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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). Castleman's disease.

### **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, and Crohn'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. Castleman's disease, patient is under the care of an oncologist or hematologist.

### **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. 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.

## **ALPHA-1 PROTEINASE INHIBITORS**

### **Affected Drugs**

ARALAST NP®  
PROLASTIN C®  
PROLASTIN®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Alpha-1 antitrypsin (AAT) deficiency-associated panniculitis.

### **Exclusion Criteria**

Use in the management of 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), or bronchiectasis (without alpha1-antitrypsin deficiency). Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

For AAT [Alpha 1-antitrypsin] deficiency with emphysema (or COPD [Chronic Obstructive Pulmonary Disease]), approve in patients with baseline (pretreatment) alpha1-antitrypsin serum concentration less than 11 microM (11 micromol/L) or 80 mg/dL.

### **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 with emphysema (or COPD [Chronic Obstructive Pulmonary Disease]), approve in patients with baseline (pretreatment) alpha1-antitrypsin serum concentration less than 11 microM (11 micromol/L) or 80 mg/dL.

## **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 (PsA). Lichen planus (LP).

### **Exclusion Criteria**

Alefacept should not be given in combination with a tumor necrosis factor (TNF) alpha antagonist (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), anakinra, or ustekinumab. Use in the management of RA [Rheumatoid Arthritis], graft versus host disease, alopecia areata, alopecia universalis, pyoderma gangrenosum, or atopic dermatitis. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

Greater than 16 years of age.

### **Prescriber Restrictions**

Plaque psoriasis (initial course) and psoriasis of hand and/or foot (initial course). Prescribed by a dermatologist or in consultation with a dermatologist.

### **Coverage Duration**

PP/PsA/LP, 12 week. Hd/ft Ps, 16 week. Approve 2nd course (exc LP), if off Amevive 12 or 16 week, respectively.

### **Other Criteria**

Plaque psoriasis (PP) and hand/foot psoriasis. Patients with body surface area (BSA) of 5% or more or with PP of palms, soles, head and neck, nails, intertriginous areas or genitalia must try a systemic therapy for 2 months with one of the following-methotrexate (MTX), cyclosporine, acitretin, etanercept, infliximab, adalimumab, or ustekinumab, OR phototherapy for psoriasis for 2 months with ultraviolet B (UVB) OR oral methoxsalen plus UVA light (PUVA). Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Plaque psoriasis (PP) and hand/foot psoriasis. Patient has BSA [Body surface

area] of less than 5%, approve if they have had an inadequate response to a 2-month trial of either topical therapy OR localized phototherapy (with UVB or PUVA), AND had an inadequate response to a 2-month trial of systemic therapy (MTX, cyclosporine, acitretin, etanercept, infliximab, adalimumab, or ustekinumab) or has contraindications to all of these, AND has significant disability or impairment in physical or mental functioning according to the treating physician. PP and hand/foot psoriasis, the above criteria do not have to be met for a second course of alefacept therapy. Psoriatic arthritis. Patient has tried adalimumab, etanercept, infliximab, or golimumab for at least 2 months AND the patient will be receiving alefacept in combination with MTX [methotrexate]. LP, patient has tried two other systemic therapies (photochemotherapy, acitretin, oral corticosteroid, mycophenolate mofetil, azathioprine, cyclosporine, oral tacrolimus, or 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], 90 days. Subsequent authorization for 12 months if patient had a response.

### **Other Criteria**

For initial approval for MS [Multiple Sclerosis], authorize for 90 days. After up to 90 days 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.

## **ANABOLIC STEROIDS**

### **Affected Drugs**

ANADROL-50®  
OXANDROLONE

### **Covered Uses**

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

### **Exclusion Criteria**

Coverage of oxandrolone and oxymetholone is not recommended in the management of anorexia, weight gain (other than detailed in the FDA-approved indications or other covered uses), weight loss, or for athletic performance (ability) enhancement. Coverage is not recommended for circumstances not listed in the Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

Aged 8 years and older for girls with Turner's Syndrome or Ullrich-Turner Syndrome.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

**Other Criteria**

Oxandrolone 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. Oxandrolone or oxymetholone for the prevention/prophylaxis of hereditary angioedema, approve if the patient has tried danazol.

# 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. 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).

## Exclusion Criteria

Any 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. Treatment of anemia of chronic disease/anemia of chronic inflammation (eg, anemia in inflammatory bowel disease [ulcerative colitis, Crohn's disease], rheumatoid arthritis, systemic lupus erythematosus). 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 10.0 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 chemotherapy, 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 pretreatment 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 pretreatment 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. An additional 6 months of therapy after initial 6 months allowed if Hb is 12.0 g/dL or less. Anemia due to ribavirin in Hepatitis C patients. Approve therapy if Hb is 10.0 g/dL or less. Deny if Hb exceeds 12.0 g/dL in any situation.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Chemo course +8 week after last chemo dose. Riba use/CRF=12 months. MDS=6 months. additional 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. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.

## **ARCALYST**

### **Affected Drugs**

ARCALYST®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus patient already started on riloncept for Muckle Wells Syndrome (MWS) or Familial Cold Autoinflammatory Syndrome (FCAS).

### **Exclusion Criteria**

Use in the management of neonatal onset multisystem inflammatory disorder (NOMID) or chronic infantile neurological cutaneous and articular syndrome (CINCA), systemic juvenile idiopathic arthritis (JIA), gout, or Familial Mediterranean fever (FMF). Riloncept should not be given in combination with tumor necrosis factor (TNF) blocking agents (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), anakinra, or canakinumab. 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**

Initial approval of MWS [Muckle-Wells syndrome]/FCAS, 2 months. Subsequent authorization for 12 months if patient had a response.

### **Other Criteria**

For initial approval for MWS [Muckle-Wells syndrome]/FCAS, authorize for 2 months. After patient has received at least 6 weeks of therapy with riloncept and has had a response to therapy as determined by prescribing physician, then an additional authorization is allowed. Patients already started on riloncept for MWS [Muckle-Wells syndrome]/FCAS may receive continued authorization if they have had a response and are continuing therapy to maintain response/remission.

## **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 multiple sclerosis (MS) or have experienced an attack and who are at risk of MS [Multiple Sclerosis].

### **Exclusion Criteria**

Concurrent use of Rebif, Betaseron, Extavia, 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

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

### **Affected Drugs**

ATGAM®  
AZASAN®  
AZATHIOPRINE  
AZATHIOPRINE SODIUM  
CALCITRIOL  
CARIMUNE NF NANOFILTERED®  
CELLCEPT®  
CUBICIN®  
CYCLOPHOSPHAMIDE  
CYCLOSPORINE  
CYCLOSPORINE MODIFIED  
DRONABINOL  
EMEND®  
GAMUNEX®  
GENGRAF  
GRANISETRON HCL  
GRANISOL  
HEPARIN SODIUM  
HEPARIN SODIUM IN 0.45% NACL  
HEPARIN SODIUM IN 0.9% NACL  
HEPARIN SODIUM IN 5% DEXTROSE  
LEVOCARNITINE  
METHOTREXATE  
MIACALCIN®  
MITOXANTRONE HCL  
MYCOPHENOLATE MOFETIL  
MYFORTIC®  
ONDANSETRON HCL  
ONDANSETRON ODT  
ORTHOCLONE OKT-3®  
PAMIDRONATE DISODIUM  
PRIVIGEN®  
PROGRAF®  
RAPAMUNE®  
SANDIMMUNE®  
SIMULECT®  
TACROLIMUS  
VANCOMYCIN HCL

## ZORTRESS®

### **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/EXTAVIA**

### **Affected Drugs**

BETASERON®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D worded as patients with a diagnosis of multiple sclerosis (MS) or have experienced an attack and who are at risk of MS [Multiple Sclerosis].

### **Exclusion Criteria**

Concurrent use of Avonex, Rebif, 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

# **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. Dysphagia. Frey's syndrome (gustatory sweating). Ophthalmic disorders (eg, esotropia, exotropia, nystagmus, facial nerve paresis). Speech/voice disorders (eg, dysphonias). Tourette's syndrome. Additional indications will be evaluated by a pharmacist and/or a physician on a case-by-case basis.

## **Exclusion Criteria**

Use in the management of 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, vaginismus, interstitial cystitis, or Crocodile tears syndrome.

## **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 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. 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). 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). 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).

## **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. Postinfectious cough (ie, cough persisting after an acute respiratory infection has resolved).

### **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 multiple sclerosis (MS) or have experienced an attack and who are at risk of MS [Multiple Sclerosis].

### **Exclusion Criteria**

Concurrent use of Rebif, Betaseron, Extavia, Avonex, 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

## **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 (pityriasis 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**

Use of topical ciclopirox 8% solution with Diflucan (fluconazole) is not permitted. 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 topical ciclopirox 8% solution 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 if the patient has tried terbinafine tablets or itraconazole capsules unless the patient has a medical condition or other clinical reason to not utilize these agents (e. g. , drug-drug interactions, heart failure).

## **EGRIFTA**

### **Affected Drugs**

EGRIFTA®

### **Covered Uses**

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

### **Exclusion Criteria**

Use in the management of abdominal obesity in patients without HIV infection. Use in the management of HIV-related cachexia, weight loss, or fat distribution other than lipodystrophy. Coverage is not recommended for circumstances not listed in Covered Uses.

### **Required Medical Information**

Diagnosis is HIV-associated lipodystrophy. Egrifta is prescribed for the reduction of excess abdominal fat. Patient is HIV-infected.

### **Age Restrictions**

Adults.

### **Prescriber Restrictions**

Prescribed by or in consultation with an endocrinologist or a physician specializing in the treatment of HIV (eg, infectious disease, oncology).

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

N/A

# **ENBREL**

## **Affected Drugs**

ENBREL®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus patient already on etanercept. Active juvenile spondyloarthritis. Undifferentiated spondyloarthritis (undifferentiated arthritis). Reactive arthritis (Reiter's disease). Still's disease. Uveitis (noninfectious). Scleritis or sterile corneal ulceration. Chronic inflammatory demyelinating polyneuropathy. Myasthenia gravis. Acute or chronic 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 [cicatricial pemphigoid]). Systemic sclerosis (scleroderma) with inflammatory joint involvement. Tumor necrosis factor receptor-associated periodic syndrome (TRAPS).

## **Exclusion Criteria**

Concurrent use with anakinra, abatacept, certolizumab pegol, ustekinumab, infliximab, rituximab, or golimumab. Intra-articular injection of etanercept. Use in the management of alopecia areata, alopecia totalis, alopecia universalis, asthma, Crohn's disease, dermatomyositis/polymyositis, inclusion body myositis, Graves ophthalmopathy, hepatitis C, alcoholic hepatitis, idiopathic pulmonary fibrosis, immune-mediated cochleovestibular disorders, immune thrombocytopenic purpura, myelodysplastic syndrome, prevention of peri-prosthetic osteolysis, primary sclerosing cholangitis, recurrent spontaneous pregnancy loss, ocular sarcoidosis, pulmonary sarcoidosis, sciatica, Sjogren's syndrome, Takayasu's arteritis, Wegener's granulomatosis, cancer anorexia/weight loss syndrome, new-onset diabetes mellitus type 1, keloids, and Alzheimer's disease. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

For patients with systemic sclerosis, the patient must have inflammatory joint involvement.

## **Age Restrictions**

For use in Still's disease and RA [Rheumatoid Arthritis], approve for adults. For uveitis (non-infectious), approve for children aged less than 18 years. For JIA [Juvenile Idiopathic Arthritis] approve for children aged 2 years and older.

## Prescriber Restrictions

N/A

## Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

## Other Criteria

RA [Rheumatoid Arthritis], patient tried one DMARD [Disease-modifying antirheumatic drug] for at least 2 months (includes other biologic DMARDs [Disease-modifying antirheumatic drugs] for at least 2 months), or the patient is concurrently receiving methotrexate (MTX). JIA [Juvenile Idiopathic Arthritis] or JRA [Juvenile Rheumatoid Arthritis], polyarticular course, patient has tried MTX [methotrexate] or will be starting on etanercept concurrently with MTX [methotrexate]. Approve without trying MTX [methotrexate] if the patient has an absolute contraindication to MTX [methotrexate]. Plaque psoriasis (PP). 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 PP of palms, soles, head and neck, nails, intertriginous areas or genitalia. patient has a minimum BSA [Body surface area] of 5% or more, exceptions allowed for patients with less than 5% BSA [Body surface area] if they have had an inadequate response to a 2-month trial of either topical therapy OR localized phototherapy (with ultraviolet B [UVB] or oral methoxsalen plus UVA light [PUVA]), and had an inadequate response to a 2-month trial of systemic therapy (with one of the following - MTX [methotrexate], cyclosporine (CSA), acritretin, adalimumab, alefacept, infliximab, or ustekinumab) or has contraindications to all of these, and has significant disability or impairment in physical or mental functioning according to the treating physician. patient has tried a systemic therapy (MTX, CSA, acritretin, adalimumab, alefacept, infliximab, or ustekinumab) or phototherapy with UVB or PUVA for psoriasis for 2 months. Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Juvenile spondylarthropathy. Tried at least one other DMARD [Disease-modifying antirheumatic drug]. Reactive arthritis. Tried an NSAID [Non-steroidal anti-inflammatory drug] and at least one DMARD [Disease-modifying antirheumatic drug]. Still's disease. Tried one DMARD [Disease-modifying antirheumatic drug] or is currently receiving MTX [methotrexate] for at least 2 months. Uveitis (non-infectious). Tried topical (ophthalmic) or systemic corticosteroids (SCs), MTX [methotrexate], or CSA. Scleritis/corneal ulcer. Tried one other therapy for these conditions. CIDP. Tried two of the following- IVIG [Intravenous Immune Globulin], SC, plasmapheresis, azathioprine, CSA, cyclophosphamide, interferon alfa. Myasthenia gravis. Approve if receiving corticosteroids and have received at least one other immunosuppressive agent. GVHD [Graft-Versus-Host disease]. Approve if managed by a transplant center and has tried or

currently is receiving with etanercept one conventional GVHD [Graft-Versus-Host disease] treatment (high-dose SC, CSA, tacrolimus, etc. ). Behcet's. Have not responded to at least one conventional therapy (eg, SCs, immunosuppressives, etc). Giant cell arteritis. Tried corticosteroids but are unable to withdraw systemic steroid therapy. HS. Tried one other therapy (eg, intralesional/oral corticosteroids, topical/systemic antibiotics, isotretinoin). PMR. Tried corticosteroids but unable to reduce dose or withdraw steroid therapy. PG. Tried one other systemic therapy (eg, intralesional corticosteroids or CSA, SCs or immunosuppressives, etc. ) AMBD. Tried conventional therapy (SCs AND immunosuppressive agent) or has contraindications to conventional treatment. Systemic sclerosis. Tried an NSAID [Non-steroidal anti-inflammatory drug] AND at least one DMARD [Disease-modifying antirheumatic drug]. TRAPS. Tried corticosteroids.

# 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).

## Exclusion Criteria

Any 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. 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 10.0 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 chemotherapy. 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 pretreatment 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

pretreatment 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. An additional 6 months allowed after first 6 months if Hb is 12.0 g/dL or less. Anemia in HIV (+ zidovudine), Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 units/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. All conditions, deny if Hb exceeds 12.0 g/dL.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Chemo course +8 week after last chemo dose. MDS=6mo. additional 6 mo, Hb 12 or less. Transfus=3wk. 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 reinstitution of epoetin alfa must include a dose reduction of 25% from the previously administered dose. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.

# **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 those using medicine that resulted in bone loss (eg, steroids [prednisone]). For use in hypoparathyroidism (primary or secondary).

## **Exclusion Criteria**

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

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

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

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

Forteo may be approved for the covered osteoporosis indications if the patient has tried an oral or intravenous bisphosphonate (eg, alendronate, risedronate, ibandronate, zoledronic acid [Reclast]), or if the patient has severe renal impairment (eg, creatinine clearance less than 30 mL/min) or chronic kidney disease, or if the patient has multiple vertebral fractures in the setting of vertebral T-scores less than -3.5.

## **GILENYA**

### **Affected Drugs**

GILENYA®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

For use in Multiple Sclerosis (MS), patient has a relapsing form of MS [Multiple Sclerosis].

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

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

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

For use in MS [Multiple Sclerosis], patient has a relapsing form of MS [Multiple Sclerosis] and patient has tried interferon beta-1a intramuscular (Avonex), interferon beta-1a subcutaneous (Rebif), interferon beta-1b (Betaseron or Extavia), or glatiramer acetate (Copaxone). Exceptions to having tried an interferon beta-1a or -1b product (Avonex, Betaseron, Extavia, or Rebif) or glatiramer acetate (Copaxone) can be made if the patient is unable to administer injections due to dexterity issues or visual impairment. Patients who have tried natalizumab (Tysabri) for MS [Multiple Sclerosis] and have a relapsing form of MS [Multiple Sclerosis] will receive authorization, they are not required to try an interferon beta product or glatiramer acetate.

## **GLUCAGON-LIKE PEPTIDE-1 AGONISTS**

### **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

## **GROWTH HORMONES**

### **Affected Drugs**

OMNITROPE®  
TEV-TROPIN®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Growth hormone (GH) deficiency. Non-GH [growth hormone] deficient short stature (idiopathic short stature). Turner's syndrome. SHOX (short stature homeobox-containing gene) deficiency. Chronic renal insufficiency. Prader-Willi syndrome. Short child born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) including those with Silver-Russell syndrome. Noonan syndrome. Short bowel syndrome. HIV infection with wasting or cachexia (Serostim only). HIV-associated failure to thrive (Serostim only).

### **Exclusion Criteria**

Use in the management of acute critical illness due to complications of surgery, trauma, or with acute respiratory failure, as antiaging therapy, to improve functional status in elderly, somatopause, enhancement of athletic ability, BMT [Bone Marrow Transplant] without total body irradiation, bony dysplasias, burn injury, cardiac transplantation, central precocious puberty, chronic fatigue syndrome, congenital adrenal hyperplasia, constitutional delay of growth and puberty, corticosteroid-induced short stature including a variety of chronic glucocorticoid-dependent conditions, such as asthma, juvenile rheumatoid arthritis, after renal, heart, liver, or bone marrow transplantation, Crohn's disease, cystic fibrosis, dilated cardiomyopathy/heart failure, ESRD in adults undergoing hemodialysis, Down's syndrome, familial dysautonomia, fibromyalgia, HIV-infected patients with alterations in body fat distribution, infertility, kidney transplant patients (children) with a functional renal allograft, liver transplantation, multiple system atrophy, myelomeningocele, obesity, osteogenesis imperfecta, osteoporosis (postmenopausal, idiopathic in men, glucocorticoid-induced), thalassemia, and X-linked hypophosphatemic rickets (familial hypophosphatemia, hypophosphatemic rickets).

### **Required Medical Information**

Child/adolesc w/GH [growth hormone] DF (initial treatment), eval by a pediatric endocrinologist (PE), documented GH [growth hormone] stim test (levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon) w/GH [growth hormone] response of less than 10 ng/mL AND baseline height (Ht) less than the 3rd percentile for gender/age AND pretreatment Ht growth rate (GR) child less than 3 years of less than 7 cm/year and child greater than or equal to 3 years of less than 4 cm/year OR child of

any age GR less than the 10th percentile for age/gender based on at least 6 months of data. Child w/brain radiation does not have to meet baseline Ht criteria. Congenital hypopituitarism does not have to meet Ht or GR criteria. Child w/hypophysectomy, approve. Child/adolesc w/GH [growth hormone] DF, continued treatment, GR increased by 2.5 cm/year or more in most recent year (MRY) per MD AND epiphyses open (older than 12 years), both crit exclude adolesc w/hypopituitarism. Review patients GR annually (does not apply to hypopituitarism). Adoles/young adults who completed linear growth (GR less than 2 cm/yr), review for treatment of adult GH [growth hormone] DF. Greater than 18 years, auth not allowed if mid-parental ht attained. Non-GH [growth hormone] DF short stature (ISS) child w/open epiphyses. 6 mo trial. Baseline Ht less than 3rd percentile (greater than 2 SD below mean for gender/age) AND pretreatment GR child less than 3 years of less than 7 cm/year and child greater than or equal to 3 years of less than 4 cm/year OR child of any age GR less than the 10th percentile for age/gender based on at least 6 months of data AND PE certifies child's basic activities of daily living limited by short stature and has condition for which GH [growth hormone] is effective (or may be effective during treatment trial) AND PE certifies vis bone-age x-ray, predicted adult Ht less than 3rd percentile. Authorization after initial treatment (auth for 12 months) based on adequate clinical response (annualized GR doubles). continued treatment (after 12 to 18 months), GR increased by 2.5 cm/year or more in MRY per MD AND epiphyses open (older than 12 years). Greater than 18 years, auth not allowed if mid-parental ht attained.

### **Age Restrictions**

Turner' syndrome, children. SHOX/CRI, children/adolescents. SGA [Short child born small for gestational age], 2 to 8 years. Noonan, 17 years or younger. HIV failure to thrive, less than 17 years. SBS [Short Bowel Syndrome]/HIV cachexia, adults.

### **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**

GH [growth hormone] def, 12 months. SBS [Short Bowel Syndrome] 4 weeks. NonGH def short stat 6 months HIV wasting 24 weeks. HIV failure to thrive 12 weeks.

### **Other Criteria**

Adult GH [growth hormone] def (start) AND adult onset (GH alone or multiple hormone deficiencies/hypopituitarism from pituitary dz, hypothalamic dz, surgery, cranial radiation treatment, tumor treatment, traumatic brain injury, or subarachnoid

hemorrhage) or childhood-onset AND negative response to 1 GH [growth hormone] stimulation test (insulin tolerance [peak less than 5 mcg/L], or glucagon [peak less than 3 mcg/L]) [GHRH plus arginine may be used if available], transition adole off somatropin 1 mo before retesting, OR 3 or more pituitary hormone deficiencies (TSH, ACTH, LH/FSH, or AVP) AND serum IGF-1 84 microg/L or less using the Esoterix ECB RIA or age/gender adjusted serum IGF-1 SDS below the 2.5 percentile. Turners, initial treatment, female, and has short stature. continued treatment, GR increased by 2.5 cm/year or more in most recent year AND epiphyses open. SHOX, start, open epiphyses. continued treatment, GR increased by 2.5 cm/year or more in most recent year AND epiphyses open. CRI, start, approve. continued treatment, GR increased by 2.5 cm/year or more in most recent year AND epiphyses open. Prader-Willi, initial treatment, approve. continued treatment, GR increased by 2.5 cm/year or more in most recent year AND epiphyses open. SGA [Short child born small for gestational age]/IUGR [Intrauterine growth retardation], initial treatment, born SGA [Short child born small for gestational age], AND no sufficient catch-up growth before age 4 year, AND age 2 to 8 years, if older than 8 years, approve 1 year trial if prepubertal, AND baseline ht less than 3rd percentile for gender/age. continued treatment, GR increased by 2.5 cm/year or more in most recent, if aged 2 to 8 years, or by 3 or more cm/year if older than 8 years and prepubertal. Noonan syndrome, initial treatment, baseline ht less than 3rd percentile. continued treatment, GR increased by 2.5 cm/year or more in most recent year AND epiphyses open. HIV infection w/wasting or cachexia, HIV-positive AND have 1 of the following, documented unintentional wt loss of greater than or equal to 10% from baseline OR wt less than 90% of the lower limit of ideal body wt OR BMI less than or equal to 20 kg/m<sup>2</sup> AND able to consume or be fed via parenteral or enteral feedings 75% or more of maintenance energy requirements based on current body weight AND on antiretroviral treatment greater than or equal to 30 days prior to beginning GH [growth hormone] treatment and will continue antiretroviral treatment throughout GH [growth hormone] treatment. Repeat 12 or 24-week courses of GH [growth hormone] may be authorized after initial 12 or 24-week GH [growth hormone] course for HIV infection w/wasting or cachexia provided that they are off GH [growth hormone] for at least 1 mo and meet all of previous HIV criteria. HIV-associated failure to thrive. Able to consume or be fed via parenteral or enteral feedings 75% or more of maintenance energy requirements based on current body wt AND on antiretroviral treatment for greater than or equal to 30 days prior to beginning GH [growth hormone] treatment and will continue antiretroviral treatment. SBS [Short Bowel Syndrome] patients eval on case-by-case basis for more than one 4-week course per year.

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

### **Affected Drugs**

CYPROHEPTADINE HCL  
DEXCHLORPHENIRAMINE MALEATE  
DIPHENHYDRAMINE HCL  
HYDROXYZINE HCL  
HYDROXYZINE PAMOATE  
PROMETHAZINE HCL

### **Covered Uses**

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

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

Approve if the patient has tried a prescription oral second generation antihistamine product (cetirizine, fexofenadine, desloratadine, levocetirizine, fexofenadine/pseudoephedrine, or desloratadine/pseudoephedrine) for the current condition. Approve promethazine hydrochloride tablets or syrup if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, palonosetron, aprepitant) for the current condition. Approve diphenhydramine (capsules or elixir) if the patient has tried at least two other FDA-approved products for the management of insomnia. Approve hydroxyzine hydrochloride (tablets and syrup) or hydroxyzine pamoate (capsules) if the patient has tried at least two other FDA-approved products for the management of anxiety.

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

### **Affected Drugs**

CARISOPRODOL  
CARISOPRODOL COMPOUND  
CARISOPRODOL COMPOUND-CODEINE  
CHLORZOXAZONE  
CYCLOBENZAPRINE HCL  
METAXALONE  
METHOCARBAMOL  
ORPHENADRINE CITRATE  
ORPHENADRINE COMPOUND  
ORPHENADRINE COMPOUND FORTE

### **Covered Uses**

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

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 1 month.

### **Other Criteria**

Musculoskeletal conditions/disorders, approve if the patient has tried two other therapies for the current condition.

# HUMIRA

## Affected Drugs

HUMIRA®

## Covered Uses

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

## Exclusion Criteria

Concurrent use with anakinra, abatacept, rituximab, ustekinumab, certolizumab pegol, etanercept, infliximab, or golimumab. Use in the management of osteoarthritis, ulcerative colitis, recurrent spontaneous pregnancy loss, in vitro fertilization (IVF). Intra-articular injection of adalimumab. Coverage not recommended for anything not listed under Covered Uses.

## Required Medical Information

N/A

## Age Restrictions

RA [Rheumatoid Arthritis], adults. Crohn's disease adults and adolescents aged 15 to up to 18 years.

## Prescriber Restrictions

N/A

## Coverage Duration

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

## Other Criteria

RA [Rheumatoid Arthritis], patient has tried one DMARD [Disease-modifying antirheumatic drug] (brand or generic, 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 the patient is concurrently receiving methotrexate (MTX). JIA [Juvenile Idiopathic Arthritis]/JRA [Juvenile Rheumatoid Arthritis] polyarticular course. Tried MTX [methotrexate] or will be starting on adalimumab concurrently with MTX [methotrexate]. Approve without trying MTX

[methotrexate] if patient has absolute contraindication to MTX [methotrexate]. Plaque psoriasis (PP). 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 PP of palms, soles, head and neck, nails, intertriginous areas or genitalia. patient has a minimum BSA [Body surface area] of 5% or more, exceptions allowed for patients with less than 5% BSA [Body surface area] if they have had an inadequate response to a 2-month trial of either topical therapy OR localized phototherapy (with ultraviolet B [UVB] or oral methoxsalen plus UVA light [PUVA]), and had an inadequate response to a 2-month trial of systemic therapy (with one of the following - MTX [methotrexate], cyclosporine (CSA), acritretin, etanercept, alefacept, infliximab, or ustekinumab) or has contraindications to all of these, and has significant disability or impairment in physical or mental functioning according to the treating physician. patient has tried a systemic therapy (MTX, CSA, acritretin, etanercept, alefacept, infliximab, or ustekinumab) for 2 months or phototherapy with UVB or PUVA for psoriasis for 2 months. Rarely, a patient may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. CD [Crohn's Disease] to induce remission. Tried corticosteroids or if corticosteroids are contraindicated or if patient currently on corticosteroids (adolescents with CD [Crohn's Disease] must also have tried infliximab). CD [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 tried azathioprine, 6-mercaptopurine, or MTX [methotrexate] or has tried infliximab (or certolizumab pegol for adults). Uveitis (non-infectious). Tried periocular/intraocular corticosteroids, immunosuppressants, or etanercept or infliximab. Behcet's. patient has not responded to at least one conventional treatment (eg, systemic corticosteroids, immunosuppressants, interferon alfa, or infliximab). Sarcoidosis. Tried corticosteroid and immunosuppressive agent, or infliximab, or chloroquine, or thalidomide. PG. Tried one other systemic therapy (eg, systemic corticosteroids, immunosuppressives, cyclophosphamide, chlorambucil, infliximab, or intralesional corticosteroids or CSA). HS. Tried one other therapy (eg, intralesional/oral corticosteroids, antibiotics, isotretinoin).

## **IMMUNE GLOBULIN SUBCUTANEOUS**

### **Affected Drugs**

HIZENTRA®

### **Covered Uses**

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

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Primary immunodeficiency (PID), if prescribed by a or in consultation with an immunologist.

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

Approve for patients with PID after a trial with an intravenous (IV) immune globulin product (eg, Gamunex, Flebogamma, Octagam, etc. ). Approve for patients with PID who have been previously treated with immune globulin therapy given subcutaneously (SC) or who are continuing subcutaneous immune globulin therapy previously started.

# **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. Use in patients with closed epiphyses. 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 at baseline AND Age adjusted Basal IGF-1 standard deviation score is less than or equal to -3.0 at baseline AND Growth hormone concentration is normal or increased at baseline.

## **Age Restrictions**

Children.

## **Prescriber Restrictions**

Pediatric endocrinologist or after consultation with pediatric endocrinologist.

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

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 at baseline AND Age adjusted Basal IGF-1 standard deviation score is less than or equal to -3.0 at baseline AND Growth hormone concentration is normal or increased at baseline.

# **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 (MWS). 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**

Use in the management of symptomatic osteoarthritis, lupus arthritis, or type 2 diabetes mellitus. Anakinra should not be given in combination with TNF [Tumor necrosis factor] blocking agents (etanercept, adalimumab, infliximab, certolizumab pegol, and golimumab), or abatacept, or rituximab. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

RA [Rheumatoid Arthritis] and Still's disease, adults.

## **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 adalimumab, etanercept, or infliximab for at least 2 months. JIA [Juvenile Idiopathic Arthritis], JRA [Juvenile Rheumatoid Arthritis] (regardless of onset), approve if patient has tried etanercept, adalimumab, or abatacept. Systemic onset of JIA [Juvenile Idiopathic Arthritis], approve if patient has tried a systemic corticosteroid. Ankylosing spondylitis,

approve if the patient has tried etanercept, infliximab, golimumab, or adalimumab. Adult with Still's disease, approve if patient has tried one DMARD [Disease-modifying antirheumatic drug] or is currently receiving MTX [methotrexate]. MWS [Muckle-Wells syndrome], approve if patient has tried two other drugs (rilonacept, canakinumab, colchicine, corticosteroids, chlorambucil, antihistamines, dapsone, azathioprine, mycophenolate mofetil) for MWS [Muckle-Wells syndrome]. FCAS, approve if patient has tried two other drugs (eg, colchicine, corticosteroids, antihistamines, azathioprine, mycophenolate mofetil, rilonacept, or canakinumab) for FCAS. Schnitzler's syndrome, approve if patient has tried one other prescription medication used in Schnitzler's syndrome (eg, NSAIDs [Non-steroidal anti-inflammatory drugs], antihistamines, colchicine, corticosteroids, immunosuppressive drugs). 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 corticosteroids.

## **LAMISIL**

### **Affected Drugs**

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**

Use in the management of tinea versicolor (pityriasis versicolor), systemic fungal infections, or oral, esophageal or vaginal candidiasis. Use of topical ciclopirox 8% solution with terbinafine is not permitted. Use of 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 topical ciclopirox 8% solution with terbinafine is not permitted.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **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 oral azole antifungal. Other superficial fungal skin infections after a trial of a topical antifungal agent or an oral antifungal agent.

## **LETAIRIS/TRACLEER**

### **Affected Drugs**

LETAIRIS®  
TRACLEER®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Patients currently on Letairis or Tracleer for treatment of pulmonary arterial hypertension. Digital ulcers (Tracleer). Chronic thromboembolic pulmonary hypertension (CTEPH) (Tracleer).

### **Exclusion Criteria**

Coverage is not recommended for circumstances not listed in the Covered Uses.

### **Required Medical Information**

For the FDA-approved indication of pulmonary arterial hypertension, patients not currently on Letairis or Tracleer are required to have had a right-heart catheterization to confirm the diagnosis of PAH [Pulmonary Arterial Hypertension] to ensure appropriate medical assessment. For the FDA-approved indication of pulmonary arterial hypertension, patients currently on Letairis or Tracleer may continue therapy if they have a diagnosis of PAH [Pulmonary Arterial Hypertension].

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

For treatment of pulmonary arterial hypertension, Letairis or Tracleer must be prescribed by or in consultation with a cardiologist or a pulmonologist.

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

Digital ulcers, approve Tracleer if the patient has tried two other therapies for this condition such as calcium channel blockers (eg, amlodipine, felodipine, isradipine, nifedipine), alpha-adrenergic blockers (eg, prazosin), nitroglycerin, phosphodiesterase-5 inhibitors (eg, sildenafil, vardenafil), or angiotensin-converting enzyme inhibitors (ACE inhibitors), or the patient has tried one vasodilator product (eg, intravenous epoprostenol, intravenous alprostadil).

## **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. Osteoarthritis (OA).

### **Exclusion Criteria**

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]). OA, approve after trying at least two other pharmacologic therapies (e. g. , acetaminophen, COX-2 inhibitors, NSAIDs [Non-steroidal anti-inflammatory drugs], salicylates, tramadol, opioids, intraarticular glucocorticoids, topical capsaicin, topical methylsalicylate, or intraarticular hyaluronan). 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 myelosuppressive chemotherapy. Radiation injury.

### **Exclusion Criteria**

Use after undergoing peripheral blood progenitor cell (PBPC) transplantation. Use in the management of myelodysplastic syndrome. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Radiation 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.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Cancer patients receiving chemotherapy, if prescribed by or in consultation with an oncologist or hematologist. Radiation 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**

Radiation 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 myelosuppressive chemotherapy, patients with AML [Acute Myeloid Lymphoma] receiving chemotherapy, cancer patients receiving BMT [Bone Marrow Transplant], patients undergoing peripheral blood progenitor cell (PBPC) collection and therapy, and patients with severe chronic neutropenia [SCN] (e. g. , congenital neutropenia, cyclic neutropenia, idiopathic neutropenia). Neutropenia associated with HIV or AIDS. Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL). Radiation injury. Radiation therapy.

## Exclusion Criteria

Coverage not recommended for anything not listed under Covered Uses.

## Required Medical Information

Radiation 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.

## Age Restrictions

N/A

## Prescriber Restrictions

Cancer/AML [Acute Myeloid Lymphoma], PBPC collection/therapy, MDS [Myelodysplastic syndrome], AA, ALL, oncologist or a hematologist. SCN, hematologist. HIV/AIDS neutropenia, ID MD, hematologist, or MD specializing in HIV/AIDS. Radiation injury, a physician with experience in treating acute radiation syndrome. Radiation therapy, an oncologist, radiologist, or radiation oncologist.

## Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

## Other Criteria

Radiation 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.

## **NUEDEXTA**

### **Affected Drugs**

NUEDEXTA®

### **Covered Uses**

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

### **Exclusion Criteria**

Use in the management of neuropathic pain. Use in the management of heroin detoxification. 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

## **NUVIGIL/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] in patients less than 18 years. Adjunctive/augmentation for treatment of depression in adults. EDS [Excessive daytime sleepiness] in Parkinson's. Idiopathic hypersomnia. Fatigue associated with HIV infection. Myasthenia gravis. Fatigue or sleepiness associated with chronic use of narcotic analgesics. Cancer-related fatigue.

### **Exclusion Criteria**

Use in the management of alcoholic organic brain syndrome, chronic fatigue syndrome, EDS [Excessive daytime sleepiness] associated with primary insomnia, adjunctive therapy in the treatment of schizophrenia, seasonal affective disorder, post-stroke sleep-wake disorders or sleep disorders, bipolar disorder (including bipolar depression), fatigue and EDS [Excessive daytime sleepiness] in chronic traumatic brain injury, fatigue in post-polio patients, and spasticity due to cerebral palsy. 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**

ADHD [Attention Deficit Hyperactive Disorder] or ADD [Attention Deficit Disorder] in patients less than 18 years. 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, unless otherwise specified.

## **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 less than 18 years who have tried two alternative medications for ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder] from two different classes as follows: methylphenidate products (e. g. , methylphenidate, dexmethylphenidate), 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. Fatigue associated with HIV infection/Fatigue or sleepiness due to chronic use of narcotic analgesics, if the patient has tried one CNS stimulant (eg, methylphenidate, dextroamphetamine), unless use of CNS stimulant is not clinically appropriate (eg, contraindication, comorbid condition, history of substance abuse).

## **ORAL TRANSMUCOSAL FENTANYL DRUGS**

### **Affected Drugs**

FENTANYL CITRATE

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus breakthrough chronic (non-cancer) pain.

### **Exclusion Criteria**

Use in the management of acute and/or postoperative pain including surgery/post-surgery, trauma/post-trauma, acute medical illness (acute abdominal pain, pelvic pain, muscle spasm). Use as 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**

For breakthrough chronic (non-cancer) pain, prescriber is a pain management specialist.

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

For breakthrough pain in patients with cancer and for breakthrough chronic (non-cancer) pain, 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).

# **ORENCIA**

## **Affected Drugs**

ORENCIA®

## **Covered Uses**

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

## **Exclusion Criteria**

Concurrent use with a tumor necrosis factor (TNF) alpha antagonist (e. g. , etanercept, adalimumab, infliximab) or with anakinra. Use in the management of psoriasis, undifferentiated arthritis, or systemic lupus erythematosus. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

RA [Rheumatoid Arthritis], adults.

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

Adult RA [Rheumatoid Arthritis], approve if the patient has tried one DMARD [Disease-modifying antirheumatic drug] (brand or generic, 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 patient is concurrently receiving methotrexate (MTX). 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]. JIA [Juvenile Idiopathic Arthritis]/JRA [Juvenile Rheumatoid Arthritis], may approve without trying MTX [methotrexate] if the patient has an absolute contraindication to MTX [methotrexate].

## **PEGYLATED INTERFERONS**

### **Affected Drugs**

PEGASYS®

PEGINTRON REDIPEN®

PEGINTRON®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Pediatric patients aged 3 to 17 years who have not been previously treated with interferon alfa or peginterferon alfa AND who are not HIV co-infected. Coinfection 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). Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Hepatitis C, depending on genotype, response in HCV RNA, liver fibrosis, HIV status, and HIV RNA. See Other Criteria and Covered Uses for details.

### **Age Restrictions**

Acute hepatitis, coinfection w/hepatitis B and C, retreatment in patients previously treated for Hepatitis C with interferon alfa or pegylated interferon alfa, recurrent Hepatitis C after liver transplant, or chronic Hepatitis C on waiting list for liver transplant. Adults.

### **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

Adult not previously treated for chronic hepatitis C (HC) with interferon alfa (IA)/peginterferon alfa (PA) and not HIV co-infected, HC genotype 2/3 authorize 24 weeks initial treatment, or HC genotype 3 with a high level of HCV RNA (per MD) or advanced fibrosis authorize 48 weeks (total), or HC genotypes 1/4 authorize 12 weeks initial treatment (document baseline HCV RNA) and reassess viral titer at 12 weeks, if decreased by 2log<sub>10</sub> or more and virus is undetectable, authorize 36 weeks (total 48 weeks), or if not decreased by 2log<sub>10</sub>, authorize 12 weeks and reassess at 24 weeks, or genotype 1 with viral titer decrease of 2log<sub>10</sub> but virus still detectable, authorize 12 weeks and reassess at 24 weeks. At 24 week, if advanced fibrosis (via liver bx) and undetectable virus, authorize 24 weeks (48 weeks total), or if advanced fibrosis and detectable HCV RNA MD and patient to decide whether to continued with another 24 weeks OR If no advanced fibrosis and do not have greater than or equal to 2 log<sub>10</sub> decrease or virus undetectable, no further authorization, or if genotype 1 with 2log<sub>10</sub> decrease AND detectable virus at week 12 but no detectable virus at week 24, then authorize for 48 weeks (72 weeks total, retreatment). HC viral genotype 5/6 use genotype 1/4 criteria above. Coinfected with HIV/HC (genotype 1, 2, 3, 4) and not previously treated for HC, authorize for up to 48 weeks (total). Children 2 to 17 years with HC (genotypes 1, 2, 3, 4) who have not been previously treated for HC w/IA/PA AND not HIV co-infected, authorize 24 weeks initial treatment. At 24 week, if viral titer is undetectable after 24 weeks or if viral titer decreased by 2log<sub>10</sub> after 12 weeks of treatment, authorize 24 weeks (48 weeks total), or if viral titer is still detectable after 24 weeks of treatment, then no further authorization. Coinfected with HC and Hep B, authorize 48 weeks. Acute Hepatitis C (ie, infection within 6 months of exposure), authorize 6 to 12 months of treatment if at least 2 to 4 months after acute onset. Retreatment of patients who have been previously treated for HC with IA or PA, authorize 48 weeks. Retreatment of patients who failed to attain a sustained virologic response (SVR) [undetectable HCV RNA at the end of treatment and 24 weeks after treatment completion] with PA and ribavirin is not recommended unless specific factors that contributed to the nonresponse are identified and corrected before retxment. Recurrent Hepatitis C after liver transplant, authorize 48 weeks if PA prescribed by hepatologist or liver transplant MD affiliated with a liver transplant program. HC on waiting list for liver transplantation, authorize initial 12 weeks if administered in liver clinic affiliated with liver transplant program. At 12 weeks, genotype 2/3 and viral titer decreased by 2log<sub>10</sub> or more and virus undetectable authorize 24 weeks total from the time patient has achieved an optimal dose of PA and ribavirin, for genotype 1 and viral titer decreased by 2log<sub>10</sub> or more and virus undetectable authorize 48 weeks total from the time patient has achieved an optimal dose of PA and ribavirin, or genotype 1/2/3 and viral titer not decreased by 2log<sub>10</sub>, then no further 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 topical ciclopirox 8% solution with terbinafine, itraconazole, or fluconazole (for onychomycosis use) is not permitted.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for up to 48 weeks.

### **Other Criteria**

N/A

## PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

### Affected Drugs

ADCIRCA®  
REVATIO®

### Covered Uses

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

### Exclusion Criteria

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

### Required Medical Information

For initial approval for use in PAH [Pulmonary Arterial Hypertension], approve if patient has had a right-heart catheterization to confirm diagnosis of PAH [Pulmonary Arterial Hypertension]. For patients currently receiving sildenafil or tadalafil, approve if patient has a diagnosis of PAH [Pulmonary Arterial Hypertension].

### Age Restrictions

N/A

### Prescriber Restrictions

For PAH [Pulmonary Arterial Hypertension], if prescribed by, or in consultation with, a cardiologist or a pulmonologist.

### Coverage Duration

Authorization will be for 12 months, unless otherwise specified.

### Other Criteria

N/A

# **PRADAXA**

## **Affected Drugs**

PRADAXA®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus use in patients with atrial flutter. Treatment of acute venous thromboembolism. Prevention of venous thromboembolism after hip replacement surgery. Prevention of venous thromboembolism after knee replacement surgery. Additional indications will be evaluated by a pharmacist and/or a physician on a case-by-case basis.

## **Exclusion Criteria**

Use in the management of acute coronary syndromes, primary and secondary prevention of chronic coronary arter disease (eg, unstable angina, non-ST segment elevation myocardial infarction [MI], ST-elevation MI, post percutaneous coronary intervention or intracoronary stent placement), prevention of thromboembolic events related to hereditary factor deficiencies or clotting disorders (eg, protein S deficiency, hereditary antithrombin deficiency), or management of mechanical heart valves or indwelling cardiac assistive devices. 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**

Authorize use of Pradaxa for patients with non-valvular atrial fibrillation or flutter. Authorization may be given for treatment of acute venous thromboembolism (VTE), prevention of VTE after hip or knee replacement surgery, or additional indications evaluated by a pharmacist and/or a physician on a case-by-case basis, if the patient has tried one of the following therapies for the condition: warfarin (Coumadin), fondaparinux (Arixtra), or a low molecular weight heparin (LMWH) product (enoxaparin

[Lovenox], tinzaparin [Innohep], dalteparin [Fragmin]), OR if the patient is unable to take one of these medications listed for the condition for one of the following reasons: patient has allergic, immunologic or inherited disorder, patient had adverse effect (eg, major organ toxicity, major bleeding), the patient has experienced ineffectiveness to the agent in a prior setting, the patient has drug-drug interactions that cannot be managed (warfarin), the patient lacks access to proper monitoring (warfarin), the patient has experienced prior heparin-induced thrombocytopenia (HIT) or heparin-induced thrombocytopenia and thrombosis (HITT) (fondaparinux [Arixtra] or LMWH), or the patient is unable to perform injections or have injections administered to them (fondaparinux [Arixtra] or LMWH).

## **REBIF**

### **Affected Drugs**

REBIF®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D worded as patients with a diagnosis of multiple sclerosis (MS) or have experienced an attack and who are at risk of MS [Multiple Sclerosis].

### **Exclusion Criteria**

Concurrent use of Avonex, Betaseron, Extavia, 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

# **RECLAST**

## **Affected Drugs**

RECLAST®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus treatment of non-postmenopausal, non-glucocorticoid induced osteoporosis in women. Plus osteogenesis imperfecta. Plus patients already started on Reclast for an FDA-approved indication or for treatment of non-postmenopausal, non-glucocorticoid induced osteoporosis, or for osteogenesis imperfecta.

## **Exclusion Criteria**

Use in management of hypercalcemia of malignancy, management of multiple myeloma, management of patients with documented bone metastases from solid tumors, management of osteolytic bone metastases of breast cancer, management of osteolytic lesions of multiple myeloma, treatment of osteopenia or the prevention of bone loss in cancer patients, or prevention of bone loss or fracture after transplantation (eg, allogeneic stem cell transplantation, liver transplantation, renal transplantation). Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

For patients who have tried an oral bisphosphonate-containing product, an assessment by the prescribing physician to determine the response to therapy. For patients who cannot take an oral bisphosphonate-containing product, an assessment by the prescribing physician to determine if the patient has a chronic and complex existing medication regimen in which an oral bisphosphonate agent would likely compromise therapy, will be evaluated by a pharmacist and/or physician on a case-by-case basis.

## **Coverage Duration**

Authorization will be for 12 months.

## **Other Criteria**

Reclast may be approved for the covered osteoporosis indications and osteogenesis imperfecta, if 1) the patient has tried one oral bisphosphonate or oral bisphosphonate-

containing product AND the patient has an inadequate response as determined by the prescribing physician or the patient has intolerance to an oral bisphosphonate, or 2) the patient cannot take an oral bisphosphonate product because they cannot swallow, or because they cannot remain in an upright position post oral bisphosphonate administration, or because the patient has a chronic and complex existing medication regimen in which an oral bisphosphonate agent will likely compromise therapy as determined by the prescribing physician, this exception will be evaluated by a pharmacist and/or physician on a case-by-case basis, or because the patient has a pre-existing gastrointestinal medical condition (eg, esophageal lesions, esophageal ulcers, etc. ) in which intravenous bisphosphonate therapy may be medically preferred over oral therapy.

# **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.

## **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), III or IV.

## **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 granulating ulcer/wound classified as 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 patients already started on infliximab for non-Crohn's disease uses. Crohn's disease (CD) patients already on infliximab. Undifferentiated spondyloarthropathy/spondyloarthritis (undifferentiated arthritis). Juvenile rheumatoid arthritis (JRA) or juvenile idiopathic arthritis (JIA), polyarticular course. Behcet's disease. Still's disease. Uveitis. Sarcoidosis. 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. Cogan's syndrome. Crohn's disease after ileocolonic resection, to reduce the chance of recurrence. Pouchitis. Scleritis or Sterile Corneal Ulceration (SCU).

## Exclusion Criteria

Use in the management of primary Sjorgren's syndrome, sciatica, fistulas in patients without Crohn's disease, myelodysplastic syndrome, COPD [Chronic Obstructive Pulmonary Disease], asthma, atopic dermatitis, renal cell carcinoma, systemic vasculitis, giant cell arteritis, Takayasu's arteritis, primary sclerosing cholangitis, inflammatory myopathies (polymyositis, dermatomyositis, inclusion body myositis), or diffuse cutaneous systemic sclerosis (scleroderma). Concurrent use with anakinra, abatacept, rituximab, ustekinumab, certolizumab pegol, etanercept, adalimumab, or golimumab. Intra-articular injection of infliximab. Coverage not recommended for anything not listed under Covered Uses.

## Required Medical Information

Pouchitis, patient has active disease.

## Age Restrictions

RA [Rheumatoid Arthritis], Still's disease. Adults.

## 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

RA [Rheumatoid Arthritis], Tried 1 DMARD [Disease-modifying antirheumatic drug] for 2 months or concurrently receiving MTX [methotrexate]. CD [Crohn's Disease], induce remission. Tried a corticosteroid (CS) or if CSs are contraindicated or if currently on a CS. CD [Crohn's Disease] maintain remission. Got 3 doses of infliximab and responded or if not received infliximab for remission induction then if tried azathioprine (AZA), 6-mercaptopurine (6MP), MTX [methotrexate], adalimumab, or certolizumab pegol. Fistulizing CD [Crohn's Disease], induce remission, approve. Fistulizing CD [Crohn's Disease], maintain remission. patient received 3 doses of infliximab and responded. Plaque psoriasis (PP). A minimum body surface area (BSA) of 5% or more, exceptions for less than 5% BSA [Body surface area] if PP of palms, soles, head and neck, nails, intertriginous areas or genitalia. A minimum BSA [Body surface area] of 5% or more, exceptions allowed for less than 5% BSA [Body surface area] if patient had inadequate response to a 2-mo trial of topical treatment OR localized phototx (ultraviolet B [UVB] or oral methoxsalen plus UVA light [PUVA]), and inadequate response to 2-mo trial of systemic treatment (with one of the following-MTX, cyclosporine (CSA), acritretin, adalimumab, alefacept, etanercept, or ustekinumab) or contraindications to all of these, and significant disability or impairment in physical or mental functioning according to treating MD. Tried a systemic treatment (MTX, CSA, acritretin, etanercept, alefacept, adalimumab, or ustekinumab) for 2 months or phototx (UVB or PUVA) for 2 months. Rarely, patient has contraindications to nearly all other txs, exceptions can be made on a case-by-case basis. UC [Ulcerative colitis]. Tried 2-mo trial of systemic CS, 6-MP, AZA, CSA or tacrolimus. JIA [Juvenile Idiopathic Arthritis]/JRA [Juvenile Rheumatoid Arthritis], tried MTX [methotrexate] or starting on infliximab concurrently with MTX [methotrexate]. Behcet's. patient has not responded to 1 conventional treatment (eg, systemic CSs, immunosuppressants, or interferon alfa), Enbrel or Humira. Still's disease. Tried a CS AND an inadequate response to one non-biologic DMARD [Disease-modifying antirheumatic drug] (eg, MTX [methotrexate]) for 2 months, or was intolerant to a non-biologic DMARD [Disease-modifying antirheumatic drug]. Uveitis. Tried periocular/intraocular CSs, systemic CSs, immunosuppressants, Enbrel, or Humira. Sarcoidosis. Tried CS and immunosuppressant, or chloroquine, or thalidomide. PG. Tried one other systemic treatment (eg, systemic CSs, immunosuppressives, cyclophosphamide, chlorambucil, intralesional CSs or CSA, Enbrel or Humira) for 2 months. HS. Tried one other treatment (eg, intralesional/oral CSs, antibiotics, isotretinoin). GVHD [Graft-Versus-Host disease]. Tried one conventional treatment (eg, high-dose CSs, CSA, thalidomide, tacrolimus, etc. ) or receiving Remicade concurrently. Indeterminate colitis. Tried systemic CS AND an inadequate response to mesalamine, AND either AZA or 6-MP. CD [Crohn's Disease] enterovesical fistulas. Tried another treatment (eg, AZA, 6-MP, mycophenolate, CSA, tacrolimus). ME. If refractory to laser

therapy. Orbital myositis. Tried systemic CSs, immunosuppressant, or radiotherapy. SAPHO. Tried an NSAID [Non-steroidal anti-inflammatory drug] and MTX [methotrexate], systemic CS, sulfasalazine, or CSA. Cogan's. Tried CSs and an immunosuppressive agent. Pouchitis. Tried an antibiotic (metronidazole, ciprofloxacin), probiotic, CS enema, or mesalamine enema. Scleritis/SCU. Tried one other treatment (eg, oral, topical/ophthalmic or IV CSs, MTX [methotrexate], CSA, or other immunosuppressant).

# 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

Concurrent use with a tumor necrosis factor (TNF) alpha antagonist (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), or anakinra, or abatacept. Coverage not recommended for anything not listed under Covered Uses.

## Required Medical Information

N/A

## Age Restrictions

RA [Rheumatoid Arthritis], adults.

## Prescriber Restrictions

Adult with RA [Rheumatoid Arthritis] (initial and repeat courses). Prescribed by a rheumatologist or in consultation with a rheumatologist. Non-RA [Rheumatoid Arthritis] indications, if prescribed by or in consultation with an oncologist, hematologist, neurologist, MS [Multiple Sclerosis] specialist, rheumatologist, dermatologist, or immunologist, or who are being managed by a transplant center.

## Coverage Duration

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

## Other Criteria

Adult with RA [Rheumatoid Arthritis] (initial course), approve if patient has tried at least 1 of the following biologic DMARDs [Disease-modifying antirheumatic drugs], etanercept, certolizumab pegol, golimumab, infliximab, or adalimumab, for at least 2 months. Adult with RA [Rheumatoid Arthritis] (repeat course), approve if 24 weeks or more (or based on clinical evaluation no sooner than 16 weeks) after the first dose of the previous rituximab regimen and the patient has responded (eg, less joint pain, morning stiffness, or fatigue, or improved mobility, or decreased soft tissue swelling in joints or tendon sheaths) as determined by the prescribing physician.

## **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).

# **SOLARAZE**

## **Affected Drugs**

SOLARAZE®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Actinic cheilitis. Bowen's disease. Disseminated superficial actinic porokeratosis (DSAP).

## **Exclusion Criteria**

Use in the treatment of cosmetic conditions (e. g. , liver spots, wrinkles, alopecia areata). Use for the treatment of osteoarthritis. 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 noted.

## **Other Criteria**

For Bowen's disease, approve Solaraze after a trial of at least one other therapy used for the management of Bowen's disease (eg, topical 5-fluorouracil [5-FU], imiquimod, cryotherapy, photodynamic therapy, curettage, excision, laser, or radiotherapy). For DSAP, approve Solaraze after a trial of at least two other therapies used for the management of DSAP (eg, topical 5-FU, imiquimod, topical corticosteroid, topical vitamin D3 analogues, topical or oral retinoid, cryotherapy, photodynamic therapy, and laser).

# **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. Candida onychomycosis.

## **Exclusion Criteria**

Management of candidiasis hypersensitivity syndrome. Itraconazole should not be administered for the treatment of onychomycosis in patients with CHF [Congestive Heart Failure]. Use of topical ciclopirox 8% solution with itraconazole is not permitted. 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 topical ciclopirox 8% solution with itraconazole is not permitted. Itraconazole 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 Candida onychomycosis if they have a culture positive for Candida.

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Ony=12wks toenails, 8wks fingernails. Candida ony, 4 months. 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 RETINOID PRODUCTS**

### **Affected Drugs**

ADAPALENE  
TRETINOIN

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. For topical tretinoin products (examples include Atralin, Avita, Retin-A, Retin-A Micro, Tretin-X, and generic topical tretinoin), additional covered uses include: 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). For topical adapalene products (examples include Differin gel, Differin cream, etc. , and generic adapalene products), additional covered uses include: Acne rosacea. Actinic keratosis/treatment of precancerous skin lesions. 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, Darier's disease, molluscum contagiosum). Coverage of the combination of clindamycin plus tretinoin (Ziana) and the combination of adapalene plus benzoyl peroxide (Epiduo) is recommended for acne vulgaris ONLY.

### **Exclusion Criteria**

Use in the treatment of 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). 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 noted.

**Other Criteria**

For topical tretinoin products (examples include Atralin, Avita, Retin-A, Retin-A Micro, Tretin-X, and generic topical tretinoin), approval for the treatment of other non-cosmetic conditions (eg, dermatitis/eczema, folliculitis, milia, keratosis pilaris, sebaceous hyperplasia/cyst, basal cell carcinoma [skin cancer], confluent and reticulated papillomatosis) can be made if the patient has tried at least 1 other therapy. For topical adapalene products (examples include Differin gel, Differin cream, etc. and generic adapalene products), approval for the treatment of other non-cosmetic conditions (eg, dermatitis/eczema, folliculitis, milia, keratosis pilaris, sebaceous hyperplasia/cyst, basal cell carcinoma [skin cancer], confluent and reticulated papillomatosis, Darier's disease, molluscum contagiosum) can be made if the patient has tried at least 1 other therapy. Coverage of the combination clindamycin plus tretinoin product (Ziana) and the combination adapalene plus benzoyl peroxide product (Epiduo) is recommended for acne vulgaris ONLY and all other indications are not recommended.

## **TOPICAL TESTOSTERONE PRODUCTS**

### **Affected Drugs**

TESTIM®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Delayed puberty or induction of puberty in males.

### **Exclusion Criteria**

To enhance athletic performance. Use in males with carcinoma of the breast. Use in males with known or suspected carcinoma of the prostate. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Diagnosis of delayed puberty or induction of puberty in males.

### **Age Restrictions**

For delayed puberty or induction of puberty in males aged 12 years or older.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

# **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, Extavia, Copaxone or Avonex) in multiple sclerosis (MS) patients. Use in MS [Multiple Sclerosis] patients with chronic progressive MS [Multiple Sclerosis]. Concurrent use with immunosuppressants (eg, 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) or tumor necrosis factor (TNF) alfa inhibitors (eg, infliximab, adalimumab, certolizumab pegol) in Crohn's disease (CD) patients. Ulcerative colitis is a not covered indication. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

Adults with MS [Multiple Sclerosis]. Patient has a relapsing form of MS [Multiple Sclerosis]. Adults with CD [Crohn's Disease]. Patient has moderately to severely active CD [Crohn's Disease] with evidence of inflammation (eg, elevated C-reactive protein).

## **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, unless otherwise specified.

## **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] medications, Avonex, Rebif, Betaseron, Extavia, or Copaxone, or Gilenya. Exceptions to having tried an interferon beta-1a or -1b product (Avonex, Betaseron, Extavia, or Rebif) can be made if the patient has depression or a mood disorder. In these cases, the patient should try glatiramer acetate (Copaxone) or fingolimod (Gilenya), but is not required to try an interferon beta-

1a or -1b. Adults with CD [Crohn's Disease]. Patient has moderately to severely active CD [Crohn's Disease] with evidence of inflammation (eg, elevated C-reactive protein) and has had an inadequate response to treatment with corticosteroids (systemic), azathioprine, 6-mercaptopurine, or methotrexate, and patient has tried two TNF [Tumor necrosis factor] antagonists for CD [Crohn's Disease] for at least 2 months each, adalimumab, certolizumab pegol, or infliximab, and had an inadequate response or was intolerant to the TNF [Tumor necrosis factor] antagonists. Exception to the CD [Crohn's Disease] criteria of treatment with corticosteroids (systemic) are allowed if steroids are contraindicated or not desired, then azathioprine, 6-mercaptopurine, or methotrexate must be tried if they are not contraindicated.

## **VFEND**

### **Affected Drugs**

VFEND®  
VORICONAZOLE

### **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**

Use in the management of onychomycosis, treatment or prevention of vaginal or vulvovaginal candidiasis, tinea cruris, tinea manuum, tinea pedis, tinea faciei, tinea capitis, tinea barbae, tinea corporis, tinea versicolor (pityriasis versicolor), or other superficial fungal infections. Coverage is not recommended for circumstances not listed in the Covered Uses.

### **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**

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 14-day course.

## **XENAZINE**

### **Affected Drugs**

XENAZINE®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Primary hyperkinetic dystonia. Hemiballism.

### **Exclusion Criteria**

Coverage is not recommended for circumstances not listed in the Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, primary hyperkinetic dystonia, or hemiballism, Xenazine must be prescribed by or after consultation with a neurologist. For TD, Xenazine must be prescribed by or after consultation with a neurologist or psychiatrist.

### **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. Seasonal or perennial allergic rhinitis. Eosinophilic gastroenteritis (EG), eosinophilic esophagitis (EE), or eosinophilic colitis (EC).

## **Exclusion Criteria**

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/EC, diagnosis confirmed by biopsy with at least 15 eosinophils/HPF.

## **Age Restrictions**

Patients aged 12 years and older. Asthma patients aged 6 to 12 years, if already started and stabilized on omalizumab.

## **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. EG/EE/EC, if prescribed by or in consultation with an allergist, immunologist, or gastroenterologist.

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

Moderate to severe persistent asthma must meet all criteria patient's asthma symptoms have not been adequately controlled by concomitant use of at least 2 months of inhaled corticosteroid and a long-acting beta-agonist (LABA), if LABA contraindicated or patient has intolerance then alternatives include sustained-release theophylline or a leukotriene modifier (eg, montelukast), or LABA alternative AND inadequate control demonstrated by hospitalization for asthma, requirement for systemic corticosteroids to control asthma exacerbation(s), or increasing need (eg, more than 4 times a day) for short-acting inhaled beta2 agonists for symptoms (excluding preventative use for exercise-induced asthma). SAR [Seasonal allergic rhinitis]/PAR [Perennial allergic rhinitis] must meet the following criteria - patient has tried concurrent therapy with at least one drug from 2 of the following classes, a non-sedating or low-sedating antihistamine/nasal antihistamine, a nasal corticosteroid, or montelukast or patient has tried at least one drug from all 3 of these classes during one allergy season AND patient has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy, AND for patients with allergies to animals, these animals must be removed from the patient's immediate environment (eg, work, home). EG/EE/EC, patient has tried therapy with a systemic or orally administered topical corticosteroid.

## **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. For patients already started on linezolid, approve oral linezolid for patients already started in hospital, or other inpatient facility, or as an outpatient on intravenous linezolid (which is now being switched to oral linezolid for continuation of therapy). For patients already started on linezolid, approve oral linezolid for patients already started in hospital or other inpatient facility on oral linezolid (to allow continuation of therapy).

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

For non-FDA-approved indications, linezolid must be prescribed by, or after consultation with, an infectious disease physician.

### **Coverage Duration**

Authorization will be for one fill up to one month.

### **Other Criteria**

Approve linezolid for use in other infections that are resistant to other antibiotics, but the identified organism(s) is/are susceptible to linezolid. 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.

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