

## 2010 Medicare High Performance PA Criteria

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## **ACTEMRA**

### **Affected Drugs**

ACTEMRA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus patients already started on tocilizumab. Systemic-onset juvenile idiopathic arthritis (JIA).

### **Exclusion Criteria**

Tocilizumab should not be given in combination with tumor necrosis factor (TNF) antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), abatacept, anakinra, or rituximab. Other uses excluded from coverage include JIA [Juvenile Idiopathic Arthritis] types other than systemic onset, Crohn's disease, and Castleman's disease. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria.

### **Required Medical Information**

N/A

### **Age Restrictions**

For indication of systemic-onset JIA [Juvenile Idiopathic Arthritis], may approve for children and adolescents 18 years of age or younger. For rheumatoid arthritis (RA), approve for adults.

### **Prescriber Restrictions**

Adults with RA [Rheumatoid Arthritis], tocilizumab is to be prescribed by a rheumatologist or in consultation with a rheumatologist. Systemic-onset JIA [Juvenile Idiopathic Arthritis], tocilizumab is to be prescribed by a rheumatologist.

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

Adults with RA [Rheumatoid Arthritis], approve for patients who have tried one of the following TNF [Tumor necrosis factor] antagonists for at least 2 months, adalimumab, certolizumab pegol, etanercept, golimumab, or infliximab, AND patient must be receiving methotrexate (MTX) or another nonbiologic disease-modifying antirheumatic drug (DMARD) (eg, hydroxychloroquine, leflunomide, sulfasalazine) in combination with tocilizumab. Patients are not required to use MTX [methotrexate] concurrently with tocilizumab if there are contraindications to MTX [methotrexate] or the patient has a

history of intolerance to MTX [methotrexate] or to use other nonbiologic DMARDs [Disease-modifying antirheumatic drugs] concurrently with tocilizumab if there are contraindications or a history of intolerance. Systemic-onset JIA [Juvenile Idiopathic Arthritis], approve for patients who have tried a systemic corticosteroid, and either MTX [methotrexate] or sulfasalazine or another DMARD [Disease-modifying antirheumatic drug] such as etanercept.

## **ACTIQ/FENTORA**

### **Affected Drugs**

FENTANYL CITRATE

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Acute and/or postoperative pain including surgery/post-surgery, trauma/post-trauma, acute medical illness (acute abdominal pain, pelvic pain, muscle spasm). Pre-anesthesia (preoperative anxiolysis and sedation and/or supplement to anesthesia. Coverage is not recommended for circumstances not listed in the Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

Breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate).

## **ADCIRCA**

### **Affected Drugs**

ADCIRCA®

### **Covered Uses**

All FDA approved indications not otherwise excluded from Part D plus Eisenmenger syndrome with pulmonary arterial hypertension (PAH) [men or women]. For Raynaud disease, refer to Levitra.

### **Exclusion Criteria**

Patients taking nitrates. Use of Adcirca for the treatment of erectile dysfunction. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

## **ALPHA-1 PROTEINASE INHIBITORS**

### **Affected Drugs**

ARALAST®  
PROLASTIN®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Other phenotypes with an alpha1-antitrypsin serum concentration less than 11 microM (11 micromol/L) or 80 mg/dL (eg, PiSZ phenotype). Alpha-1 antitrypsin (AAT) deficiency-associated panniculitis.

### **Exclusion Criteria**

PiMZ or PiMS phenotype of alpha1-antitrypsin deficiency, unless alpha1-antitrypsin serum concentrations are less than 11 microM (11 micromol/L) or 80 mg/dL. Cystic fibrosis. COPD [Chronic Obstructive Pulmonary Disease] without alpha1-antitrypsin deficiency. Alpha1-antitrypsin deficiency without lung disease, even if deficiency-induced hepatic disease is present. Bronchiectasis (without alpha1-antitrypsin deficiency). Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

For AAT [Alpha 1-antitrypsin] deficiency and emphysema of other phenotypes that are not FDA-approved (eg, PiSZ, PiMZ or PiMS phenotype), an alpha1-antitrypsin serum concentration of less than 11 microM (11 micromol/L) or 80 mg/dL is required.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

For AAT [Alpha 1-antitrypsin] deficiency and emphysema of other phenotypes that are not FDA-approved (eg, PiSZ, PiMZ or PiMS phenotype), an alpha1-antitrypsin serum concentration of less than 11 microM (11 micromol/L) or 80 mg/dL is required.

## **AMEVIVE**

### **Affected Drugs**

AMEVIVE®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus psoriasis of hand and/or foot (may be palmoplantar pustulosis, palmoplantar pustular psoriasis, or palmar plantar pustulosis). Psoriatic arthritis.

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

Greater than or equal to 16 years of age.

### **Prescriber Restrictions**

Plaque psoriasis. Prescribed by a dermatologist or in consultation with a dermatologist. Psoriasis of hand and/or foot (palmoplantar pustulosis, palmoplantar pustular psoriasis, or palmar plantar pustulosis). Prescribed by a dermatologist.

### **Coverage Duration**

PP/PsA [Psoriatic arthritis], 12 week. Hand/ft psor, 16 week. Approve 2nd 12 or 16 week, respectively, if patient off Amevive for 12 week.

### **Other Criteria**

Plaque psoriasis. Patient has tried a systemic therapy (e. g. , MTX [methotrexate], azathioprine, cyclosporine, Soriatane, Prograf, Raptiva, Enbrel, Remicade, Humira, Stelara, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil) or phototherapy (UVB, OR oral methoxsalen plus UVA light [PUVA]) for psoriasis. Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA [Body surface area] if they have plaque psoriasis of palms, soles, head and neck, nails, intertriginous areas or genitalia. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA [Body surface area] if they have had an inadequate response to either topical therapy OR localized phototherapy, and had an inadequate response to systemic therapy, and had significant

disability or impairment in physical or mental functioning according to the treating physician. Hand and/or foot psoriasis, same criteria as plaque psoriasis except all psoriasis types (not just plaque) are allowed. Psoriatic arthritis. Patient has tried Humira, Enbrel, Simponi, or Remicade for at least 3 months AND the patient will be receiving Amevive in combination with MTX [methotrexate].

## **AMPYRA**

### **Affected Drugs**

AMPYRA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus patient already started on dalfampridine extended-release for Multiple Sclerosis (MS).

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

MS [Multiple Sclerosis]. If prescribed by, or in consultation with, an MS [Multiple Sclerosis] specialist.

### **Coverage Duration**

Initial approval for MS [Multiple Sclerosis], 2 months. Subsequent authorization for 12 months if patient had a response.

### **Other Criteria**

For initial approval for MS [Multiple Sclerosis], authorize for 2 months. After up to 2 months of dalfampridine extended-release therapy, if MS [Multiple Sclerosis] patient has had a response to therapy as determined by prescribing physician (eg, increased walking distance, improved leg/limb strength, improvement in activities of daily living), then an additional authorization is allowed. Patients may be given another 2-month trial of dalfampridine extended-release for MS [Multiple Sclerosis] (after previous use and discontinuation) if the patient's MS [Multiple Sclerosis] condition has deteriorated or worsened.

## **ANABOLIC STEROIDS**

### **Affected Drugs**

ANADROL-50®

OXANDROLONE

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus Oxandrin for inclusion body myositis (IBM) sporadic form. Oxandrin for ALS [Amyotrophic Lateral Sclerosis] for maintenance/improvement in muscle strength and/or respiratory capacity. Oxandrin for quadriplegic/tetraplegic patients for maintenance/improvement in respiratory muscle strength, pulmonary function, and/or dyspnea. Oxandrin for Duchenne muscular dystrophy. Oxandrin for constitutional delay of growth or growth and puberty in prepubertal boys with psychosocial difficulties or psychological distress due to their condition. Oxandrin for girls (8 years old and older) w/Turner's Syndrome or Ullrich-Turner Syndrome. Oxandrin for management of protein catabolism w/burns or burn injury. Oxandrin for AIDS wasting and cachexia due to a chronic disease. Oxandrin for cachexia due to cancer. Oxandrin for alcoholic liver disease (hepatitis). Anadrol-50 for prevention/prophylaxis of hereditary angioedema. Anadrol-50 for AIDS wasting and cachexia due to a chronic disease. Anadrol-50 for antithrombin III deficiency. Anadrol-50 for anemia of chronic kidney disease.

### **Exclusion Criteria**

Coverage of Oxandrin AND Anadrol-50 is not recommended in the following circumstances: Management of weight gain, other than detailed in the FDA-approved indications or other covered uses. Management of weight loss. HIV-associated lipodystrophy. Chronkhite-Canada Syndrome. Heart failure in patients with idiopathic dilated cardiomyopathy (IDC), mitral regurgitation, or aortic regurgitation. Athletic performance (ability) enhancement. Coverage of Anadrol-50 is not recommended in the following circumstances: alcoholic liver disease (hepatitis). Relief of bone pain due to osteoporosis or conditions other than osteoporosis. Coverage of Oxandrin is not recommended in the following circumstances: anemia of chronic kidney disease. Coverage is not recommended for circumstances not listed in the Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

**Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

**Other Criteria**

Oxandrin for the management of protein catabolism associated with burns/burn injury. Approve for patients who have tried a beta-blocker or who have a contraindication to beta-blocker use. Anadrol-50 for anemia due to chronic kidney disease. Approve for patients who have tried or are unable to take erythroid-stimulant agents (Procrit, Epogen, Aranesp).

## **ARANESP**

### **Affected Drugs**

ARANESP®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Plus anemia due to myelodysplastic syndrome (MDS). Anemia in heart failure. Anemia associated with the use of ribavirin therapy for hepatitis C (in combination with interferon or pegylated interferon alfa 2a/2b products). Anemia of chronic disease/anemia of chronic inflammation (eg, anemia in inflammatory bowel disease (ulcerative colitis, Crohns disease), rheumatoid arthritis, systemic lupus erythematosus).

### **Exclusion Criteria**

Anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis. Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML [Acute Myeloid Lymphoma]), or erythroid cancers. Anemia of cancer not related to cancer treatment. Any anemia associated only with radiotherapy. Prophylactic use to prevent chemotherapy-induced anemia. Prophylactic use to reduce tumor hypoxia. Use in patients with erythropoietin-type resistance due to neutralizing antibodies. Anemia due to cancer treatment if patients have uncontrolled hypertension. To enhance athletic performance. Anemia in patients due to acute blood loss. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Anemia w/CRF [Chronic Renal Failure]. A hemoglobin (Hb) of less than or equal to 11.0 g/dL required for start, Hb has to be less than or equal to 12.0 g/dL if previously receiving epoetin alfa (EA) or Aranesp. Deny if Hb exceeds 12.0 g/dL. Anemia due to myelosuppressive chemotx, Hb immediately prior start/maintenance of Aranesp is 10.0 g/dL or less (hematocrit [Hct] is 30% or less). Maintenance of Aranesp is the starting dose if the Hb remains 10.0 g/dL or less (or Hct remains 30% or less) 4 weeks after therapy start and the rise in Hb is 1.0 g/dL or more (or Hct rise is 3% or more). patients whose Hb rises less than 1.0 g/dL (Hct rise less than 3%) compared to pretx baseline over 4 weeks of treatment and whose Hb remains less than 10.0 g/dL after the 4 weeks of treatment (or the Hct is less than 30%), the recommended FDA starting dose may be increased once by 25%. Continued Aranesp is not reasonable or necessary if the Hb rises less than 1.0 g/dL (Hct rise less than 3%) compared to pretx baseline by 8 weeks

of treatment. Continued Aranesp is not reasonable and necessary if there is a rapid rise in Hb more than 1.0 g/dL (Hct more than 3%) over 2 weeks of treatment unless the Hb remains below or subsequently falls to less than 10.0 g/dL (or the Hct is less than 30%). Continuation and reinstatement of Aranesp must include a dose reduction of 25% from the previously admin dose. MDS [Myelodysplastic syndrome], approve treatment if Hb is 12.0 g/dL or less. Aranesp treatment is not recommended if Hb is more than 12.0 g/dL in any situation. If the patient has previously been receiving Aranesp or EA, approve only if Hb is 12.0 g/dL or less. Anemia in HF, approve in patients with New York Heart Association (NYHA) functional class III or IV with Hb of 10.0 g/dL or less and according to the MD underlying causes of anemia persist despite transfusions or patient has contraindications to transfusions. Addtl treatment allowed if patient has Hb of 12.0 g/dL or less. Aranesp is not recommended if Hb is more than 12.0 g/dL. If patient had previously been receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Chemotherapy course +8 week after last chemo dose. CRF=12 months. MS [Multiple Sclerosis]/HC=6 mo. HF=6 months. Addtl 6 months, Hb 12.0 or less.

### **Other Criteria**

Anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. patients with Hb rise of less than 1.0 g/dL (or Hct 3% or less) and Hb levels is less than 10.0 g/dL after 4 weeks therapy, the recommended FDA dose may be increased once by 25%. Continued Aranesp use is not reasonable or necessary if the Hb rise is less than 1.0 g/dL (or Hct is less than 3%) compared to pretreatment baseline by 8 weeks of treatment. Continued Aranesp administration is not reasonable and necessary if there is a rapid rise in Hb or more than 1.0 g/dL (or Hct more than 3%) over 2 weeks of treatment unless the Hb remains below or subsequently falls to less than 10.0 g/dL (or Hct less than 30%). Continuation and reinstatement of Aranesp must include a dose reduction of 25% from the previously administered dose. Anemia assoc with ribavirin for hepatitis C patients, approve treatment if Hb is 10.0 g/dL or less. Aranesp is not recommended if Hb is more than 12.0 g/dL in any situation. Anemia of chronic disease/inflammation, Patients will be evaluated by a pharmacist and/or physician on a case-by-case basis. Consideration

is given to those with symptomatic anemia with low Hb (10.0 g/dL or less) despite transfusions (eg, transfusion dependent) or cannot tolerate or undergo transfusions. Other factors considered are low erythropoietin levels or failure of other treatment modalities (eg, iron supplementation). Other causes of anemia should have been ruled out. Aranesp is not recommended if Hb is 12.0 g/dL or more. Initial approval is for 3 months. Further approval after initial therapy will be determined on a case-by-case basis and response.

## **ARCALYST**

### **Affected Drugs**

ARCALYST®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Neonatal onset multisystem inflammatory disorder (NOMID) or chronic infantile neurological cutaneous and articular syndrome (CINCA). Juvenile idiopathic arthritis (JIA). Gout. Familial Mediterranean fever (FMF). Arcalyst should not be given in combination with tumor necrosis factor (TNF) blocking agents (Enbrel, Humira, Remicade) or Kineret. Coverage is not recommended for circumstances not listed in the Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

Greater than or equal to 12 years of age.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **AVONEX**

### **Affected Drugs**

AVONEX ADMINISTRATION PACK®  
AVONEX®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D worded as patients with a diagnosis of MS [Multiple Sclerosis] or have experienced an attack and who are at risk of MS [Multiple Sclerosis] and prescribed by, or after consultation with, a neurologist or an MS-specialist.

### **Exclusion Criteria**

Concurrent use of Rebif, Betaseron, Copaxone or Tysarbi. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Prescribed by or after consultation with a neurologist or an MS [Multiple Sclerosis] specialist.

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

N/A

## **B VS D - PART B VERSUS PART D COVERAGE PA**

### **Affected Drugs**

AZASAN®  
AZATHIOPRINE  
AZATHIOPRINE SODIUM  
CARIMUNE NF NANOFILTERED®  
CELLCEPT®  
CYCLOPHOSPHAMIDE  
CYCLOSPORINE  
CYCLOSPORINE MODIFIED  
DRONABINOL  
EMEND®  
FLEBOGAMMA®  
GAMUNEX®  
GENGRAF  
GRANISETRON HCL  
GRANISOL  
METHOTREXATE  
MITOXANTRONE HCL  
MYCOPHENOLATE MOFETIL  
MYFORTIC®  
ONDANSETRON HCL  
ONDANSETRON ODT  
ORTHOCLONE OKT-3®  
POLYGAM S-D®  
PRIVIGEN®  
PROGRAF®  
RAPAMUNE®  
SANDIMMUNE®  
SIMULECT®  
TACROLIMUS

### **Covered Uses**

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

# **BETASERON**

## **Affected Drugs**

BETASERON®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D worded as patients with a diagnosis of MS [Multiple Sclerosis] or have experienced an attack and who are at risk of MS [Multiple Sclerosis] and prescribed by, or after consultation with, a neurologist or an MS-specialist.

## **Exclusion Criteria**

Concurrent use of Avonex, Rebif, Copaxone or Tysarbi. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

Prescribed by or after consultation with a neurologist or an MS [Multiple Sclerosis] specialist.

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

N/A

# **BOTOX**

## **Affected Drugs**

BOTOX®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus Achalasia. Anal Fissure. BPH [Benign Prostatic Hypertrophy]. Chronic facial pain/pain associated with TMJ [Temporomandibular joint and muscle] dysfunction. Chronic low back pain. Plantar fasciitis. Tinnitus. Headache (migraine, chronic tension HA [Headache], whiplash, chronic daily HA [Headache]). Palmar/plantar and facial hyperhidrosis. Myofascial pain. Salivary hypersecretion. Spasticity (eg, due to cerebral palsy, stroke, brain injury, spinal cord injury, MS [Multiple Sclerosis], hemifacial spasm). Essential tremor. Dystonia other than cervical (eg, focal dystonias, tardive dystonia, anismus). Bladder/voiding/urethral dysfunction. Gastroparesis. Vaginismus. Dysphagia. Interstitial cystitis. Frey's syndrome. Ophthalmic disorders (eg, esotropia, exotropia, nystagmus, facial nerve paresis). Speech/voice disorders (eg, dysphonias). Tourette's syndrome. Crocodile tears syndrome. Fibromyalgia.

## **Exclusion Criteria**

Cosmetic uses (eg, facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal bands, rejuvenation of the peri-orbital region. Allergic rhinitis. Gait freezing in Parkinsons disease. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

Tinnitus if prescribed by ENT. Headache if prescribed by, or after consultation with, a neurologist or HA [Headache] specialist.

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

Primary axillary hyperhidrosis after trial with at least 1 topical agent (eg, aluminum chloride). BPH [Benign Prostatic Hypertrophy] after trial with at least 2 other therapies

(eg, alpha1-blocker, 5 alpha-reductase inhibitor, TURP [Transurethral resection of the prostate], transurethral microwave heat treatment, TUNA [Transurethral needle ablation], interstitial laser therapy, stents, various forms of surgery). Chronic low back pain after a trial with at least 2 other pharmacologic therapies (eg, NSAID [Non-steroidal anti-inflammatory drug], antispasmodics, muscle relaxants, opioids, antidepressants) and if being used as part of a multimodal therapeutic pain management program.

Tinnitus after a trial with at least 2 other pharmacologic therapies (eg, lidocaine, antihistamines, antidepressants, anxiolytics, diuretics, anticonvulsants, antispasmodics) and tinnitus retraining therapy and prescribed by an ENT (eg, otolaryngologist). Headache (eg, migraine, chronic tension headache, whiplash, chronic daily headache) after a trial with at least 2 other pharmacologic therapies (eg, anticonvulsants, antidepressants, beta-blockers, calcium channel blockers, non-steroidal anti-inflammatory drugs) and prescribed by or after consultation with a neurologist/headache specialist.

Palmar/plantar and facial hyperhidrosis after a trial with at least 1 topical agent (eg, aluminum chloride). Essential tremor after a trial with at least 1 other pharmacologic therapy (eg, primidone, propranolol, benzodiazepines, gabapentin, topiramate).

Bladder/Voiding/Urethral dysfunction after a trial with at least 1 other pharmacologic therapy (eg, oral antimuscarinic agents). Gastroparesis after a trial with at least 1 promotility drug (eg, metoclopramide, tegaserod, erythromycin). Vaginismus after a trial with at least 2 other treatment options (eg, behavior therapy, psychotherapy, biofeedback, dilatation techniques, deep muscle relaxation exercises, anesthetic creams, vaginal lubricants, propranolol, alprazolam). Interstitial cystitis after a trial with at least 1 other pharmacologic therapy (eg, pentosan polysulfate, heparin, antihistamines, TCAs [Tricyclic Antidepressants], intravesical dimethyl sulfoxide, bacilli Calmette-Guérin). Tourette's syndrome if after a trial with at least 1 more commonly used pharmacologic therapy (eg, neuroleptics, clonidine, SSRIs [Selective Serotonin Reuptake Inhibitors], psychostimulants). Fibromyalgia if after a trial of at least 2 or more commonly used pharmacologic therapies (eg, TCAs [Tricyclic Antidepressants], SSRIs [Selective Serotonin Reuptake Inhibitors], SNRIs [Selective Norepinephrine Reuptake Inhibitors], dopamine agonists, and sedative hypnotics, or lidocaine injection into "trigger points").

## **BYETTA**

### **Affected Drugs**

BYETTA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Weight loss treatment. Type 1 diabetes. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

# **CEREZYME**

## **Affected Drugs**

CEREZYME®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Type 1 Gaucher disease if being prescribed by, or after consultation with, a physician that specializes in the treatment of inherited metabolic disorders or the patient was referred to a center that specializes in the treatment of Gaucher disease. Type 2 or 3 Gaucher disease if the agent is being prescribed by, or after consultation with, a physician that specializes in the treatment of inherited metabolic disorders or the patient was referred to a center that specializes in the treatment of Gaucher disease.

## **Exclusion Criteria**

Tay-Sachs disease. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

Type 1, 2, or 3 Gaucher disease if prescribed by or after consultation with, a physician that specializes in the treatment of inherited metabolic disorders.

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

N/A

## **COMBINATION BETA2-AGONIST/CORTICOSTEROID INHALERS**

### **Affected Drugs**

ADVAIR DISKUS®

ADVAIR HFA®

SYMBICORT®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus COPD [Chronic Obstructive Pulmonary Disease]. Chronic bronchitis. Emphysema.

### **Exclusion Criteria**

Treatment of symptoms associated with a current rhinovirus infection/cough associated with a current episode of the common cold. Treatment of chronic cough due to GERD [Gastroesophageal Reflux Disease]. Treatment of symptoms due to an acute respiratory infection (eg, acute bronchitis, sinusitis, pneumonia). Treatment of chronic cough due to NAEB [Nonasthmatic eosinophilic bronchitis]. Treatment of chronic cough due to bronchiolitis. Treatment of chronic cough due to bronchiectasis. Whooping cough/pertussis. ACE inhibitor-induced cough. Psychogenic cough/habit cough/tic cough. Coverage is not recommended for circumstances not listed in the Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

# **COPAXONE**

## **Affected Drugs**

COPAXONE®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D worded as patients with a diagnosis of MS [Multiple Sclerosis] or have experienced an attack and who are at risk of MS [Multiple Sclerosis] and prescribed by, or after consultation with, a neurologist or an MS-specialist.

## **Exclusion Criteria**

Patient is receiving Avonex, Rebif, Betaseron or Tysabri. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

Prescribed by or after consultation with a neurologist or an MS [Multiple Sclerosis] specialist.

## **Coverage Duration**

Authorization will be for 12 months.

## **Other Criteria**

N/A

## **DIFLUCAN (FLUCONAZOLE)**

### **Affected Drugs**

FLUCONAZOLE

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Prevention of recurrent vulvovaginal or vaginal candidiasis. Tinea corporis and tinea versicolor (petyriasis versicolor). Tinea cruris, manuum, pedis, and faciei. Tinea capitis. Tinea barbae. Treatment or prevention of other superficial, systemic or suspected fungal infections. Continuation therapy for patients started and stabilized on IV or oral fluconazole for systemic infection. Onychomycosis.

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

'Onychomycosis must be judged to be medically significant (causing impaired mobility, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) and a positive KOH, fungal culture, DTM [dermatophyte test medium] culture, nail biopsy, or histologic examination (PAS) is required before therapy initiation. Before a second course of treatment is permitted for onychomycosis, a culture must demonstrate a fungal infection. Use of Penlac with Diflucan (fluconazole) is not permitted.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Onychomycosis = 6 months for toenails, 3 months for fingernails. Other conditions = 12 months.

### **Other Criteria**

Criteria only applies to the 50, 100 and 200 mg tablets (not the 150-mg tablet) and oral suspension. Tinea corporis and tinea versicolor after a trial of a topical antifungal agent, except for extensive conditions. Tinea cruris, manuum, pedis, and faciei after a trial of a topical antifungal agent. Onychomycosis. Approve fluconazole tablets or oral suspension for if the patient has tried terbinafine tablets or itraconazole capsules unless

the patients has a medical condition or other clinical reason to not utilize these agents (e. g. , drug-drug interactions, heart failure).

## **ENBREL**

### **Affected Drugs**

ENBREL®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus patient already on Enbrel. Juvenile spondyloarthritis. Undifferentiated spondyloarthritis. Reactive arthritis (Reiter's disease). Adult with Still's disease. Uveitis (noninfectious) in children. Scleritis or sterile corneal ulceration. Amyloidosis(primary). Amyloidosis with renal involvement. Chronic inflammatory demyelinating polyneuropathy. Myasthenia gravis. Acute or chronic GVHD [Graft-Versus-Host disease]. Behcet's disease. Giant cell arteritis. Hidradenitis suppurativa. Polymyalgia rheumatica. Pyoderma gangrenosum. Autoimmune mucocutaneous blistering diseases (pemphigus vulgaris, mucous membrane pemphigoid [cicatrical pemphigoid]). Systemic sclerosis (scleroderma) with inflammatory joint involvement. Tumor necrosis factor receptor-associated periodic syndrome (TRAPS).

### **Exclusion Criteria**

Enbrel should not be given in combination with Kineret or Orencia. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

Adults with RA [Rheumatoid Arthritis], approve if patient has tried 1 DMARD [Disease-modifying antirheumatic drug] for at least 2 months or is concurrently receiving MTX [methotrexate]. JIA [Juvenile Idiopathic Arthritis] or JRA [Juvenile Rheumatoid Arthritis], polyarticular course, approve if the patient has tried MTX [methotrexate] or will be starting on Enbrel concurrently with MTX [methotrexate]. Approve without trying MTX [methotrexate] if the patient has an absolute contraindication to MTX [methotrexate] (eg,

pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias). Plaque psoriasis. Patient has tried a systemic therapy (e. g. , MTX [methotrexate], azathioprine, cyclosporine, Soriatane, Prograf, Raptiva, Amevive, Remicade, Humira, Stelara, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil) or phototherapy (UVB, OR oral methoxsalen plus UVA light [PUVA]) for psoriasis. Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA [Body surface area] if they have plaque psoriasis of palms, soles, head and neck, nails, intertriginous areas or genitalia. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA [Body surface area] if they have had an inadequate response to either topical therapy OR localized phototherapy, and had an inadequate response to systemic therapy, and had significant disability or impairment in physical or mental functioning according to the treating physician.

# EPOETIN/PROCRIT

## Affected Drugs

PROCRIT®

## Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Plus anemia in patients with HIV who are receiving zidovudine. Anemic patients (Hb of 13.0 g/dL or less) at high risk for perioperative transfusions (secondary to significant, anticipated blood loss and are scheduled to undergo elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusions). Anemia due to myelodysplastic syndrome (MDS). Anemia associated with use of ribavirin therapy for hepatitis C (in combination with interferon or pegylated interferon alfa 2a/2b products). Anemia in HIV-infected patients. Preoperative use in patients undergoing major surgery utilizing hemodilution intraoperatively. Treatment of aplastic anemia. Anemia in heart failure (HF). Anemia of chronic disease/anemia of chronic inflammation (eg, anemia in inflammatory bowel disease (ulcerative colitis, Crohns disease), rheumatoid arthritis, systemic lupus erythematosus).

## Exclusion Criteria

Anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis. Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML [Acute Myeloid Lymphoma]), or erythroid cancers. Anemia of cancer not related to cancer treatment. Any anemia associated only with radiotherapy. Prophylactic use to prevent chemotherapy-induced anemia. Prophylactic use to reduce tumor hypoxia. Use in patients with erythropoietin-type resistance due to neutralizing antibodies. Anemia due to cancer treatment if patients have uncontrolled hypertension. To enhance athletic performance. Anemia in patients due to acute blood loss. Non-anemic patients (Hb more than 13.0 g/dL) prior to surgery. Coverage not recommended for anything not listed under Covered Uses.

## Required Medical Information

CRF [Chronic Renal Failure] anemia. Hemoglobin (Hb) of less than or equal to 11.0 g/dL to start. Hb less than or equal to 12.0 g/dL if previously on epoetin alfa (EA) or Aranesp. Anemia w/myelosuppressive chemotx. Hb immediately prior to EA is 10.0 g/dL or less (or hematocrit [Hct] is 30% or less). EA maintenance is starting dose if Hb level remains 10.0 g/dL or less (or Hct remains 30% or less) 4 weeks after start and Hb

rise is 1.0 g/dL or more (Hct rise is 3% or more). patients w/Hb rises less than 1.0 g/dL (Hct rise less than 3%) vs pretx baseline over 4 weeks of treatment and Hb is less than 10.0 g/dL after 4 weeks of treatment (Hct is less than 30%), the recommended FDA starting dose may be increased once by 25%. Continued use is not reasonable/necessary if Hb rises less than 1.0 g/dL (Hct rise less than 3%) vs pretx baseline by 8 weeks of treatment. Continued EA is not reasonable/necessary if there is a rapid Hb rise more than 1.0 g/dL (Hct more than 3%) over 2 weeks of treatment unless Hb remains below or subsequently falls to less than 10.0 g/dL (or Hct is less than 30%). Continuation/reinstitution of EA must have dose reduction of 25% of previous dose. MDS [Myelodysplastic syndrome], approve if Hb is 12.0 g/dL or less. Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HF, approve for New York Heart Association functional class III or IV patients w/Hb 10.0 g/dL or less and per MD underlying anemia causes persist despite transfusions or patient has contraindications to transfusions. Addtl treatment allowed if patient has Hb of 12.0 g/dL or less. Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV (+/- zidovudine), Hb is 10.0 g/dL or less or endogenous erythropoetin levels are 500 munits/mL or less at treatment start. Previously on EA approve if Hb is 12.0 g/dL or less. Anemia due to ribavirin for Hepatitis C, Hb is 10.0 g/dL or less at treatment start. Aplastic anemia, Hb is 12.0 g/dL or less. Previously on EA approve if Hb is 12.0 g/dL or less. All conds, deny if Hb exceeds 12.0 g/dL.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

For aplastic anemia epoetin alfa has to be prescribed by a hematologist.

### **Coverage Duration**

Chemotherapy course +8 week. MDS=6mo. HF=6mo. Addtl 6 mo, Hb 12.0 or less. Transfus=3wk. Hemodilut=1 mo. Other=12mo.

### **Other Criteria**

Anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. patients with Hb rise of less than 1.0 g/dL (or Hct 3% or less) and Hb levels is less than 10.0 g/dL after 4 weeks therapy, the recommended FDA dose may be increased once by 25%. Continued epoetin alfa use is not reasonable or necessary if the Hb rise is less than 1.0 g/dL (or Hct is less than 3%) compared to pretreatment baseline by 8 weeks of treatment. Continued epoetin alfa administration is not reasonable and necessary if there is a rapid rise in Hb or more than 1.0 g/dL (or Hct more than 3%) over 2 weeks of treatment

unless the Hb remains below or subsequently falls to less than 10.0 g/dL (or Hct less than 30%). Continuation and reinstatement of epoetin alfa must include a dose reduction of 25% from the previously administered dose. Anemia of chronic disease/inflammation, Patients will be evaluated by a pharmacist and/or physician on a case-by-case basis. Consideration is given to those with symptomatic anemia with low Hb (10.0 g/dL or less) despite transfusions (eg, transfusion dependent) or cannot tolerate or undergo transfusions. Other factors considered are low erythropoietin levels or failure of other treatment modalities (eg, iron supplementation). Other causes of anemia should have been ruled out. Aranesp is not recommended if Hb is 12.0 g/dL or more. Initial approval is for 3 months. Further approval after initial therapy will be determined on a case-by-case basis and response.

## **FABRAZYME**

### **Affected Drugs**

FABRAZYME®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Male patients with a diagnosis of Fabry disease based on clinical symptoms or by genetic testing. Female patients with presumed symptoms of Fabry disease (heterozygous carriers) based on family history and/or genetic testing.

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Fabry disease in male patients based on clinical symptoms or by genetic testing.  
Fabry disease in female patients based on family history and/or genetic testing.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

# **FORTEO**

## **Affected Drugs**

FORTEO®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. For the treatment of osteoporosis in patients (women and men) who are at high risk for fracture. Patients at high risk include those with a history of osteoporotic fracture, those with a medical condition that has resulted in bone loss significantly greater than would be expected for the patient's age (eg, chronic liver disease), patients with a very low BMD [Bone mass density] (defined as (ie, BMD [Bone mass density] T-score below -2.0) or ), and those using medicine that resulted in bone loss (eg, steroids [prednisone]). For use in hypoparathyroidism (primary or secondary) if the patient is under the care of an endocrinologist.

## **Exclusion Criteria**

Prevention of osteoporosis (women and men). Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

T-score below -2.0 may be required for some patients for the treatment of osteoporosis indication.

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

For hypoparathyroidism that patient must be under the care of an endocrinologist.

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

Patients that have tried other medications for the treatment of osteoporosis (eg, bisphosphonates, intranasal calcitonin, raloxifene), are currently receiving such medications, or are intolerant to these agents may receive Forteo regarding of risk status of the treatment of osteoporosis.

## **GROWTH HORMONES**

### **Affected Drugs**

OMNITROPE®  
TEV-TROPIN®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Turner's syndrome. Child with SHOX (short stature homeobox-containing gene) deficiency. Short child born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) including those with Silver-Russell syndrome. Child, Noonan syndrome. Short bowel syndrome.

### **Exclusion Criteria**

Constitutional delay of growth and puberty. Down's syndrome. Corticosteroid-induced short stature including a variety of chronic glucocorticoid-dependent conditions, such as asthma, Crohn's disease, juvenile rheumatoid arthritis, as well as after renal, heart, liver, or bone marrow transplantation. Kidney transplant patients (children) with a functional renal allograft. Liver transplantation. Cardiac transplantation. Bone marrow transplantation without total body irradiation (cranial radiation). Congenital adrenal hyperplasia. Bony dysplasias (achondroplasia, hypochondroplasia). Osteogenesis imperfecta. X-linked hypophosphatemic rickets (familial hypophosphatemia, hypophosphatemic rickets). Myelomeningocele. Dilated cardiomyopathy and heart failure. Athletic ability (enhancement). Aging (ie, antiaging) to improve functional status in elderly patients and somatopause. Infertility. Acute critical illness due to complications following surgery, multiple accidental trauma, or with acute respiratory failure. Osteoporosis, postmenopausal or idiopathic in men. Adults with end-stage renal disease undergoing hemodialysis. HIV-infected patients with alterations in body fat distribution (e. g. , increased abdominal girth, buffalo hump). Crohn's disease. Chronic fatigue syndrome. Fibromyalgia. Cystic fibrosis. Familial dysautonomia (Riley-Day syndrome, hereditary sensory autonomic neuropathy). Children with severe burn injury. Multiple system atrophy (MSA).

### **Required Medical Information**

Child w/acquired GH [growth hormone] deficiency (DF). 1 documented GH [growth hormone] stimulation test (levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon) shows diminished serum GH [growth hormone] response of less than 10 ng/mL AND baseline height (Ht) less than the 3rd percentile for gender/age AND pretx Ht velocity (VEL) in child less than 3 years of less than 7 cm/year and in child greater than or equal to 3 years of less than 4 cm/year OR child of any age growth VEL less than the 10th percentile for age/gender based on at least 6 months of data. Child had

brain radiation does not have to meet baseline Ht criteria. Congenital hypopituitarism does not have to meet Ht or growth VEL criteria. Child w/hypophysectomy does not have to meet any criteria. Adolescents (diagnosed as child with GH [growth hormone] DF or with idiopathic short stature [ISS]) with prior GH [growth hormone] use and aged 16 years or older, growth rate (GR) must be at least 2.5 cm/year in recent year. Review patients annually for this GR (does not apply to documented hypopituitarism). Further approval is not recommended if GR is less than 2.5 cm/year. Adolescents, young adults with ISS who completed linear growth (GR less than 2 cm/year), review for treatment of adult GH [growth hormone] DF. Non-GH [growth hormone] deficient short stature (ISS) child w/open epiphyses. 6 mo trial. Baseline Ht less than 3rd percentile (ie, greater than 2 SD below the mean for gender/age AND pretx Ht VEL in child less than 3 years of less than 7 cm/year and in child greater than or equal to 3 years of less than 4 cm/year OR child of any age growth VEL less than the 10th percentile for age/gender based on at least 6 months of data AND pediatric endocrinologist (PE) must certify child's basic activities of daily living is limited by short stature and child has a condition for which GH [growth hormone] is effective (or may be effective during the initial trial of treatment) AND PE must certify based on bone-age x-ray, predicted adult Ht is less than 3rd percentile. Authorization for cont treatment based on adequate clinical response (an annualized GR that doubles in comparison to previous year).

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

For adults with GH [growth hormone] deficiency, the endocrinologist must certify that the somatropin is not being prescribed for anti-aging therapy or to enhance athletic ability.

### **Coverage Duration**

SBS [Short Bowel Syndrome] 4 weeks. NonGH def short stat 6 months Adult with HIV wasting 24 weeks. HIV failure to thrive 12 weeks.

### **Other Criteria**

Therapy should be discontinued if there is no significant increase in growth rate during the first year. Adult GH [growth hormone] deficiency. 1 of the following diagnoses Adult onset (GH alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage) OR Childhood-onset AND must have a negative response to 1 standard GH [growth hormone] stimulation test as follows, 1 of the following stimulation tests must be used (insulin tolerance,

glucagon, GH [growth hormone] releasing hormone (GHRH) plus arginine, or GHRH [growth hormone releasing hormone] plus GH [growth hormone] releasing peptide (GHRP-6). Arginine alone may be used in non-obese adolescents with childhood onset. Cutoff values for GH [growth hormone] peak for each test are For the insulin tolerance or glucagon peak less than 3 mcg/L, For GHRH [growth hormone releasing hormone] plus arginine, peak less than 11 mcg/L with BMI less than 25 kg/m<sup>2</sup> or less than 20 kg/m<sup>2</sup>. Patients will be evaluated by a pharmacist and/or a physician on a case-by-case basis for more than 4 weeks of therapy or more than one 4-week course per year. Adults with HIV infection with wasting or cachexia. All of the following, HIV-positive and have wasting or cachexia AND have 1 of the following, documented unintentional weight loss of greater than or equal to 10% from baseline OR weight less than 90% of the lower limit of ideal body weight OR BMI less than or equal to 20 kg/m<sup>2</sup> AND must be able to consume or be fed through parenteral or enteral feedings greater than or equal to 75% of maintenance energy requirements based on current body weight AND must have been on antiretroviral therapy for greater than or equal to 30 days prior to beginning GH [growth hormone] therapy and will continue antiretroviral therapy throughout the course of GH [growth hormone] treatment AND Therapy with GH [growth hormone] is limited to 24 weeks. Repeat 12 or 24-week courses of GH [growth hormone] may be authorized in patients who have received a previous 12 or 24-week course of GH [growth hormone] for HIV infection with wasting or cachexia provided that they have been off GH [growth hormone] for at least 1 month and meet all of the previous criteria. HIV-associated failure to thrive. Child less than 17 years AND must be able to consume or be fed through parenteral or enteral feedings greater than or equal to 75% of maintenance energy requirements based on current body weight AND has been on antiretroviral therapy for greater than or equal to 30 days prior to beginning GH [growth hormone] therapy and will continue antiretroviral treatment.

# **HUMIRA**

## **Affected Drugs**

HUMIRA®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus patients already started on adalimumab. Undifferentiated spondylarthritis (undifferentiated arthritis). Crohn's disease (induction/remission) in adolescents (15 up to 18 years). Uveitis (noninfectious) in children or adults. Behcet's disease. Sarcoidosis. Pyoderma gangrenosum. Hidradenitis suppurativa.

## **Exclusion Criteria**

Humira should not be given in combination with Kineret or Orencia. Children aged less than 15 years with Crohn's disease. Osteoarthritis. Ulcerative colitis. Intra-articular injection. Recurrent spontaneous pregnancy loss. In vitro fertiliation (IVF). Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

Crohn's disease adults and adolescents aged 15 to up to 18 years. No age range specified.

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Crohn's disease=12 weeks for induction. All other conds=12mos.

## **Other Criteria**

Adults with RA [Rheumatoid Arthritis], approve if the patient has tried 1 DMARD [Disease-modifying antirheumatic drug] or is concurrently receiving MTX [methotrexate]. Adults with Crohn's disease to induce remission. Approve if patient has tried corticosteroids or if corticosteroids are contraindicated or if patient currently on corticosteroids. Adults with Crohn's disease to maintain remission. Patient has received 2 doses or 12 weeks of adalimumab and has responded or if has not received adalimumab for induction of remission then authorize if patient has tried azathioprine, 6-mercaptopurine, or MTX [methotrexate] or if patient has tried infliximab or certolizumab pegol. Plaque psoriasis in patients. patient has tried a systemic therapy (e. g. , MTX

[methotrexate], azathioprine, cyclosporine, Soriatane, Prograf, Enbrel, Raptiva, Amevive, Remicade, Stelara, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil) or phototherapy (UVB, OR oral methoxsalen plus UVA light [PUVA]) for psoriasis. Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA [Body surface area] if they have plaque psoriasis of palms, soles, head and neck, nails, intertriginous areas or genitalia. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA [Body surface area] if they have had an inadequate response to either topical therapy OR localized phototherapy, and had an inadequate response to systemic therapy, and had significant disability or impairment in physical or mental functioning according to the treating physician. JIA [Juvenile Idiopathic Arthritis] or JRA [Juvenile Rheumatoid Arthritis], polyarticular course. Approve if the patient has tried MTX [methotrexate] or will be starting on Humira concurrently with MTX [methotrexate]. Approve without trying MTX [methotrexate] if the patient has an absolute contraindication to MTX [methotrexate] (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias).

## **INCRELEX**

### **Affected Drugs**

INCRELEX®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Patients with primary IGFD [Increlex growth forum database] with height standard deviation score greater than -3.0 and IGF-1 standard deviation score of greater than -3.0. Idiopathic short stature, growth hormone deficiency. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Children diagnosed with severe Primary IGFD [Increlex growth forum database] must meet the following criteria Height standard deviation score is less than or equal to -3.0 AND Age adjusted Basal IGF-1 standard deviation score is less than or equal to -3.0 AND Growth hormone concentration is normal or increased.

### **Age Restrictions**

Children age not specified.

### **Prescriber Restrictions**

Pediatric endocrinologist or after consultation with pediatric endocrinologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

# **KINERET**

## **Affected Drugs**

KINERET®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus Patient already started on anakinra. Juvenile idiopathic arthritis (JIA) or juvenile rheumatoid arthritis (JRA), polyarticular course (regardless of type of onset). Systemic onset JIA [Juvenile Idiopathic Arthritis]. Ankylosing spondylitis. Adult with Still's disease. Muckle-Wells syndrome. Familial cold autoinflammatory syndrome (FCAS). Neonatal Onset Multisystem Inflammatory disease (NOMID) or Chronic infantile neurological cutaneous and articular (CINCA) syndrome. Schnitzler's syndrome. Acute gout. Familial Mediterranean fever. Tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS).

## **Exclusion Criteria**

Osteoarthritis, symptomatic. Lupus arthritis. Type 2 diabetes mellitus. Anakinra should not be given in combination with TNF [Tumor necrosis factor] blocking agents (Enbrel, Humira, Remicade, Cimzia) or with Orencia. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Acute gout, approve 3 doses. Approve 12 months for all other conditions/uses.

## **Other Criteria**

Adults with RA [Rheumatoid Arthritis]. Approve if the patient has tried Humira, Enbrel, or Remicade for at least 2 months. JIA [Juvenile Idiopathic Arthritis], JRA [Juvenile Rheumatoid Arthritis] (regardless of onset), approve if patient has tried Enbrel, Humira, or Orencia. Systemic onset of JIA [Juvenile Idiopathic Arthritis], approve if patient has tried a systemic corticosteroid. Ankylosing spondylitis, approve if the patient has tried Enbrel, Remicade, or Humira. Adult with Still's disease, approve if patient has

tried one DMART or is currently receiving MTX [methotrexate]. MWS, approve if patient has tried two other drugs (Aralyst, colchicine, corticosteroids, chlorambucil, antihistamines, dapsone, azathioprine, CellCept). FCAS, approve if patient has tried two other drugs (eg, colchicine, corticosteroids, antihistamines, azathioprine, Cellcept, Aralyst). Schnitzler's syndrome, approve if patient has tried one other prescription medication used in Schnitzler's syndrome. Acute gout, patient has tried 2 standard therapies for acute gout (eg, NSAIDs [Non-steroidal anti-inflammatory drugs], colchicine, corticosteroid) or patient cannot tolerate or has contraindications to standard therapies. FMF [Familial Mediterranean fever], approve in patients who have tried colchicine. TRAPS, approve in patients who have tried colchicine.

# **LAMISIL**

## **Affected Drugs**

LAMISIL®  
TERBINAFINE HCL

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Tinea corporis. Tinea cruris, faciei, manuum, pedis, and imbricate. Plantar- or moccasin-type dry tinea pedis. Black piedra. Tinea capitis. Tinea barbae. Cutaneous (skin) candidiasis. Other superficial fungal skin infections. Eumycetoma/mycetoma.

## **Exclusion Criteria**

Tinea versicolor (pityriasis versicolor). Systemic fungal infections. Oral, esophageal or vaginal candidiasis. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

Onychomycosis must be judged to be medically significant (causing impaired mobility, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) and a positive KOH, fungal culture, DTM [dermatophyte test medium] culture, nail biopsy, or histologic examination (PAS) is required before therapy initiation. Before a second course of treatment is permitted for onychomycosis, a culture must demonstrate a fungal infection. Use of Penlac with Lamisil is not permitted.

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

Physician must consider onychomycosis to be medically significant.

## **Coverage Duration**

Ony=6wks fingernails, 12 weeks toenails. Other conds=12mos.

## **Other Criteria**

Tinea corporis if the patient has trial a topical antifungal agent, except for extensive conditions. Tinea cruris, faciei, manuum, pedis, and imbricate after a trial of a topical antifungal agent. Cutaneous (skin) candidiasis after a trial of a topical antifungal agent and an azole antifungal. Other superficial fungal skin infections after a trial of a topical antifungal agent or an oral antifungal agent.

## **LEUPROLIDE (LONG ACTING)**

### **Affected Drugs**

ELIGARD®

LUPRON DEPOT®

LUPRON DEPOT-PED®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D but specific to the following drugs as follows: Prostate cancer (Lupron Depot OR Eligard), Endometriosis (Lupron Depot), Uterine leiomyomata (Lupron Depot), Treatment of central precocious puberty (Lupron Depot Ped). Ovarian cancer (Lupron Depot, Lupron Depot Ped). Breast cancer (Lupron Depot, Lupron Depot Ped). Preserve ovarian function/fertility in women undergoing chemotherapy (Lupron Depot, Lupron Depot Ped). Induce amenorrhea during bone marrow transplant (Lupron Depot, Lupron Depot Ped). Premenstrual syndrome (Lupron Depot, Lupron Depot Ped). Menstrual migraine (Lupron Depot, Lupron Depot Ped). Catamenial pneumothorax (Lupron Depot, Lupron Depot Ped). Paraphilias or other inappropriate sexual behaviors or disorders (Lupron Depot, Lupron Depot Ped). Dysfunctional uterine bleeding (Lupron Depot, Lupron Depot Ped). Lymphangi leiomyomatosis (Lupron Depot, Lupron Depot Ped).

### **Exclusion Criteria**

Polycystic ovarian syndrome (PCOS). Hirsutism. Benign prostatic hyperplasia (BPH). Functional bowel syndrome/irritable bowel syndrome. Orchitis/epididymo-orchitis. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

For dysfunctional uterine bleeding approve for up to 6 months and all other indications x 12 months.

### **Other Criteria**

Premenstrual syndrome (PMS) for patients that have tried two other therapies (e. g. , selective serotonin reuptake inhibitors [SSRIs], oral contraceptives [OCs]). Menstrual migraine approve if the patient has tried two other therapies for the treatment of acute migraine (e. g. , NSAIDs [Non-steroidal anti-inflammatory drugs], triptans, ergotamines) or prophylaxis of migraine (e. g. , beta-blockers, amitriptyline, divalproex).

## **LIDODERM**

### **Affected Drugs**

LIDODERM®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus neuropathic pain. Myofascial pain. Low back pain. Carpal tunnel syndrome.

### **Exclusion Criteria**

RA [Rheumatoid Arthritis]. Fibromyalgia. Coverage is not recommended for circumstances not listed in the Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

Myofascial pain as adjunctive therapy. Approve if being used in combination with a standard myofascial trigger point (MTP) treatment modalities (e. g. , physical therapy, MTP injections of local anesthetic, relaxation techniques). Low back pain. Approve after trying at two other pharmacologic therapies commonly used to treat low back pain (e. g. , acetaminophen, nonsteroidal anti-inflammatory agents [NSAIDs], muscle relaxants, opioids, cyclooxygenase-2 [COX-2] inhibitors, tramadol, gabapentin, tricyclic antidepressants [amitriptyline]). Carpal tunnel syndrome. Approve after a trying one other pharmacological therapy used to treat carpal tunnel syndrome (e. g. , steroids [oral or injectable], NSAIDs [Non-steroidal anti-inflammatory drugs]).

## **NEULASTA**

### **Affected Drugs**

NEULASTA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D but worded more broadly as cancer patients receiving chemotherapy. Patients undergoing peripheral blood progenitor cell mobilization/autologous stem cell transplantation. Radiation injury.

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

RA [Rheumatoid Arthritis]diation injury, if prescribed by, or in consultation with, a physician with experience in treating acute radiation syndrome.

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

RA [Rheumatoid Arthritis]diation injury, approve if the estimated whole body or significant partial-body exposure is at least 3 Grays in adults aged less than 60 years, or at least 2 Grays in children (aged 12 years or less) or in adults aged 60 years or older, or in those who have major trauma injuries or burns.

# NEUPOGEN

## Affected Drugs

NEUPOGEN®

## Covered Uses

All FDA-approved indications not otherwise excluded from Part D worded more broadly as cancer patients receiving chemotherapy, patients with AML [Acute Myeloid Lymphoma] receiving chemotherapy, cancer patients receiving BMT [Bone Marrow Transplant], patients undergoing peripheral blood progenitor cell collection and therapy, and patients with severe chronic neutropenia (e. g. , congenital neutropenia, cyclic neutropenia, idiopathic neutropenia). Neutropenia associated with HIV or AIDS. Treatment of myelodysplastic syndromes. Drug induced agranulocytosis or neutropenia. BMT [Bone Marrow Transplant] patients with delayed or inadequate neutrophil engraftment after PBPC transplantation. Hematopoietic stem cell transplant patients (for promotion of myeloid engraftment). Aplastic anemia. Acute lymphocytic leukemia (ALL). Radiation injury. Radiation therapy.

## Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses.

## Required Medical Information

N/A

## Age Restrictions

N/A

## Prescriber Restrictions

ALL, if prescribed by, or in consultation with, an oncologist or a hematologist. Radiation injury, if prescribed by, or in consultation with, a physician with experience in treating acute radiation syndrome. Radiation therapy, if prescribed by or in consultation with, an oncologist, radiologist, or radiation oncologist.

## Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

## Other Criteria

RA [Rheumatoid Arthritis]diation injury, approve if the estimated whole body or significant partial-body exposure is at least 3 Grays in adults aged less than 60 years, or at least 2 Grays in children (aged 12 years or less) or in adults aged 60 years or older, or in those who have major trauma injuries or burns.

# **ORENCIA**

## **Affected Drugs**

ORENCIA®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus patients who have already been started on Orencia.

## **Exclusion Criteria**

Orencia should not be given in combination with a TNF $\alpha$  antagonist (e. g. , etanercept, adalimumab, infliximab) or with anakinra. Psoriasis. Systemic lupus erythematosus. Multiple sclerosis. Prevention of RA [Rheumatoid Arthritis]. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

Adults with rheumatoid arthritis approve if the patient has tried one DMARD [Disease-modifying antirheumatic drug] (oral or injectable) for at least 2 months, [this includes patients who have tried other biologic DMARDs [Disease-modifying antirheumatic drugs] for at least 2 months] OR approve if the patients is concurrently receiving MTX [methotrexate]. Juvenile idiopathic arthritis (JIA) [or JRA], polyarticular course approve if the patient has tried MTX [methotrexate] or will be starting on abatacept concurrently with MTX [methotrexate] or if the patient has tried at least one of the following biologic DMARDs [Disease-modifying antirheumatic drugs], adalimumab (Humira), etanercept (Enbrel), or infliximab (Remicade), for at least 2 months or was intolerant to one of these TNF [Tumor necrosis factor] antagonists, approve without trying MTX [methotrexate] if the patient has an absolute contraindication to MTX [methotrexate].

## **PEGYLATED INTERFERONS**

### **Affected Drugs**

PEGASYS®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D (note all are in patients with Hepatitis C). Pediatric patients aged 3 to 17 years who have not been previously txd with interferon alfa or peginterferon alfa AND who are not HIV co-infected. Adult patient coinfectd with Hepatitis C and hep B. Acute Hepatitis C. Retreatment of Hepatitis C. Recurrent Hepatitis C after liver transplant and grade II fibrosis or greater. Chronic Hepatitis C on waiting list for liver transplant. Any indication besides Hepatitis C.

### **Exclusion Criteria**

Maintenance treatment of Hepatitis C extending treatment to 72 weeks or longer (one exception for 72 weeks for genotype 1 Hepatitis C). Therapy for 72 weeks is not recommended in prior nonresponders and relapsers. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Hepatitis C. depending on genotype, response in HCV RNA, liver fibrosis, CD4 count, and HIV RNA. See Other Criteria and Covered Uses for details. Chronic Hepatitis C on waiting list for liver transplant. Response assessed after 12 weeks. In genotype 2 and 3 if HCVRNA has decreased by greater than or equal to 2 log<sub>10</sub> or virus undetectable, then authorize for a total of 6 months of therapy from the time the patient has achieved an optimal dose of both peginterferon and ribavirin OR In genotype 1, if the HCV RNA has decreased by greater than or equal to 2 log<sub>10</sub> (or undetectable), then authorize for a total of 12 months of therapy from the time that the patient has achieved an optimal dose of both peginterferon and ribavirin OR In genotype 1, 2 or 3, if the HCV RNA has not decreased by greater than or equal to 2 log<sub>10</sub> (or virus undetectable), then further authorization not recommended.

### **Age Restrictions**

Children less than 3 years old for hepatic C. Children less than 18 years old for all other conditions/circumstances.

### **Prescriber Restrictions**

For all patients with hepatitis C, must be prescribed by an infectious disease MD, gastroenterologist, hepatologist, or a transplant MD or in consultation with one of these MDS [Myelodysplastic syndrome].

## Coverage Duration

Hepatitis C. 12, 24, 48, 72 weeks Acute Hepatitis C. 6 to 12 mo Chronic Hepatitis C liver transplant 12 weeks non-Hepatitis C 12 mo.

## Other Criteria

A. Patient not previously treated for Hepatitis C with interferon/peginterferon alfa. Obtain Hepatitis C genotype and HCV RNA titer before starting therapy (HCV RNA not required for genotype 2/3). A1. Chronic Hepatitis C (genotype 2/3) not coinfecting with HIV and not previously treated for hepatitis C. Approve 24 weeks. OR A2. Chronic Hepatitis C genotype 3 not coinfecting with HIV and not previously treated for Hepatitis C and a high level of HCV RNA (determined by physician) or advanced fibrosis. Authorize 48 weeks of therapy (total). OR A3. Chronic Hepatitis C (genotype 1 or 4) who is not coinfecting with HIV and not previously treated for Hepatitis C. Authorize 12 weeks and reassess again in 12 weeks. Record baseline HCV RNA. After 12 weeks assess and If HCV RNA has decreased by greater than or equal to 2 log<sub>10</sub> (or undetectable) authorize for 36 weeks OR If HCV RNA has not decreased by greater than or equal to 2 log<sub>10</sub> (or undetectable) authorize for 12 weeks more and reassess again after total of 24 weeks OR If genotype 1 and HCV RNA has decreased by greater than or equal to 2 log<sub>10</sub> and virus is still detectable, then authorize for 12 more weeks and reassess after 24 weeks (if undetectable at week 24, authorize 48 more weeks, total 72 weeks using non FDA approved indication). A3 continues. After 24 weeks If advanced fibrosis and HCV RNA undetectable then authorize 24 more weeks (48 total) OR If advanced fibrosis and detectable HCV RNA physician and patient will decide whether to continue with another 24 weeks OR If does not have advanced fibrosis and do not have a greater than or equal to 2 log<sub>10</sub> decrease or virus undetectable, no further authorization. OR A4. Chronic Hepatitis C viral genotype 5 or 6 not coinfecting with HIV and not previously treated for Hepatitis C use criteria for genotype 1 and 4 above. OR A5. Coinfecting with HIV and chronic Hepatitis C genotype 2 or 3 and not previously treated for Hepatitis C. If HCV RNA is detectable and CD4 count is greater than or equal to 200 cells/microL authorize 48 weeks. OR If HCV RNA is detectable and CD4 count is 100 - 199 cells/microL and HIV RNA is less than 5000 copies/mL authorize 48 weeks. OR If HCV RNA is undetectable or CD4 count is less than 100 cells/microL no authorization. OR A6. Coinfecting with HIV and chronic Hepatitis C genotype 1 and not previously treated for Hepatitis C. If HCV RNA is detectable and CD4 count is greater than or equal to 200 cells/microL authorize 24 weeks and reassess after week 24. OR If HCV RNA is detectable and CD4 count is 100 - 199 cells/microL and HIV RNA is less than 5000 copies/mL authorize 24 weeks and reassess after 24 weeks. OR If HCV RNA is undetectable or CD4 count is less than 100 cells/microL or HIV RNA is less than 5000 copies/mL with CD4 count less than 100

cells/microL no authorization. A6 continues. After 24 weeks If HCV RNA is decreased by greater than or equal to 2 log<sub>10</sub> or virus undetectable authorize 24 more weeks OR If HCV RNA has not decreased by greater than or equal to 2 log<sub>10</sub> or virus undetectable no authorization.

## **PENLAC**

### **Affected Drugs**

CICLOPIROX

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Treatment with other systemic antifungal agents used for the treatment of onychomycosis (fluconazole, itraconazole, terbinafine). Prophylactic therapy for onychomycosis. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Onychomycosis must be judged to be medically significant (causing impaired mobility, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) and a positive KOH, fungal culture, DTM [dermatophyte test medium] culture, nail biopsy, or histologic examination (PAS) is required before therapy initiation. Before a second course of treatment is permitted for onychomycosis, a culture must demonstrate a fungal infection. Use of Penlac with Lamisil is not permitted.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Physician must consider onychomycosis to be medically significant.

### **Coverage Duration**

Authorization will be for up to 48 weeks.

### **Other Criteria**

N/A

## **PROVIGIL**

### **Affected Drugs**

PROVIGIL®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Fatigue associated with MS [Multiple Sclerosis]. Excessive daytime sleepiness (EDS) due to myotonic dystrophy. ADHD [Attention Deficit Hyperactive Disorder] and ADD [Attention Deficit Disorder]. Adjunctive/augmentation for treatment of depression in adults. EDS [Excessive daytime sleepiness] in Parkinson's. Idiopathic hypersomnia. Spasticity due to cerebral palsy. Cancer-related fatigue.

### **Exclusion Criteria**

Alcoholic organic brain syndrome. Enhancement of performance in situations of induced sleep deprivation. Fibromyalgia. Chronic fatigue syndrome. EDS [Excessive daytime sleepiness] associated with primary insomnia. ALS [Amyotrophic Lateral Sclerosis]. Adjunctive therapy in the treatment of schizophrenia. Seasonal affective disorder. Post-stroke sleep-wake disorders or sleep disorders. Bipolar disorder, including bipolar depression. Hypersomnia, fatigue, or sleepiness due to other specific conditions or of unknown etiology. Fatigue and EDS [Excessive daytime sleepiness] in chronic traumatic brain injury. Fatigue in post-polio patients. Coverage is not recommended for circumstances not listed in Covered Uses.

### **Required Medical Information**

For the FDA-approved indication of obstructive sleep apnea/hypoapnea syndrome patients must have tried CPAP [Continuous positive airway pressure]. For the FDA-approved indication of excessive sleepiness due to shift-work sleep disorder, patients must be working at least 5 overnight shifts per month.

### **Age Restrictions**

Adjunctive augmentation treatment for depression must be in adults.

### **Prescriber Restrictions**

Idiopathic hypersomnia must have the diagnosis confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders.

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

Excessive sleepiness due to OSAHS [Obstructive sleep apnea/hypoapnea syndrome] if the patient has tried CPAP [Continuous positive airway pressure]. Excessive sleepiness due to SWSD [Shift work sleep disorder] if the patient is working at least 5 overnight shifts per month. ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder] for patients who have tried two alternative medication for ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder] from two different classes as follows: methylphenidate products (e. g. , methylphenidate, dexamethylphenidate), amphetamines (e. g. , mixed amphetamine salts, dextroamphetamine), atomoxetine, bupropion or tricyclic antidepressants (TCAs e. g. , imipramine, desipramine). Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression. Idiopathic hypersomnia if the diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i. e. , sleep center). Spasticity due to cerebral palsy, approve if patient has tried one other agent for spasticity (eg, benzos, baclofen, dantrolene, tizanidine, or botulinum toxin).

## **REBIF**

### **Affected Drugs**

REBIF®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Concurrent use of Avonex, Betaseron, Copaxone or Tysabri. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Prescribed by or after consultation with a neurologist or an MS [Multiple Sclerosis] specialist.

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **REGRANEX**

### **Affected Drugs**

REGRANEX®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus any granulating ulcer/wound (eg, pressure ulcers, venous stasis ulcers) that is classified as NPUAP Stage III or IV.

### **Exclusion Criteria**

Prevention of ulcers/wounds. First-line therapy for the treatment of Stage II ulcers/wounds. Treatment of wounds/ulcers classified as Stage I. Coverage is not recommended for circumstances not listed in the Covered Uses.

### **Required Medical Information**

Diabetic neuropathic ulcer(s) that is/are classified as NPUAP Stage III or IV. Any clean and granulating ulcer/wound classified as Stage II (e. g. , Stage II diabetic neuropathic ulcers and pressure ulcers).

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

Diabetic neuropathic ulcer(s) that is/are classified as NPUAP Stage III or IV. Any clean and granulating ulcer/wound classified as Stage II (e. g. , Stage II diabetic neuropathic ulcers and pressure ulcers), if the patient has tried other standard ulcer/wound care therapies (eg, debridement, topical therapies [papain-urea]) for at least 4 weeks.

# REMICADE

## Affected Drugs

REMICADE®

## Covered Uses

All FDA-approved indications not otherwise excluded from Part D plus current Remicade therapy. Undifferentiated spondyloarthritis/spondyloarthritis. JRA [Juvenile Rheumatoid Arthritis] or JIA [Juvenile Idiopathic Arthritis]. Behcet's disease. Adult with Still's disease. Uveitis. Sarcoidosis. Amyloidosis with renal involvement. Pyoderma gangrenosum. Hidradenitis suppurativa. Graft-versus-host disease, treatment. Indeterminate colitis. Enterovesical fistulas in patients with Crohn's disease. Macular edema in type 2 diabetes. Orbital myositis (chronic idiopathic orbital inflammation). SAPHO (synovitis, acne, pustulosis, hyperostosis, osteitis) syndrome. Familial Mediterranean fever. Cogan's syndrome. Crohn's disease after ileocolonic resection, to reduce the chance of recurrence. Pouchitis.

## Exclusion Criteria

Primary Sjorgren's syndrome. Sciatica. Fistulas in patients without Crohn's disease. MDS [Myelodysplastic syndrome]. COPD [Chronic Obstructive Pulmonary Disease]. Asthma. Atopic dermatitis. Wegener's granulomatosis. Systemic vasculitis. Giant cell arteritis. Takayasu's arteritis. Primary sclerosing cholangitis. Inflammatory myopathies (polymyositis, dermatomyositis, inclusion body myositis). Diffuse cutaneous systemic sclerosis (scleroderma, SSc). Concurrent with Kineret or Orencia. Intra-articular injection. Coverage not recommended for anything not listed under Covered Uses.

## Required Medical Information

N/A

## Age Restrictions

N/A

## Prescriber Restrictions

N/A

## Coverage Duration

CD [Crohn's Disease] (w/ or w/out fistulas)=12 weeks for induction. All other conds=12mos.

## Other Criteria

Adults with RA [Rheumatoid Arthritis], approve if patient has tried 1 DMARD [Disease-modifying antirheumatic drug] for at least 2 months or is concurrently receiving MTX [methotrexate]. Crohn's disease to induce remission. Approve if patient has tried a corticosteroid or if corticosteroids are contraindicated or if patient currently on a corticosteroid. Crohn's disease to maintain remission. Patient has received 3 doses of infliximab and has responded or if has not received infliximab for induction of remission then authorize if patients has tried azathioprine, 6-mercaptopurine, or MTX [methotrexate] or if patient has tried adalimumab or certolizumab pegol. Fistulizing Crohn's disease to induce remission, approve. Fistulizing Crohn's disease to maintain remission. Patient has received 3 doses of infliximab and has reponded. JIA [Juvenile Idiopathic Arthritis] or JRA [Juvenile Rheumatoid Arthritis], polyarticular course, approve if the patient has tried MTX [methotrexate] or will be starting on Remicade concurrently with MTX [methotrexate]. Approve without trying MTX [methotrexate] if the patient has an absolute contraindication to MTX [methotrexate] (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias). Plaque psoriasis. Patient has tried a systemic therapy (e. g. , MTX [methotrexate], azathioprine, cyclosporine, Soriatane, Prograf, Raptiva, Enbrel, Amevive, Humira, Stelara, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil) or phototherapy (UVB, OR oral methoxsalen plus UVA light [PUVA]) for psoriasis AND patient has a minimum body surface area (BSA) of 5% or more. Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Exceptions allowed for patients with less than 5% BSA [Body surface area] if they have plaque psoriasis of palms, soles, head and neck, nails, intertriginous areas or genitalia. Exceptions allowed for patients with less than 5% BSA [Body surface area] if they have had an inadequate response to either topical therapy OR localized phototherapy, AND had an inadequate response to systemic therapy, and had significant disability or impairment in physical or mental functioning according to the treating physician. Ulcerative colitis. Patient has tried 1 other oral or IV therapy for UC [Ulcerative colitis].

## **REVATIO**

### **Affected Drugs**

REVATIO®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus Eisenmenger syndrome with pulmonary arterial hypertension (PAH) [men or women]. For Raynaud disease, refer to Viagra.

### **Exclusion Criteria**

Patients taking nitrates. Use of Revatio for the treatment of erectile dysfunction. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

# **RITUXAN**

## **Affected Drugs**

RITUXAN®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D. Patients already started on Rituxan for RA [Rheumatoid Arthritis].

## **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

Adult with RA [Rheumatoid Arthritis]. Prescribed by a rheumatologist or in consultation with a rheumatologist.

## **Coverage Duration**

RA [Rheumatoid Arthritis]. Approve 2 doses. 6 months or more after, approve 2 more doses if response per MD. Other conds=12 months.

## **Other Criteria**

Adult with RA [Rheumatoid Arthritis]. Patient has tried at least 1 of the following biologic DMARDs [Disease-modifying antirheumatic drugs], Enbrel, Remicade, or Humira for at least 2 months.

## **SAMSCA**

### **Affected Drugs**

SAMSCA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus patients already started on tolvaptan for the treatment of hyponatremia.

### **Exclusion Criteria**

Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria.

### **Required Medical Information**

Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

For the treatment of clinically significant hypervolemic and euvolemic hyponatremia with serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).

## **SOMAVERT**

### **Affected Drugs**

SOMAVERT®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus treatment of excessive growth hormone associated with McCune-Albright Syndrome.

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Acromegaly and treatment of excess growth hormone associated with McCune-Albright syndrome. Prescribed by an endocrinologist or in consultation with an endocrinologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

# **SPORANOX**

## **Affected Drugs**

ITRACONAZOLE

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Tinea corporis. Tinea cruris, faciei, manuum, imbricata, and pedis (nonmoccasin or chronic type). Plantar- or moccasin-type dry tinea pedis. Tinea or pityriasis versicolor. Tinea capitis. Tinea barbae. Treatment of vaginal candidiasis. Prevention of recurrent vulvovaginal or vaginal candidiasis. Treatment or prevention of other superficial, systemic or suspected fungal infections. Patient has been started and stabilized on IV itraconazole therapy or oral itraconazole for a systemic infection and it is being used as continuation therapy.

## **Exclusion Criteria**

Candidiasis hypersensitivity syndrome. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

Onychomycosis must be judged to be medically significant (causing impaired mobility, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) and a positive KOH, fungal culture, DTM [dermatophyte test medium] culture, nail biopsy, or histologic examination (PAS) is required before therapy initiation. Before a second course of treatment is permitted for onychomycosis, a culture must demonstrate a fungal infection. Use of Penlac with Sporanox is not permitted. Sporanox should not be given for the treatment of onychomycosis in patients with CHF [Congestive Heart Failure]. Itraconazole is permitted for the treatment of patients with a culture positive for Candida.

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Ony=12wks toenails, 8wks fingernails. Other conds=12mos.

## **Other Criteria**

Tinea corporis after a trial of a topical antifungal agent, except for extensive conditions. Tinea cruris, faciei, manuum, imbricata, and pedis (nonmoccasin or chronic

type) after a trial of a topical antifungal agent. Tinea or pityriasis versicolor after trial of a topical antifungal agent, except for extensive conditions. Treatment of vaginal candidiasis after a trial of oral fluconazole.

## **SYMLIN**

### **Affected Drugs**

SYMLIN®  
SYMLINPEN 120®  
SYMLINPEN 60®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D worded as patient has type 1 or 2 diabetes mellitus.

### **Exclusion Criteria**

Weight loss treatment. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

# TAZORAC

## Affected Drugs

TAZORAC®

## Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus psoriasis of fingernails or toenails. Oral lichen planus. Congenital ichthyoses (X-linked recessive ichthyosis, non-erythrodermic autosomal recessive lamellar ichthyosis, autosomal dominant ichthyosis vulgaris). Basal cell carcinoma. Mycosis fungoides lesions/cutaneous T-cell lymphomas. Keratosis pilaris (atrophicans). Treatment of other non-cosmetic conditions (eg, actinic keratoses, skin neoplasms, warts, dermatitis/eczema, folliculitis, acne rosacea, cystic acne, comedonal acne).

## Exclusion Criteria

Cosmetic skin conditions (eg, alopecia, hyperpigmentation, liver spots, melasma/cholasma, seborrheic keratosis, stretch marks, scarring, wrinkles, premature aging, photo-aged or photo-damaged skin, mottled hyper- and hypopigmentation, benign facial lentigines, roughness, telangiectasia, skin laxity, keratinocytic atypia, melanocytic atypia, dermal elastosis). Coverage not recommended for anything not listed under Covered Uses.

## Required Medical Information

N/A

## Age Restrictions

N/A

## Prescriber Restrictions

N/A

## Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

## Other Criteria

Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene). For the treatment of other non-cosmetic conditions exceptions can be made if the patient has tried at least 1 other therapy (eg, actinic keratoses, skin neoplasms, warts, dermatitis/eczema, folliculitis, acne rosacea, cystic acne, comedonal acne).

## **TOPAMAX/ZONEGRAN**

### **Affected Drugs**

TOPIRAMATE  
ZONISAMIDE

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Weight loss treatment except if patient is being treated for seizures, bipolar disorder, migraine prevention, bulimia nervosa, binge-eating disorder, etc with topiramate or zonisamide (exceptions are not recommended for patients with seizures, bipolar disorder, migraine headache, bulimia nervosa, binge-eating disorder, etc who are using topiramate or zonisamide only for weight loss OR for patients who are using topiramate or zonisamide to prevent weight gain or produce weight loss caused by other medications such as antipsychotics [eg, clozapine, olanzapine, quetiapine, risperidone, thioridazine] or antidepressants). Smoking cessation therapy (exceptions are not recommended for patients with psychiatric conditions who are using topiramate or zonisamide only for smoking cessation OR patients who have successfully stopped smoking and are using topiramate or zonisamide to prevent relapse). Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **TOPICAL TRETINOIN PRODUCTS**

### **Affected Drugs**

TRETINOIN

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Acne rosacea. Actinic keratosis/treatment of precancerous skin lesions. Ichthyosis. Diabetic foot ulcers. Mucositis. Warts. Keloids. Lichen planus. Lichen sclerosus. Pseudofolliculitis. Oral leukoplakia. Molluscum contagiosum. Darier's disease (keratosis follicularis). Treatment of other non-cosmetic conditions therapy (eg, dermatitis/eczema, folliculitis, milia, keratosis pilaris, sebaceous hyperplasia/cyst, basal cell carcinoma [skin cancer], confluent and reticulated papillomatosis). Coverage of the combination of clindamycin plus tretinoin (Ziana) is recommended for acne vulgaris ONLY.

### **Exclusion Criteria**

Cosmetic conditions (e. g. , liver spots, stretch marks, scarring, solar elastosis, premature aging, treatment of photo-aged or photo-damaged skin, solar lentigines, skin roughness, mottled hyperpigmentation, age spots, wrinkles, geographic tongue, hyperpigmentation caused by folliculitis, acne, or eczema, melasma/cholasma, alopecia androgenetic, alopecia areata, seborrheic keratosis). Psoriasis. Coverage of Ziana is not recommended for any non-FDA approved indication. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

For the treatment of other non-cosmetic conditions exceptions can be made if the patient has tried at least 1 other therapy (eg, dermatitis/eczema, folliculitis, milia, keratosis pilaris, sebaceous hyperplasia/cyst, basal cell carcinoma [skin cancer], confluent and reticulated papillomatosis). Coverage of the combination clindamycin plus

tretinoin (Ziana) is recommended for acne vulgaris ONLY and all other indications are not recommended.

# **TYSABRI**

## **Affected Drugs**

TYSABRI®

## **Covered Uses**

All FDA approved indications not otherwise excluded from Part D.

## **Exclusion Criteria**

Concurrent use of another immunomodulator (eg, Rebif, Betaseron, Copaxone or Avonex) in MS [Multiple Sclerosis] patients. MS [Multiple Sclerosis] patients with chronic progressive MS [Multiple Sclerosis]. Concurrent use with immunosuppressants (eg, 6MP, azathioprine, CSA, MTX [methotrexate]) or TNF [Tumor necrosis factor] alfa inhibitors (eg, Remicade, Humira, Cimzia) in CD [Crohn's Disease] patients. Ulcerative colitis. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

Adults.

## **Prescriber Restrictions**

MS [Multiple Sclerosis]. Prescribed by a neurologist or an MS [Multiple Sclerosis] specialist registered with the TOUCH prescribing program. CD [Crohn's Disease]. Prescribed by a physician registered with the TOUCH program.

## **Coverage Duration**

Authorization will be for 12 months.

## **Other Criteria**

Adults with MS [Multiple Sclerosis]. Patient has a relapsing form of MS [Multiple Sclerosis] and has had an inadequate response to, or is unable to tolerate, therapy with at least two of the following MS [Multiple Sclerosis] drug groups - interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), or glatiramer acetate (Copaxone). Exceptions to having tried interferon beta-1a or -1b can be made if the patient has depression or a mood disorder, these patients then need to try glatiramer acetate but are not required to try an interferon beta-1a or -1b product. Adults with CD [Crohn's Disease]. Patient has moderately to severely active CD [Crohn's Disease] with evidence of inflammation (elevated C-reactive protein), and has had an inadequate response to treatment with systemic corticosteroids, azathioprine (AZA), 6-

mercaptopurine (6MP), or methotrexate (MTX) (if steroids are contraindicated or not desired, patient must try AZA, 6MP, or MTX [methotrexate] if not contraindicated), and has tried at least two of the following TNF [Tumor necrosis factor] alfa inhibitors for at least 2 months each and had an inadequate response to or was intolerant of the TNF [Tumor necrosis factor] alfa inhibitors - adalimumab (Humira), certolizumab pegol (Cimzia), and infliximab (Remicade).

## **VFEND**

### **Affected Drugs**

VFEND®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D worded as invasive aspergillosis, esophageal candidiasis, treatment of fungal infections caused by *Scedosporium apiospermum* and *Fusarium* spp. , and treatment of candidemia in nonneutropenic patients and the following *Candida* infections: disseminated infections in skin and infections in the abdomen, kidney, bladder wall, and wounds. Treatment/prevention of other serious systemic or suspected systemic fungal infections. Continuation therapy for patients started/stabilized on IV or oral voriconazole for a systemic infection.

### **Exclusion Criteria**

Onychomycosis. Treatment or prevention of vaginal or vulvovaginal candidiasis. *Tinea cruris*, *manuum*, *pedis*, *faciei*, *capitis*, *barbae*, *corporis* and *versicolor* (*pityriasis versicolor*). Other superficial fungal infections.

### **Required Medical Information**

Esophageal candidiasis requires a trial of one other systemic agent (eg. , fluconazole, IV amphotericin B, itraconazole).

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

# **XOLAIR**

## **Affected Drugs**

XOLAIR®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus patients with seasonal or perennial allergic rhinitis.

## **Exclusion Criteria**

For treatment of peanut allergy. For the treatment of latex allergy in health care workers with occupational latex allergy. For the treatment of atopic dermatitis. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

Moderate to severe persistent asthma and SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis], baseline IgE level of at least 30 IU/mL. For asthma, patient has a positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). For SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis], patient has positive skin testing (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach) and/or positive in vitro testing (ie, a blood test for allergen-specific IgE antibodies) for one or more relevant allergens (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach). For EG/EE/eosinophilic colitis, biopsy with at least 15 eosinophils/HPF.

## **Age Restrictions**

Moderate to severe persistent asthma, patient is at least 6 years old. SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis], patient is at least 12 years old.

## **Prescriber Restrictions**

Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis] if prescribed by an allergist, immunologist, or pulmonologist.

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

Patients with moderate to severe persistent asthma must meet all criteria prescribed by or in consultation with an allergist, immunologist, or pulmonologist AND baseline IgE of at least 30 IU/mL AND patient has a positive skin test or in vitro testing AND/OR for 1 or more seasonal aeroallergens AND patient's asthma symptoms have not been adequately controlled by inhaled corticosteroids AND patient is at least 6 years old. patients with SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis] must meet the following criteria prescribed by an allergist, immunologist, or pulmonologist AND baseline IgE level at least 30 IU/mL AND patient has positive skin testing and/or positive in vitro testing (ie, a blood test for allergen-specific IgE antibodies) for 1 or more relevant allergens AND the patient is at least 12 years old.

## **ZYVOX**

### **Affected Drugs**

ZYVOX®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus patient already started on linezolid or intravenous vancomycin.

### **Exclusion Criteria**

Pseudomembranous colitis. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

VRE [Vancomycin resistant enterococcus], cultures must be done. Methicillin-resistant Staphylococcus, cultures must be done.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for one fill up to one month.

### **Other Criteria**

N/A

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