutritional support. Patient has previously received 4 weeks of treatment with Zorbtive.	
Age Restrictions		
Prescriber Restrictions	Prescribed by or in consult with a gastroenterologist.	
Coverage Duration	SBS: 4 weeks. All other indications: end of plan year.	
Other Criteria		
Indications	All Medically-accepted Indications.	
Off Label Uses		

### Index of Drugs

## Α

A	
ABSTRAL SUBLINGUAL TABLET	
SUBLINGUAL 400 MCG, 600 MCG, 80	0
MCG	
accutane	
ACTEMRA ACTPEN	2
ACTEMRA ACTEEN	. 2
ACTEMIRA SUBCUTANEOUS	Z
ACTHAR	
ADAKVEO	
adapalene external cream	
adapalene external gel	
adapalene external solution	42
adapalene-benzoyl peroxide external gel	
ADEMPAS	. 7
AJOVY	
alosetron hcl	
alyq	
ambrisentan	
amnesteem	
amphetamine-dextroamphetamine er	39
ANADROL-50	
ANDRODERM	
APOKYN	
ARALAST NP INTRAVENOUS SOLUTIO	
RECONSTITUTED 1000 MG	12
ARANESP (ALBUMIN FREE)	13
ARCALYST	
armodafinil oral tablet 150 mg, 200 mg, 25	
mg, 50 mg 1	10
AUBAGIO	15
AUSTEDO ORAL TABLET 12 MG, 6 MG,	0
AUSTEDU URAL TABLET 12 IVIG, 0 IVIG,	9
MG	
AVASTIN 17,	
AVITA	
AVONEX PEN	
AVONEX PREFILLED	19
В	
BENLYSTA SUBCUTANEOUS	20
BEOVU	21
BERINERT	22
BETASERON	23
C	
CABLIVI	21
carisoprodol oral tablet 350 mg	
CAYSTON	
CERDELGA	
CHOLBAM	
ciclodan	
ciclopirox external solution 1	27

CIMZIA	
CIMZIA PREFILLED KIT	
CINRYZE	
claravis	
clindamycin-tretinoin	42
CORLANOR ORAL TABLET	
COSENTYX (300 MG DOSE)	
COSENTYX SENSOREADY (300 MG)	
CRINONE	
CYSTARAN	36
D	
dalfampridine er	
DALIRESP	
deferasirox52, 8	81
deferasirox granules	81
deferiprone	56
depo-testosterone	62
dexmethylphenidate hcl	39
dexmethylphenidate hcl er oral capsule	
extended release 24 hour 10 mg, 15 mg	J,
20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 5	
mg	39
dextroamphetamine sulfate er oral capsule	Э
extended release 24 hour 10 mg, 15 mg	
5 mg	
dextroamphetamine sulfate oral tablet 10	
mg, 5 mg	39
DIACOMIT	
diclofenac sodium external solution	41
dimethyl fumarate oral1	67
dimethyl fumarate starter pack1	
E	
EGRIFTA SUBCUTANEOUS SOLUTION	
RECONSTITUTED 1 MG	43
EMGALITY	44
EMGALITY (300 MG DOSE)	
ENBREL	
ENBREL MINI	45
ENBREL SURECLICK	45
ENTRESTO	
EPIDIOLEX	
EPIDUO FORTE	
ESBRIET ORAL CAPSULE	
EVENITY	50
	51
EXTAVIA	51
EXTAVIA	51 23
EXTAVIA F FASENRA	51 23 54

FERRIPROX	56
FINTEPLA	57
FIRDAPSE	59
FLEBOGAMMA DIF INTRAVENOUS	
SOLUTION 10 GM/200ML	60
FLEBOGAMMA DIF INTRAVENOUS	
SOLUTION 5 GM/50ML	78
FORTEO	
FULPHILA	
G	
GALAFOLD	64
GAMMAGARD INJECTION SOLUTION 2	25
GM/25ML	
GAMMAGARD S/D LESS IGA	78
GAMMAKED INJECTION SOLUTION 1	10
GM/10ML	78
GAMMAPLEX INTRAVENOUS SOLUTIO	ואנ
10 GM/200ML	
GAMUNEX-C INJECTION SOLUTION 1	10
GM/10ML	70
GATTEX	
GAVRETO	
GENOTROPIN	71
GENOTROPIN MINIQUICK	
GILENYA ORAL CAPSULE 0.5 MG	
GIVLAARI	
GLASSIA 1	31
glatiramer acetate subcutaneous solution	
prefilled syringe 20 mg/ml, 40 mg/ml	32
glatopa subcutaneous solution prefilled	
syringe 20 mg/ml, 40 mg/ml	
glydo	
GRANIX	69
Н	
HARVONI ORAL PACKET 33.75-150 MG	,
45-200 MG	
HARVONI ORAL TABLET 45-200 MG	
HETLIOZ	73
HUMATROPE	71
HUMIRA75,	76
HUMIRA PEDIATRIC CROHNS START	75,
76	
HUMIRA PEN75,	
HUMIRA PEN-CD/UC/HS STARTER 75,	76
HUMIRA PEN-PS/UV/ADOL HS START	
76	- 1
HUMIRA PEN-PSOR/UVEIT STARTER.	75.
76	- 1
hydroxyprogesterone caproate	
intramuscular oil	95
	_

I	
icatibant acetate	58
ILUMYA	77
INBRIJA	79
INQOVI	
isotretinoin oral	1
itraconazole oral1	58
J	
JADENU SPRINKLE	
JATENZO 1	
JUXTAPID	82
K	
KALYDECO	
KEVEYIS	
KINERET	
KORLYM	
KOSELUGO	
KUVAN	88
L	
ledipasvir-sofosbuvir	
LEUKINE	
lidocaine external ointment	
lidocaine external patch 5 %	91
lidocaine hcl external solution	
lidocaine hcl urethral/mucosal	92
lidocaine-prilocaine external cream	92
LUPANETA PACK COMBINATION KIT	
11.25 & 5 MG, 3.75 & 5 MG	94
Μ	
MAVENCLAD (10 TABS)	
MAVENCLAD (4 TABS)	
MAVENCLAD (5 TABS)	96
MAVENCLAD (6 TABS)	96
MAVENCLAD (7 TABS)	
MAVENCLAD (8 TABS)	96
MAVENCLAD (9 TABS)	
MAVYRET	
MAYZENT ORAL TABLET 0.25 MG, 2 MG	
menest	
metadate er	
methitest	
methylphenidate hcl er (cd)	39
methylphenidate hcl er (la) oral capsule	
extended release 24 hour 10 mg, 60 m	-
	39
methylphenidate hcl er oral tablet extende	
release 10 mg, 18 mg, 20 mg, 27 mg, 3	
mg, 54 mg	39

NATPARA    104      NEULASTA    105      NEUPOGEN    106      NORDITROPIN FLEXPRO    70, 71      NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71	methylphenidate hcl er oral tablet extend release 24 hour 18 mg, 27 mg, 36 mg, mg	54 . 39 . 39
mg, 2.5 mg, 5 mg    39      methyltestosterone oral    99      miglustat    194      MIRVASO    100      modafinil    101      MULPLETA    102      MYALEPT    103      myorisan    1      N    NATPARA      NEUPOGEN    106      NORDITROPIN FLEXPRO    70, 71      NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/200ML      GM/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    50LUTION 10      GR/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    116      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENITRAM	• •	
methyltestosterone oral    99      miglustat    194      MIRVASO    100      modafinil    101      MULPLETA    102      MYALEPT    103      myorisan    1      N    NattPARA      NEUPOGEN    106      NORDITROPIN FLEXPRO    70, 71      NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/200ML      GM/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    50LUTION 10      GR/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    114      OPSUMIT    115      ORENCIA SUBCUTANEOUS    116      ORENCIA SUBCUTANEOUS    116      ORENITRAM <td< td=""><td>• •</td><td></td></td<>	• •	
miglustat.    194      MIRVASO    100      modafinil.    101      MULPLETA    102      MYALEPT    103      myorisan    1      N    104      NEULASTA    105      NEUPOGEN    106      NORDITROPIN FLEXPRO    70, 71      NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/200ML      GM/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    114      OPSUMIT    115      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENCIA SUBCUTANEOUS <td></td> <td></td>		
modafinil	miglustat	194
MULPLETA    102      MYALEPT    103      myorisan    1      N    104      NEUPOGEN    106      NORDITROPIN FLEXPRO    70, 71      NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/20ML, 2 GM/20ML      GM/200ML    112      octraedam INTRAVENOUS SOLUTION 10    GM/200ML      GM/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    50      SOLUTION CARTRIDGE    70, 71      ONUREG    114      OPSUMIT    115      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116 </td <td></td> <td></td>		
MYALEPT    103      myorisan    1      N    104      NEUPARA    104      NEUPOGEN    106      NORDITROPIN FLEXPRO    70, 71      NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/20ML, 2 GM/20ML      GOTAGAM INTRAVENOUS SOLUTION 10    GM/200ML      GM/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    50LUTION 10      GRENCIA CLICKJECT    116      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENCIA SUBCUTANEOUS    117      ORILISSA ORAL TABLET 150 MG, 200 MG    118      ORKAMBI ORAL TABLET    119      OTEZLA    120      oxandrolone oral tablet 10 mg, 2.5 mg    121      OXBRYTA    122      P		
myorisan    1      N    104      NEUPARA    105      NEUPOGEN    106      NORDITROPIN FLEXPRO    70, 71      NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/20ML, 2 GM/20ML      GOTAGAM INTRAVENOUS SOLUTION 10    GM/200ML      GM/200ML, 2 GM/20ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    70, 71      ONUREG    114      OPSUMIT    115      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENCIA CLICKJE		102
N      NATPARA    104      NEULASTA    105      NEUPOGEN    106      NORDITROPIN FLEXPRO    70, 71      NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      O    OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    114      OPSUMIT    115      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENITRAM    117      ORILISSA ORAL TABLET 150 MG, 200 MG    118      ORKAMB		
NEULASTA    105      NEUPOGEN    106      NORDITROPIN FLEXPRO    70, 71      NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/200ML      GM/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    50LUTION 10      GRENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENCIA SUBCUTANEOUS    117      ORILISSA ORAL TABLET 150 MG, 200 MG    118      ORKAMBI ORAL TABLET    119      OTEZLA    120      oxandrolone oral tablet 10 mg, 2.5 mg    121      OXBRYTA    122      P    PADCEV INTRAVENOUS SOLUTION	N	1
NEUPOGEN    106      NORDITROPIN FLEXPRO    70, 71      NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/200ML      GM/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    70, 71      ONUREG    114      OPSUMIT    115      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENTRAM    117      ORILIISSA ORAL TABLET    120      oxandrolone o	NATPARA	104
NORDITROPIN FLEXPRO    70, 71      NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      O    OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/20ML    78      OCTAGAM INTRAVENOUS SOLUTION 10    GM/200ML    112      octreotide acetate    149    0FEV    113      OMNITROPE SUBCUTANEOUS    SOLUTION CARTRIDGE    70, 71      ONUREG    114    0PSUMIT    115      ORENCIA CLICKJECT    116    0RENCIA SUBCUTANEOUS    116      ORENCIA SUBCUTANEOUS    116    0RENTRAM    117      ORILISSA ORAL TABLET    150    120    0xandrolone oral tablet 10 mg, 2.5 mg    121      OXBRYTA    122    P    P    122    123		
NORTHERA    107      NOURIANZ ORAL TABLET 20 MG, 40 MG    108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/20ML, 2 GM/20ML      GM/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    SOLUTION CARTRIDGE      SOLUTION CARTRIDGE    70, 71      ONUREG    114      OPSUMIT    115      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENCIA SUBCUTANEOUS    116      ORENCIA SUBCUTANEOUS    116      ORENTRAM    117      ORILISSA ORAL TABLET 150 MG, 200 MG    118      ORKAMBI ORAL TABLET    120      oxandrolone oral tablet 10 mg, 2.5 mg    121      OXBRYTA    122      P    PADCEV INTRAVENOUS SOLUTION		
NOURIANZ ORAL TABLET 20 MG, 40 MG      108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/20ML, 2 GM/20ML      GM/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    50LUTION 10      GR/200ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    50LUTION CARTRIDGE      SOLUTION CARTRIDGE    70, 71      ONUREG    114      OPSUMIT    115      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENITRAM    117      ORILISSA ORAL TABLET 150 MG, 200 MG    118      ORKAMBI ORAL TABLET    119      OTEZLA    120      oxandrolone oral tablet 10 mg, 2.5 mg    121      OXBRYTA    122      P    P <t< td=""><td>NORDITROPIN FLEXPRO</td><td>, 71</td></t<>	NORDITROPIN FLEXPRO	, 71
108      NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/20ML, 2 GM/20ML      GM/20ML, 2 GM/20ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    50LUTION CARTRIDGE      SOLUTION CARTRIDGE    70, 71      ONUREG    114      OPSUMIT    115      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENCIA SUBCUTANEOUS    117      ORILISSA ORAL TABLET 150 MG, 200 MG    118      ORKAMBI ORAL TABLET    119      OTEZLA    120      oxandrolone oral tablet 10 mg, 2.5 mg    121      OXBRYTA    122      P    PADCEV INTRAVENOUS SOLUTION      RECONSTITUTED 20 MG    123		
NUEDEXTA    109      NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      O    0      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    GM/20ML      GM/20ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    70, 71      ONUREG    114      OPSUMIT    115      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENITRAM    117      ORILISSA ORAL TABLET 150 MG, 200 MG    118      ORKAMBI ORAL TABLET    119      OTEZLA    120      oxandrolone oral tablet 10 mg, 2.5 mg    121      OXBRYTA    122      P    PADCEV INTRAVENOUS SOLUTION      RECONSTITUTED 20 MG    123	-	
NUTROPIN AQ NUSPIN 10    70, 71      NUTROPIN AQ NUSPIN 20    70, 71      NUTROPIN AQ NUSPIN 5    70, 71      O    111      OCALIVA    111      OCTAGAM INTRAVENOUS SOLUTION 1    3      GM/20ML, 2 GM/20ML    78      OCTAGAM INTRAVENOUS SOLUTION 10    3      GM/20ML    112      octreotide acetate    149      OFEV    113      OMNITROPE SUBCUTANEOUS    70, 71      ONUREG    114      OPSUMIT    115      ORENCIA CLICKJECT    116      ORENCIA SUBCUTANEOUS    116      ORENTRAM    117      ORILISSA ORAL TABLET 150 MG, 200 MG    118      ORKAMBI ORAL TABLET    119      OTEZLA    120      oxandrolone oral tablet 10 mg, 2.5 mg    121      OXBRYTA    122      P    PADCEV INTRAVENOUS SOLUTION      RECONSTITUTED 20 MG    123		
NUTROPIN AQ NUSPIN 2070, 71NUTROPIN AQ NUSPIN 570, 71OOCALIVA111OCTAGAM INTRAVENOUS SOLUTION 1GM/20ML, 2 GM/20ML78OCTAGAM INTRAVENOUS SOLUTION 10GM/200ML112octreotide acetate149OFEV113OMNITROPE SUBCUTANEOUS70, 71ONUREG114OPSUMIT115ORENCIA CLICKJECT116ORENCIA SUBCUTANEOUS117ORILISSA ORAL TABLET 150 MG, 200 MG118ORKAMBI ORAL TABLET119OTEZLA120oxandrolone oral tablet 10 mg, 2.5 mg121OXBRYTA122PPADCEV INTRAVENOUS SOLUTION123	NUTROPIN AQ NUSPIN 10 70.	, 71
O OCALIVA		
OCALIVA111OCTAGAM INTRAVENOUS SOLUTION 1GM/20ML, 2 GM/20ML78OCTAGAM INTRAVENOUS SOLUTION 10GM/200ML112octreotide acetate149OFEV113OMNITROPE SUBCUTANEOUSSOLUTION CARTRIDGE70, 71ONUREG114OPSUMIT115ORENCIA CLICKJECT116ORENCIA SUBCUTANEOUS116ORENITRAM117ORILISSA ORAL TABLET 150 MG, 200 MG118ORKAMBI ORAL TABLET119OTEZLA120oxandrolone oral tablet 10 mg, 2.5 mg121OXBRYTA122PPADCEV INTRAVENOUS SOLUTION123	NUTROPIN AQ NUSPIN 5 70,	, 71
OCTAGAM INTRAVENOUS SOLUTION 1 GM/20ML, 2 GM/20ML	0	
GM/20ML, 2 GM/20ML 78 OCTAGAM INTRAVENOUS SOLUTION 10 GM/200ML 112 octreotide acetate 149 OFEV 113 OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE. 70, 71 ONUREG 114 OPSUMIT 115 ORENCIA CLICKJECT 116 ORENCIA SUBCUTANEOUS 116 ORENITRAM 117 ORILISSA ORAL TABLET 150 MG, 200 MG 118 ORKAMBI ORAL TABLET 150 MG, 200 MG 118 ORKAMBI ORAL TABLET 120 oxandrolone oral tablet 10 mg, 2.5 mg 121 OXBRYTA 122 P PADCEV INTRAVENOUS SOLUTION RECONSTITUTED 20 MG 123		111
OCTAGAM INTRAVENOUS SOLUTION 10 GM/200ML		
GM/200ML	OCTAGAM INTRAVENOUS SOLUTION	10
octreotide acetate		
OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE70, 71 ONUREG		
SOLUTION CARTRIDGE70, 71 ONUREG		113
ONUREG		
OPSUMIT		,
ORENCIA CLICKJECT		
ORENCIA SUBCUTANEOUS		115 116
ORENITRAM	ORENCIA SUBCUTANEOUS	116
ORILISSA ORAL TABLET 150 MG, 200 MG 		
ORKAMBI ORAL TABLET	ORILISSA ORAL TABLET 150 MG, 200	MG
OTEZLA	······································	118
oxandrolone oral tablet 10 mg, 2.5 mg 121 OXBRYTA 122 P PADCEV INTRAVENOUS SOLUTION RECONSTITUTED 20 MG 123		
OXBRYTA 122 P PADCEV INTRAVENOUS SOLUTION RECONSTITUTED 20 MG 123		
P PADCEV INTRAVENOUS SOLUTION RECONSTITUTED 20 MG 123	OXANDROIONE ORAL TABLET 10 mg, 2.5 mg	121
PADCEV INTRAVENOUS SOLUTION RECONSTITUTED 20 MG 123		122
RECONSTITUTED 20 MG 123	-	
PALFORZIA (12 MG DAILY DOSE) 175		123
•	PALFORZIA (12 MG DAILY DOSE)	175

PALFORZIA (120 MG DAILY DOSE)175
PALFORZIA (160 MG DAILY DOSE) 175
PALFORZIA (20 MG DAILY DOSE) 175
PALFORZIA (200 MG DAILY DOSE) 175
PALFORZIA (240 MG DAILY DOSE)175
PALFORZIA (240 MG DAILY DOSE) 175
PALFORZIA (3 MG DAILY DOSE)175
PALFORZIA (300 MG MAINTENANCE) 175
PALFORZIA (300 MG TITRATION) 175
PALFORZIA (40 MG DAILY DOSE) 175
PALFORZIA (6 MG DAILY DOSE)
PALFORZIA (80 MG DAILY DOSE)175
PALFORZIA INITIAL ESCALATION175
PALYNZIQ SUBCUTANEOUS SOLUTION
PREFILLED SYRINGE 10 MG/0.5ML, 2.5
MG/0.5ML, 20 MG/ML
PEGASYS
PEGASYS PROCLICK SUBCUTANEOUS
SOLUTION 180 MCG/0.5ML 125
PEMAZYRE126
PLEGRIDY128
PLEGRIDY STARTER PACK
SUBCUTANEOUS SOLUTION PEN-
INJECTOR128
PRALUENT129
PRETOMANID130
PRIVIGEN INTRAVENOUS SOLUTION 20
GM/200ML78
PROCRIT
PROLASTIN-C INTRAVENOUS SOLUTION
RECONSTITUTED
PROLIA
PROMACTA ORAL PACKET 12.5 MG, 25
MG133
PROMACTA ORAL TABLET
PULMOZYME134
oyrimethamine oral
QINLOCK
quinine sulfate oral136
R
RAVICTI137
REBIF138
REBIF REBIDOSE
REBIF REBIDOSE TITRATION PACK 138
REBIF TITRATION PACK138
REBLOZYL139
REGRANEX140
RELISTOR ORAL141
RELISTOR SUBCUTANEOUS SOLUTION
12 MG/0.6ML, 12 MG/0.6ML (0.6ML
SYRINGE), 8 MG/0.4ML141

REPATHA	142
REPATHA PUSHTRONEX SYSTEM	
REPATHA SURECLICK	
RETACRIT	
RETEVMO	
riluzole	
RUCONEST	
S	140
SAIZEN	70, 71
SAIZENPREP	
sapropterin dihydrochloride	88
SEROSTIM	
SIGNIFOR	150
sildenafil citrate oral suspension	
reconstituted	
sildenafil citrate oral tablet 20 mg	
SILIQ SIMPONI	
SKYRIZI (150 MG DOSE)	
sofosbuvir-velpatasvir	
SOLIRIS	
SOMATULINE DEPOT SUBCUTANEO	DUS
SOLUTION 120 MG/0.5ML, 60	
MG/0.2ML, 90 MG/0.3ML	155
SOMAVERT	156
SOVALDI ORAL PACKET 150 MG, 20	
SOVALDI ORAL TABLET 400 MG	
STELARA SUBCUTANEOUS	
STRIANT BUCCAL 30 MG	
SYMLINPEN 120 SYMLINPEN 60	
T	101
TABRECTA	162
tadalafil (pah)	
tadalafil oral tablet 2.5 mg, 5 mg	
TAKHZYRO	
TALTZ	
TARGRETIN EXTERNAL	
TAZORAC EXTERNAL GEL	
TECFIDERA ORAL	
TECFIDERA ORAL CAPSULE DELAY	
RELEASE	
TEGSEDI testosterone cypionate intramuscular	

testosterone enanthate intramuscular	62
testosterone transdermal gel 20.25	
mg/1.25gm (1.62%), 20.25 mg/act	
(1.62%), 40.5 mg/2.5gm (1.62%)	62
tetrabenazine	
TREMFYA	.169
tretinoin external	42
tretinoin microsphere	42
TRIKAFTA	
TRIPTODUR	.171
TUKYSA	.172
TYSABRI	
U	
UDENYCA	.174
UPTRAVI ORAL TABLET	
UPTRAVI ORAL TABLET THERAPY PA	
	176
V	
VARIZIG	.177
VENTAVIS	
VUMERITY	
VYNDAMAX	
VYNDAQEL	
VYONDYS 53	
W	
WAKIX	183
X	
XCOPRI	184
XCOPRI (250 MG DAILY DOSE)	184
XCOPRI (350 MG DAILY DOSE)	
XELJANZ	
XELJANZ XR	
XGEVA	
XIFAXAN	
XIIDRA	
XOLAIR	
XYREM	
Z	
ZARXIO	.193
ZEMAIRA	
zenatane	
zenzedi oral tablet 10 mg, 15 mg, 2.5 mg	a.
20 mg, 30 mg, 5 mg, 7.5 mg	
ZEPOSIA	
ZEPOSIA 7-DAY STARTER PACK	
ZEPOSIA STARTER KIT	
ZORBTIVE	
	100