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

## **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). 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 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 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 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.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

Greater than or equal to 16 years of age.

### **Prescriber Restrictions**

Plaque psoriasis. Prescribed by a dermatologist.

### **Coverage Duration**

Plaque psoriasis or PsA, 12 wks of tx. May get 2nd 12 wks if other conditions met.

### **Other Criteria**

Plaque psoriasis. Patient has chronic (greater than or equal to 1 year) plaque psoriasis AND Patient has tried a systemic therapy (e.g., MTX, azathioprine, cyclosporine, Soriatane, Prograf, Raptiva, Enbrel, Remicade, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil, 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.

## **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 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 y/o and older) w/Turner's Syndrome or Ullrich-Turner Syndrome and concomitantly receiving growth hormone therapy. Oxandrin for management of protein catabolism w/burns or burn injury if patients have tried a beta-blocker or have a contraindication to beta-blocker use. Oxandrin for AIDS wasting and cachexia due to a chronic disease. Oxandrin for cachexia due to cancer. Anadrol-50 for prevention/prophylaxis of hereditary angioedema after the patient has tried danazol. Anadrol-50 for AIDS wasting and cachexia due to a chronic disease.

### **Exclusion Criteria**

Coverage of Oxandrin AND Anadrol-50 is not recommended in the following circumstances: 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 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.

## **ARANESP**

### **Affected Drugs**

ARANESP®

### **Covered Uses**

All FDA approved indications not otherwise excluded from Part D worded as anemia associated with CRF, including patients on dialysis and not on dialysis, if hemoglobin (Hb) is less than or equal to 11.0 g/dL for therapy initiation. If the patient has previously been receiving darbepoetin or epoetin alfa, approve only if Hb is less than or equal to 12.0 g/dL. Deny darbepoetin if hemoglobin exceeds 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemia in cancer due to chemotherapy approve for 4 months if the patient has a Hb less than or equal to 10.0 g/dL or Hb is greater than 10.0 g/dL but less than or equal to 12.0 g/dL and the physician anticipates a Hb decrease or the patient has comorbidities that require higher Hb levels. Also, deny darbepoetin if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemia due to myelodysplastic syndrome (MDS) but do not approve if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation).

### **Exclusion Criteria**

Anemia associated with cancer. Anemia associated with AML, CML or other myeloid cancers. Anemia associated with radiotherapy in cancer. To enhance athletic performance. Treatment of anemia in inflammatory bowel disease (eg, ulcerative colitis, Crohn's disease). Anemia in patients due to acute blood loss. 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). Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Hb value of less than or equal to 11.0 g/dL required for initiation of therapy in chronic renal failure (CRF). Also, in CRF Hb has to be less than or equal to 12.0 g/dL if previously receiving epoetin alfa or darbepoetin. CRF indication should be denied if Hb exceeds 12.0 g/dL for this condition and in any situation (continuation or initiation). For anemia in cancer patients due to chemotherapy a Hb of less than or equal to 10.0 g/dL is required or if Hb is greater than 10.0 g/dL but less than or equal to 12.0 g/dL the physician must anticipate a Hb decrease or the patient has comorbidities that require higher Hb levels. Deny darbepoetin in any situation that Hb is greater than 12.0 g/dL in cancer due to chemotherapy. For MDS, deny darbepoetin if hemoglobin is greater than 12.0 g/dL.

**Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

4 mos anemia in cancer pts d/t chemotherapy. Other indications x 12 mos, unless other specified.

**Other Criteria**

Anemia due to myelodysplastic syndrome (MDS) but treatment with darbepoetin is not allowed if Hb greater than 12.0 g/dL at anytime point.

## **ARCALYST**

### **Affected Drugs**

ARCALYST®

### **Covered Uses**

All FDA approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

N/A

### **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 or have experienced an attack and who are at risk of MS 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 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  
DRONABINOL  
EMEND®  
FLEBOGAMMA®  
GAMASTAN S-D®  
GAMUNEX®  
GENGRAF  
GRANISETRON HCL  
GRANISOL  
IVEEGAM EN®  
METHOTREXATE  
MYCOPHENOLATE MOFETIL  
MYFORTIC®  
ONDANSETRON HCL  
ONDANSETRON ODT  
ORTHOCLONE OKT-3®  
PANGLOBULIN NF®  
POLYGAM S-D®  
PROGRAF®  
RAPAMUNE®  
SIMULECT®

### **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 or have experienced an attack and who are at risk of MS 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 specialist.

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **BISPHOSPHONATES (IV)**

### **Affected Drugs**

BONIVA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Treatment of osteoporosis in men or women (non PMO). Prevention or treatment of GIO.

### **Exclusion Criteria**

N/A

### **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

# **BOTOX**

## **Affected Drugs**

BOTOX®

## **Covered Uses**

All FDA approved indications not otherwise excluded from Part D. Plus Achalasia. Anal Fissure. BPH after a trial with at least 2 other therapies. Chronic facial pain/pain associated with TMJ dysfunction. Chronic low back pain if after trial of at least 2 other pharmacologic therapies AND if being used as part of a multimodal therapeutic pain management program. Plantar fasciitis. Tinnitus after a trial with at least 2 other pharmacologic therapies AND tinnitus retraining therapy AND prescribed by an ENT. Headache (migraine, chronic tension HA, whiplash, chronic daily HA) after trial with at least 2 other pharmacologic therapies AND prescribed by or in consultation with a neurologist or HA specialist. Palmar/plantar and facial hyperhidrosis after trial with at least 1 topical agent. Myofascial pain. Salivary hypersecretion. Spasticity (eg, due to cerebral palsy, stroke, brain injury, spinal cord injury, MS, hemifacial spasm). Essential tremor after a trial with at least 1 other pharmacological therapy. Dystonia other than cervical (eg, focal dystonias, tardive dystonia, anismus). Bladder/voiding/urethral dysfunction after trial with at least 1 other pharmacologic therapy. Gastroparesis after a trial with at least 1 promotility drug. Vaginismus after a trial with at least 2 other treatment options. Dysphagia. Interstitial cystitis. Frey's syndrome. Ophthalmic disorders (eg, esotropia, exotropia, nystagmus, facial nerve paresis). Speech/voice disorders (eg, dysphonias). Tourette's syndrome after a trial with at least 1 more commonly used pharmacologic therapy. Crocodile tears syndrome. Fibromyalgia after a trial of at least 2 commonly used pharmacologic therapies.

## **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 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 after trial with at least 2 other therapies (eg, alpha1-blocker, 5 alpha-reductase inhibitor, TURP, transurethral microwave heat treatment, TUNA, interstitial laser therapy, stents, various forms of surgery). Chronic low back pain after trial with at least 2 other pharmacologic therapies (eg, NSAID, 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 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. 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, 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, psychostimulants). Fibromyalgia if after a trial of at least 2 or more commonly used pharmacologic therapies (eg, TCAs, SSRIs, SNRIs, 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 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. Treatment of symptoms due to an acute respiratory infection (eg, acute bronchitis, sinusitis, pneumonia). Treatment of chronic cough due to NAEB. 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.

### **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 or have experienced an attack and who are at risk of MS 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 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) 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. 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.

### **Exclusion Criteria**

Onychomycosis. 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**

Criteria only applies to the 50, 100 and 200 mg tablets (not the 150-mg tablet). 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.

# ENBREL

## Affected Drugs

ENBREL®

## Covered Uses

All FDA approved indications not otherwise excluded from Part D plus patient already on Enbrel. Juvenile spondyloarthritis. Patient has tried at least 1 other DMARD. Undifferentiated spondyloarthritis. Reactive arthritis. Patient has tried an NSAID and at least 1 DMARD. Adult with Still's disease. Patient has tried 1 DMARD or is currently on MTX. Uveitis (noninfectious) in children. Patient has tried topical (ophthalmic) or systemic corticosteroids, MTX or cyclosporine. Amyloidosis(primary). Patient has tried 1 other therapy. Amyloidosis with renal involvement. Patient has tried 1 DMARD or is currently receiving MTX. Chronic inflammatory demyelinating polyneuropathy. Patient has tried 2 of the following, IVIG, a corticosteroid, plasmapheresis, azathioprine, cyclosporine, cyclophosphamide, interferon alfa. Scleritis or Sterile Corneal Ulceration. Patient has tried 1 other therapy (eg, oral, topical(ophthalmic) or IV corticosteroids, MTX, topical(ophthalmic) NSAID, cyclosporine, cyclophosphamide). Myasthenia gravis. Patient is receiving corticosteroids and at least 1 other immunosuppressant (eg, azathioprine, cyclosporine, cyclophosphamide, Cellcept). Acute or chronic GVHD. Patient is being managed in a transplant center and has tried 1 conventional therapy (eg, highdose corticosteroid, Cellcept, list) or is concurrently receiving at least 1 of the medications with Enbrel. Behcet's disease. Patient has not responded to at least one conventional therapy(eg, corticosteroids, immunosuppressives(list), RoferonA). Hidradenitis suppurativa. Patient has tried 1 other therapy (eg, intralesional or oral corticosteroids, antibiotics, isotretinoin). Dermatomyositis or polymyositis. Patient has not responded to 2 conventional therapies(IVIG, steroids, immunosuppressants(list) or if these therapies are contraindicated or not tolerated. Inclusion body myositis. Pyoderma gangrenosum. Patient has 1 other systemic therapy(eg, intralesional corticosteroids or cyclosporine(for local), systemic corticosteroids or immunosuppressants(list). Autoimmune mucocutaneous blistering diseases (pemphigus vulgaris, mucous membrane pemphigoid [cicatrical pemphigoid]). Patient has tried conventional therapy (systemic corticosteroids AND immunosuppressive agents(list)) or has contraindications. Systemic sclerosis (scleroderma). Patient has inflammatory joint involvement and has tried an NSAID and at least 1 DMARD.

## Exclusion Criteria

pulmonary sarcoidosis ocular sarcoidosis prevention of peri-prosthetic osteolysis primary sclerosing cholangitis ITP Sjogren's syndrome MDS Hep C Sciatica Wegener's

granulomatosis Immune mediated cochleovestibular disorders Graves ophth Not with anakinra or abatacept other indications\* Coverage not recommended for anything not listed under Covered Uses Alopecia areata, Alopecia totalis, alopecia universalis. Asthma. Crohn's disease. Graves ophthalmopathy. Hepatitis C. Immune-mediated cochleovestibular disorders (autoimmune sensorineural hearing loss, autoimmune inner ear disease, immune-mediated Meniere's disease). Immune thrombocytopenic purpura (ITP). Myelodysplastic syndrome (MDS). Prevention of peri-prosthetic osteolysis. Primary sclerosing cholangitis. Sarcoidosis, ocular. Sarcoidosis, pulmonary. Sciatica. Sjögren's syndrome. Wegener's granulomatosis. Enbrel should not be given in combination with Kineret or Orencia. Intra-articular injection. Cancer anorexia/weight loss syndrome. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Plaque psoriasis. Prescribed by a dermatologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

Adults with RA, approve if patient has tried 1 DMARD or is concurrently receiving MTX. JIA or JRA, polyarticular course, approve if the patient has tried MTX or will be starting on Enbrel concurrently with MTX. Approve without trying MTX if the patient has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias). Patient with chronic plaque psoriasis has tried a systemic therapy.

# 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) (or renal insufficiency), including patients on dialysis and not on dialysis, if hemoglobin (Hb) is less than or equal to 11.0 g/dL for therapy initiation. If the patient has previously been receiving darbepoetin or epoetin alfa, approve only if Hb is less than or equal to 12.0 g/dL. Deny darbepoetin if hemoglobin exceeds 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemic patients with HIV who are receiving zidovudine therapy if Hb is less than or equal to 10.0 g/dL or endogenous erythropoietin levels are less than or equal to 500 munits/mL and deny epoetin alfa if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemia in cancer due to chemotherapy approve for 4 months if the patient has Hb less than or equal to 10.0 g/dL or Hb is greater than 10.0 g/dL but less than or equal to 12.0 g/dL and the physician anticipates a Hb decrease or the patient has comorbidities that require higher Hb levels. Also, deny epoetin alfa if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemic patients with Hb less than or equal to 13.0 g/dL 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 approve for 21 days. Anemia due to myelodysplastic syndrome (MDS) but do not approve if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Anemia in HIV-infected patients if Hb is less than or equal to 10.0 g/dL or endogenous erythropoietin levels are less than or equal to 500 mUnits/mL but deny if Hb is greater than 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation). Preoperative use in patients undergoing major surgery utilizing hemodilution intraoperatively for one month. Treatment of aplastic anemia if prescribed by a hematologist and to deny if Hb exceeds 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation).

## Exclusion Criteria

Anemia associated with cancer. Anemia associated with acute myeloid leukemia (AML), chronic myelogenous leukemia (CML) or other myeloid cancers. Anemia associated with radiotherapy in cancer. To enhance athletic performance. To treat orthostatic hypotension in patients with anemia. To treat thalassemia-related anemia. As an adjunct to bone marrow transplantation (BMT) for donors. Use as an adjunct to

blood donation for autologous use. Treatment of anemia associated with epidermolysis bullosa. Treatment of anemia in systemic lupus erythematosus (SLE). Treatment of anemia in rheumatoid arthritis (RA). Treatment of anemia in inflammatory bowel disease (IBD) (e.g., ulcerative colitis, Crohn's disease). Treatment of anemia in diabetes mellitus. Hemochromatosis. Anemia in patients due to acute blood loss. Non-anemic patients (Hb greater than 13.0 g/dL) prior to surgery. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Hb value of less than or equal to 11.0 g/dL required for initiation of therapy in chronic renal failure (CRF). Also, in CRF Hb has to be less than or equal to 12.0 g/dL if previously receiving epoetin alfa or darbepoetin. CRF indication should be denied if Hb exceeds 12.0 g/dL for this condition and in any situation (continuation or initiation). Anemic patients with HIV receiving zidovudine and in those with anemia due to HIV the Hb has to be less than or equal to 10.0 g/dL or endogenous erythropoietin levels are less than or equal to 500 mUnits/mL also to deny if Hb exceeds 12.0 g/dL. For anemia in cancer patients due to chemotherapy a Hb of less than or equal to 10.0 g/dL is required or if Hb is greater than 10.0 g/dL but less than or equal to 12.0 g/dL the physician must anticipate a Hb decrease or the patient has comorbidities that require higher Hb levels. Deny darbepoetin in any situation that Hb is greater than 12.0 g/dL in cancer due to chemotherapy. For anemic patients who are undergoing surgery the Hb has to be equal to or less than 13.0 g/dL. For MDS, deny darbepoetin if hemoglobin is greater than 12.0 g/dL. For the treatment of aplastic anemia deny if Hb exceeds 12.0 g/dL if previously receiving the product for this indication and in any situation (continuation or initiation).

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

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

### **Coverage Duration**

chemo 4 mos. Anemic pt surg 21 days. preop =1 mos. other 12 mos, unless otherwise specified.

### **Other Criteria**

Anemia associated with MDS Hb should not exceed 12.0 g/dL. Anemia in HIV the Hb should be less than or equal to 10.0 g/dL or endogenous erythropoietin levels are less than or equal to 500 mUnits/mL and to deny if Hb exceeds 12.0 g/dL. Treatment of

aplastic anemia approve if prescribed by a hematologist and deny if Hb exceeds 12.0 g/dL.

## **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 (defined as (ie, BMD 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**

NORDITROPIN NORDIFLEX®

NORDITROPIN®

OMNITROPE®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus mcg/L, if GH peak is between 10 and 20 mcg/L with this test, then the clinical context should be considered or a second provocative test should be done. For retesting the transition adolescent with childhood onset GH deficiency, the peak GH response for the insulin tolerance test, arginine alone, or glucagon must be less than 5 mcg/L and for GHRH plus arginine must be less than or equal to 20 mcg/L. Arginine alone may be used in a transition adolescent who is not obese. A GH stimulation test is not required in adults with childhood-onset GH deficiency who have known mutations, embryopathic lesions, or irreversible structural lesions/damage. OR both of the following if there is no GH stimulation testing, patient has 2 or more of the following pituitary hormone deficiencies TSH deficiency, ACTH deficiency, gonadotropin deficiency (LH and/or FSH deficiency are counted as 1 deficiency), and AVP deficiency (central diabetes insipidus) AND Serum IGF-I less than 84 mcg/L (11 nmol/L) using the Esoterix Endocrinology competitive binding RIA. Other causes of low serum IGF-I must be excluded (eg, malnutrition, prolonged fasting, poorly controlled diabetes mellitus, hypothyroidism, hepatic insufficiency, oral estrogen therapy) before using IGF-I as a marker of GH deficiency. Serum IGF-I alone is not specific enough for diagnosis. Turner's syndrome. Demonstrated by chromosome analysis. Child with SHOX (short stature homeobox-containing gene) deficiency. Demonstrated by chromosome analysis and epiphyses are not closed. Short child born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) including those with Silver-Russell syndrome. Child must have been born SGA, defined as birth weight and/or birth length that is greater than 2 SD below the mean for gestational age and gender and did not have sufficient catch-up growth before age 2 AND child is greater than or equal to 2 years and less than or equal to 8 years OR If child is greater than 8 years and prepubertal, coverage is recommended for 1 year on a trial basis AND If growth increases by greater than or equal to 3 cm/yr in addition to their baseline growth with therapy, then authorize for continued therapy OR If the child is greater than 8 ys and is clearly pubertal, then no exception AND baseline height is less than third percentile (greater than 2 SD below the mean for gender and age). Child with Noonan syndrome. Baseline height must be less than third percentile (greater than 2 SD below the mean for gender and age for children without Noonan syndrome). Short bowel syndrome. Adult is receiving specialized nutritional support (defined as a high carbohydrate, low-fat diet adjusted for individual

requirements and preferences) AND therapy is limited to one 4-wk course per yr. Patients will be evaluated by a pharmacist and/or a physician on a case-by-case basis for more than 4 wks tx or more than one 4-wk/ yr.

### **Exclusion Criteria**

Constitutional delay of growth and puberty. Familial short stature (normal short stature). 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**

Children with acquired GH deficiency. Documented GH stimulation testing with 1 test (levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon) showing deficiency defined by a diminished serum GH response to stimulation testing of less than 10 ng/mL AND baseline height less than the third percentile for gender and age AND pretreatment height velocity in child less than 3 yrs of less than 7 cm/yr and in child greater than or equal to 3 yrs of less than 4 cm/yr OR child of any age growth velocity less than the tenth percentile for age and gender based on at least 6 months of data. Child who has undergone brain radiation does not have to meet criteria for baseline height.. Congenital hypopituitarism does not have to meet criteria for height or growth velocity. Child who has had a hypophysectomy does not have to meet any criteria. Non-GH deficient short stature (idiopathic short stature) in child with open epiphyses. 6 month trial. Baseline height less than third percentile (ie, greater than 2 SD below the mean for gender and age AND pretreatment height velocity in child less than 3 yrs of less than 7 cm/yr and in child greater than or equal to 3 yrs of less than 4 cm/yr

OR child of any age growth velocity less than the tenth percentile for age and gender based on at least 6 months of data AND pediatric endocrinologist must certify that the child's ability to participate in basic activities of daily living is limited by their short stature and the child has a condition for which GH is effective (or will possibly be effective during the initial trial of therapy) AND pediatric endocrinologist must certify that based on bone-age x-ray, the predicted adult height is less than the third percentile. The 6-month trial of GH is to establish that the child's condition responds to GH therapy. Authorization for continued therapy is based on an adequate clinical response defined as an annualized growth rate that doubles in comparison to the previous year.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

SBS 4 wks. NonGH def short stat 6 mos Adult with HIV wasting 24 wks. HIV failure to thrive 12 wks.

### **Other Criteria**

Therapy should be discontinued if there is no significant increase in growth rate during the first year. Adult GH 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 stimulation test as follows, 1 of the following stimulation tests must be used (insulin tolerance, glucagon, GH releasing hormone (GHRH) plus arginine, or GHRH plus GH releasing peptide (GHRP-6). Arginine alone may be used in non-obese adolescents with childhood onset. Cutoff values for GH peak for each test are For the insulin tolerance or glucagon peak less than 3 mcg/L, For GHRH 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 wks of therapy or more than one 4-wk course per yr. 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 therapy and will continue antiretroviral therapy throughout the course of GH treatment AND Therapy with GH is limited to 24 weeks. Repeat 12 or 24-week courses of GH may be authorized in patients who have received a previous 12 or 24-week course of GH for HIV infection with wasting or cachexia provided that they have been off GH for at least 1 month and meet all of the previous criteria. HIV-associated failure to thrive. Child less than 17 yrs 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 therapy and will continue antiretroviral ther.

# **HUMIRA**

## **Affected Drugs**

HUMIRA®

## **Covered Uses**

All FDA approved indications not otherwise excluded from Part D plus patients already started on adalimumab. Uveitis (noninfectious) in children. Approve if patient has tried topical (ophthalmic) or systemic corticosteroids, MTX, Enbrel, Remicade, Cellcept or cyclosporine. Uveitis or other systemic manifestations of Behcet's disease in adults. Approve if patient has tried topical (ophthalmic) or systemic corticosteroids, MTX, Enbrel, Remicade, Cellcept or cyclosporine. Sarcoidosis. Approve if patient has tried corticosteroids and immunosuppressive agents (MTX, azathioprine, cyclosporine, chlorambucil) or thalidomide or chloroquine. Pyoderma gangrenosum. Approve if patient has tried 1 other systemic therapy (eg, intralesional injections of corticosteroids or cyclosporine [for localized pyoderma gangrenosum], systemic corticosteroids or immunosuppressants such as azathioprine/6-mercaptopurine, cyclosporine, cyclophosphamide, chlorambucil, Remicade).

## **Exclusion Criteria**

Sciatica. Humira should not be given in combination with Kineret or Orencia. Children with Crohn's disease. Osteoarthritis. Ulcerative colitis. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

Crohn's disease adults only. Uveitis in children. Uveitis or other systemic manifestations of Behcet's disease in adults. No age range specified.

## **Prescriber Restrictions**

Plaque psoriasis. Prescribed by a dermatologist.

## **Coverage Duration**

12 months.

## **Other Criteria**

Adults with RA, approve if the patient has tried 1 DMARD or is concurrently receiving MTX. Plaque psoriasis in patients without psoriatic arthritis. Approve if has tried a systemic therapy. JIA or JRA, polyarticular course. Approve if the patient has tried MTX

or will be starting on Humira concurrently with MTX. Approve without trying MTX if the patient has an absolute contraindication to MTX (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 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 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 rheumatoid arthritis polyarticular course. Patient has tried Enbrel. Systemic onset JLA. Patient has tried a systemic corticosteroid. Ankylosing Spondylitis. Patient has tried Enbrel, Remicade, or Humira. Adult with Still's disease. Patient has tried 1 DMARD or is currently on MTX. Muckle-Wells syndrome. Patient has tried 2 other drugs (colchicine, corticosteroids, chlorambucil, antihistamines, dapsone, azathioprine, Cellcept, Remicade) for MWS. Neonatal Onset Multisystem Inflammatory disease or chronic infantile neurological cutaneous and articular syndrome. Schnitzlers syndrome. Patient has tried 1 other prescription medication. Acute gout. Patient has tried standard therapies (nsaids, colchicine, corticosteroids) Familial Mediterranean fever. Patient has tried colchicine.

## **Exclusion Criteria**

Osteoarthritis, symptomatic. Lupus arthritis. Anakinra should not be given in combination with TNF blocking agents (Enbrel, Humira, Remicade) 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 3 doses. 12 months for all others.

## **Other Criteria**

Adults with RA. Approve if patients has tried 1 DMARD for at least 2 months or is concurrently receiving MTX and anakinra is formulary. If anakinra is nonformulary then Enbrel, Humira or Remicade must be tried first, this is in addition to having tried a DMARD such as auranofin, aurothioglucose, azathioprine, cyclosporine, d-penicillamine, gold sodium thiomalate, hydroxychloroquine, leflunomide, MTX or

sulfasalazine. Some patients with unfavorable prognostic factors (early age of disease onset, high titer of rheumatoid factor, increased ESR, swelling of greater than 20 joints, extraarticular manifestations of RA or with joint erosions) may be started early on biologic agents. Patients will be evaluated by a pharmacist or physician on a case by case basis.

## **LAMISIL**

### **Affected Drugs**

LAMISIL®  
TERBINAFINE HCL

### **Covered Uses**

All FDA approved indications not otherwise excluded from Part D. Tinea corporis after a trial of a topical antifungal agent, except for extensive conditions. Tinea cruris, faciei, manuum, pedis, and imbricate after a trial of a topical antifungal agent. Plantar- or moccasin-type dry tinea pedis. Black piedra. Tinea capitis. Tinea barbae. 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. 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 morbidity, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) and a positive KOH, fungal culture, DTM 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**

Onychomycosis = 6 wks for fingernails, toenails or 4 wks in certain cond. Other = 12 months.

### **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 and doses as follows: Prostate cancer (Lupron Depot 30 mg [4-month], 22.5 mg [3-month] and 7.5 mg OR Eligard 7.5 mg, 22.5 mg, 30 mg and 45 mg), Endometriosis (Lupron Depot 3.75 mg and 11.25 mg [3-month]), Uterine leiomyomata (Lupron Depot 3.75 mg and 11.25 mg [3-month]), Treatment of central precocious puberty (Lupron Depot Ped 7.5 mg, 11.25 mg, and 15 mg). Ovarian cancer (Lupron Depot 3.75 mg and 7.5 mg). Breast cancer (Lupron Depot). Preserve ovarian function in women undergoing chemotherapy (Lupron Depot). Induce amenorrhea during bone marrow transplant (Lupron Depot 7.5 mg). Premenstrual syndrome (Lupron Depot 3.75 mg and 7.5 mg) in patients who have tried two other therapies (e.g., SSRIs, oral contraceptives). Menstrual migraine (Lupron Depot 3.75 mg) after the patient has tried two other therapies for the treatment of acute migraine (e.g., NSAIDs, triptans, ergotamines) or prophylaxis of migraine (e.g., beta-blockers, amitriptyline, divalproex). Catamenial pneumothorax (Lupron 3.75 mg and 7.5 mg). Paraphilias (Lupron Depot 3.75 mg and 7.5 mg). Dysfunctional uterine bleeding. Lymphangiomyomatosis (Lupron Depot 3.75 mg and 11.25 mg).

### **Exclusion Criteria**

PCOS. Hirsutism. 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 mos.

**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, 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. 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**

N/A

## **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.

### **Exclusion Criteria**

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

# 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 receiving chemotherapy, cancer patients receiving BMT, 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 patients with delayed or inadequate neutrophil engraftment after PBPC transplantation. Hematopoietic stem cell transplant patients (for promotion of myeloid engraftment). Aplastic anemia with neutropenia.

## Exclusion Criteria

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

# **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? antagonist (e.g., etanercept, adalimumab, infliximab) or with anakinra. Psoriasis. Systemic lupus erythematosus. Multiple sclerosis. Prevention of RA. 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 (oral or injectable) for at least 2 months, [this includes patients who have tried other biologic DMARDs for at least 2 months] OR approve if the patients is concurrently receiving MTX. Juvenile idiopathic arthritis (JIA) [or JRA], polyarticular course approve if the patient has tried MTX or will be starting on abatacept concurrently with MTX, approve without trying MTX if the patient has an absolute contraindication to MTX.

## **PEGYLATED INTERFERONS**

### **Affected Drugs**

PEGASYS®

### **Covered Uses**

All FDA approved indications not otherwise excluded from Part D plus (note all are in patients with hep C). Patient coinfectd with hep C and hep B. Acute hep C. It is at least 2 to 4 months after acute onset. Retreatment of hep C. Genotype 1 hep C extending therapy to 72 wks. Not coinfectd with HIV and not previously treated with interferon/peginterferon if HCV RNA has decreased by greater than or equal to 2 log 10 but still detectable at week 12 AND virus undetectable at wk 24 then allow total 72 wks. Recurrent Hep C after liver transplant and grade II fibrosis or greater. Chronic hep C on waiting list for liver transplant. Administered in a liver clinic affiliated with a liver transplant program. Any indication besides hep C.

### **Exclusion Criteria**

Children less than 18 y/o. Maintenance tx of hep C extending tx to 72 wks or longer (one exception for 72 wks for genotype 1 hep 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 hep C on waiting list for liver transplant. Response assessed after 12 wks. In genotype 2 and 3 if HCVRNA has decreased by greater than or equal to 2 log10 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 log10 (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 log10 (or virus undetectable), then further authorization not recommended.

### **Age Restrictions**

Children less than or equal to 18 years of age.

### **Prescriber Restrictions**

For all patients with hepatitis C, must be prescribed by an infectious disease physician, gastroenterologist, hepatologist, or a transplant physician or in consultation with these physicians. Recurrent Hep C after liver transplant and grade II fibrosis or.

### **Coverage Duration**

Hep C. 12, 24, 48, 72 wks Acute hep C. 6 to 12 mo Chronic hep C lvr trnplnt 12 wks non-hep C 12 mo.

### **Other Criteria**

A. Patient not previously treated for hep C with interferon/peginterferon alfa. Obtain Hep C genotype and HCV RNA titer before starting therapy (HCV RNA not required for genotype 2/3). A1. Chronic hep C (genotype 2/3) not coinfecting with HIV and not previously treated for hepatitis C. Approve 24 wks. OR A2. Chronic hep C genotype 3 not coinfecting with HIV and not previously treated for hep C and a high level of HCV RNA (determined by physician) or advanced fibrosis. Authorize 48 wks of therapy (total). OR A3. Chronic hep C (genotype 1 or 4) who is not coinfecting with HIV and not previously treated for hep C. Authorize 12 wks and reassess again in 12 wks. Record baseline HCV RNA. After 12 wks assess and If HCV RNA has decreased by greater than or equal to 2 log<sub>10</sub> (or undetectable) authorize for 36 wks OR If HCV RNA has not decreased by greater than or equal to 2 log<sub>10</sub> (or undetectable) authorize for 12 wks more and reassess again after total of 24 wks 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 wks and reassess after 24 wks (if undetectable at wk 24, authorize 48 more wks, total 72 wks using non FDA approved indication). A3 continues. After 24 wks If advanced fibrosis and HCV RNA undetectable then authorize 24 more wks (48 total) OR If advanced fibrosis and detectable HCV RNA physician and patient will decide whether to continue with another 24 wks 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 hep C viral genotype 5 or 6 not coinfecting with HIV and not previously treated for hep C use criteria for genotype 1 and 4 above. OR A5. Coinfecting with HIV and chronic hep C genotype 2 or 3 and not previously treated for hep C. If HCV RNA is detectable and CD4 count is greater than or equal to 200 cells/microL authorize 48 wks. 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 wks. OR If HCV RNA is undetectable or CD4 count is less than 100 cells/microL no authorization. OR A6. Coinfecting with HIV and chronic hep C genotype 1 and not previously treated for hep C. If HCV RNA is detectable and CD4 count is greater than or equal to 200 cells/microL authorize 24 wks and reassess after wk 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 wks and reassess after 24 wks. 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 wks If HCV RNA is decreased by greater than or equal to 2 log<sub>10</sub> or virus undetectable authorize 24 more wks 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 plus treatment of onychomycosis should be considered if the condition is judged to be medically significant (i.e., causing impaired mobility, discomfort, or in the presence of diabetes mellitus or an immunocompromised condition) by the treating physician. A positive KOH preparation, fungal culture, DTM culture, nail biopsy, or histologic examination (PAS) is required prior to starting therapy. If the patient has received terbinafine or itraconazole previously for fingernails and it is greater than 6 months since finishing the course, then a positive KOH preparation, culture, or histologic examination is required. If toenails and it is greater than 9 month after finishing terbinafine and itraconazole, then a positive KOH, culture, or histology is needed. If it is less than 6 months after finishing terbinafine or itraconazole for fingernails or 9 months for toenails, then the patient must have a positive culture. Note: A culture must show that the infecting organism is a fungus before a second treatment of ciclopirox topical solution, 8%, can be initiated.

### **Exclusion Criteria**

Tx 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 morbidity, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) and a positive KOH, fungal culture, DTM 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. For the FDA-approved indication of obstructive sleep apnea/hypoapnea syndrome patients must have tried CPAP. 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. Fatigue associated with MS. Excessive daytime sleepiness (EDS) due to myotonic dystrophy. ADHD and ADD for patients who have tried two alternative medications from two different classes as follows: methylphenidate products, amphetamines, atomoxetine, bupropion, or tricyclic antidepressants. Adjuvative/augmentation for treatment of depression in adults if the patient has tried one other CNS stimulant. EDS in Parkinson's.

### **Exclusion Criteria**

Alcoholic organic brain syndrome. Fibromyalgia. ALS. Adjuvative therapy in the treatment of schizophrenia. Seasonal affective disorder.

### **Required Medical Information**

For the FDA-approved indication of obstructive sleep apnea/hypoapnea syndrome patients must have tried CPAP. 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**

Adjuvative 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 if the patient has tried CPAP. Excessive sleepiness due to SWSD if the patient is working at least 5 overnight shifts per month. ADHD/ADD for patients who have tried two alternative medication for ADHD/ADD 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 has tried one other CNS stimulant medication (e.g., methylphenidate, dextroamphetamine). 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).

## **REBIF**

### **Affected Drugs**

REBIF®

### **Covered Uses**

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

### **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 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. Any clean and granulating ulcer/wound classified as NPUAP Stage II (eg, 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.

## **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 spondyloarthropathy/spondyloarthritis. JRA or JIA. Patient has tried MTX or will be starting on Remicade concurrently with MTX. Patients with aggressive disease, as determined by the prescribing physician, may be started early on a biologic agent (such as Remicade), patients will be evaluated by a pharmacist and/or physician on a case-by-case basis. Behcet's disease. Patients has not responded to at least 1 conventional therapy (ie, corticosteroids, immunosuppressives [azathioprine, MTX, cyclosporine, tacrolimus, chlorambucil, cyclophosphamide], Roferon A). Adult w/Still's disease. Patient has tried 1 DMARD or is currently receiving MTX. Uveitis. Patient has tried periocular, intraocular, or systemic corticosteroids, or immunosuppressives (eg, MTX, cyclosporine, azathioprine, cyclophosphamide). Sarcoidosis. Patient has tried corticosteroids and immunosuppressive agents (MTX, azathioprine, cyclosporine, chlorambucil) or thalidomide or chloroquine. Amyloidosis w/renal involvement. Patient has tried 1 DMARD or is currently receiving MTX. Pyoderma gangrenosum. Patient has tried 1 other systemic therapy (eg, intralesional injection of corticosteroid or cyclosporine [for localized pyoderma gangrenosum], systemic corticosteroids or immunosuppressants such as azathioprine/6-mercaptopurine, cyclosporine, cyclophosphamide, chlorambucil). Hidradenitis suppurativa. Patient has tried 1 other therapy (eg, intralesional or oral corticosteroids, antibiotics, isotretinoin). Graft-versus-host disease. Patient has tried 1 conventional treatment for GVHD (eg, high-dose corticosteroids, antithymocyte globulin, cyclosporine, thalidomide, tacrolimus). Indeterminate colitis. Patient has tried conventional medical therapy (eg, corticosteroids, sulfasalazine, balsalazide, mesalamine, olsalazine, cyclosporine, 6-mercaptopurine, azathioprine). Enterovesical fistulas in patients w/Crohn's disease. Patient has tried another medical therapy (azathioprine, 6-mercaptopurine, Cellcept, cyclosporine, or tacrolimus). Macular edema in type 2 diabetes. Refractory to laser therapy. Orbital myositis (chronic idiopathic orbital inflammation). Patient has tried systemic corticosteroids, MTX, azathioprine, 6-mercaptopurine, cyclophosphamide, cyclosporine, or radiotherapy. SAPHO (synovitis, acne, pustulosis, hyperostosis, osteitis) syndrome. Patient has tried a NSAID and at least 1 of the following: MTX, a systemic corticosteroid, a bisphosphonate (pamidronate or zoledronic acid), or cyclosporine. Familial Mediterranean fever. Patients has tried colchicine.

### Exclusion Criteria

Primary Sjogren's syndrome. Sciatica. Fistulas in Crohn's disease. MDS. COPD. Asthma. Atopic dermatitis. Wegener's granulomatosis. Systemic vasculitis. Giant cell arteritis. 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**

Plaque psoriasis. Prescribed by a dermatologist.

**Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

**Other Criteria**

Adults with RA, approve if patient has tried 1 DMARD or is concurrently receiving MTX. JIA or JRA, polyarticular course, approve if the patient has tried MTX or will be starting on Enbrel concurrently with MTX. Approve without trying MTX if the patient has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias). Patient with chronic plaque psoriasis has tried a systemic therapy. Patient with Psoriatic arthritis (PsA) has tried 1 oral DMARD or Enbrel or Humira. Ulcerative colitis. Patient has tried 1 other oral or IV therapy for UC.

## **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. Men with 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 plus already been started on Rituxan for RA and Rituxan prescribed by a rheumatologist or in consultation with a rheumatologist or for any indication.

### **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. Prescribed by a rheumatologist or in consultation with a rheumatologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

Adult with RA. Patient has tried at least 1 of the following biologic DMARDs, Enbrel, Remicade, or Humira for at least 2 months.

## **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 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. Plantar- or moccasin-type dry tinea pedis. Tinea or pityriasis versicolor after trial of a topical antifungal agent, except for extensive conditions. Tinea capitis. Tinea barbae. Treatment of vaginal candidiasis after a trial of oral fluconazole. 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 morbidity, discomfort, or in the presence of diabetes mellitus, an immunocompromised condition) and a positive KOH, fungal culture, DTM 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. Itraconazole is permitted for the treatment of patients with a culture positive for Candida.

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Onych 3 mos for nails. pulse tx 2 or 3 x some circum. Other = 12 mos, unless otherwise spec.

**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). For the treatment of other non-cosmetic conditions not listed above 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).

## 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**

TOPAMAX®  
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. Plus 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). For treatment of other non-cosmetic conditions not listed above 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 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 patients. MS patients with chronic progressive MS. Concurrent use with immunosuppressants (eg, 6MP, azathioprine, CSA, MTX) or TNF alfa inhibitors (eg, Remicade, Humira, Cimzia) in CD patients. Ulcerative colitis. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

Adults.

### **Prescriber Restrictions**

MS. Prescribed by a neurologist or an MS specialist registered with the TOUCH prescribing program. CD. Prescribed by a physician registered with the TOUCH program.

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

Adults with MS. Patient has a relapsing form of MS and has had an inadequate response to, or is unable to tolerate, other MS therapies. Adults with CD. Patient has moderately to severely active CD with evidence of inflammation and has had an inadequate response to, or is unable to tolerate, conventional CD therapies (eg, 6MP, AZA, CSA, MTX) and TNF alfa inhibitors (Remicade, Humria, Cimzia).

## **VFEND**

### **Affected Drugs**

VFEND®

### **Covered Uses**

All FDA approved indications not otherwise excluded from Part D worded as invasive aspergillosis, esophageal candidiasis (after a trial of one other systemic agent), 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 patient has tried two other therapies for allergic rhinitis (antihistamines [nasal or oral], nasal corticosteroids, or montelukast).

## **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/PAR, 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/PAR, 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 y/o. SAR/PAR, patient is at least 12 y/o.

## **Prescriber Restrictions**

Moderate to severe persistent asthma if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. SAR/PAR if prescribed by an allergist, immunologist, or pulmonologist.

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

Pts 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 pt 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 y/o. Pts with SAR/PAR must meet the following criteria prescribed by an allergist, immunologist, or pulmonologist AND baseline IgE level at least 30 IU/mL AND pt 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 y/o.

# ZYVOX

## Affected Drugs

ZYVOX®

## Covered Uses

All FDA approved indications not otherwise excluded from Part D. Plus if prescribed by, or after consultation with, an infectious disease specialist. Patient started in hospital, other inpatient facility, or as an outpatient on intravenous (IV) Zyvox and is now being changed to oral Zyvox. Patient started in hospital or other inpatient facility on oral Zyvox. Patient started in hospital, other inpatient facility, or as an outpatient on IV vancomycin. Infection that is resistant to other antibiotics, but organism is sensitive to Zyvox. For safety reasons, if there is insufficient information available to make a determination regarding coverage and the prescribing physician or representative of the physician cannot be contacted, then approve.

## Exclusion Criteria

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

## Required Medical Information

VRE, 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