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## **ACTIQ/FENTORA**

### **Affected Drugs**

FENTANYL CITRATE

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

## **ADCIRCA**

### **Affected Drugs**

ADCIRCA®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

## **ALPHA-1 PROTEINASE INHIBITORS**

### **Affected Drugs**

ARALAST®  
PROLASTIN®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

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

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

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

## **AMEVIVE**

### **Affected Drugs**

AMEVIVE®

### **Covered Uses**

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

### **Exclusion Criteria**

### **Required Medical Information**

N/A

### **Age Restrictions**

Greater than or equal to 16 years of age.

### **Prescriber Restrictions**

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

### **Coverage Duration**

PP/PsA,12 wk.Hand/ft psor,16 wk.Approve 2nd 12 or 16 wk, respectively, if pt off Amevive for 12 wk.

### **Other Criteria**

## **ANABOLIC STEROIDS**

### **Affected Drugs**

ANADROL-50®  
OXANDROLONE

### **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

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

## **ARANESP**

### **Affected Drugs**

ARANESP®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Plus anemia due to myelodysplastic syndrome (MDS). Anemia in heart failure.

### **Exclusion Criteria**

Anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis. Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers. Anemia of cancer not related to cancer treatment. Any anemia associated only with radiotherapy. Prophylactic use to prevent chemotherapy-induced anemia. Prophylactic use to reduce tumor hypoxia. Use in patients with erythropoietin-type resistance due to neutralizing antibodies. Anemia due to cancer treatment if patients have uncontrolled hypertension. To enhance athletic performance. Anemia associated with the use of ribavirin therapy for hepatitis C (in combination with interferon or pegylated interferon alfa 2a/2b products). Treatment of anemia in inflammatory bowel disease (eg, ulcerative colitis, Crohn's disease). Anemia in patients due to acute blood loss. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Anemia w/CRF. A hemoglobin (Hb) of less than or equal to 11.0 g/dL required for start, Hb has to be less than or equal to 12.0 g/dL if previously receiving epoetin alfa (EA) or Aranesp. Deny if Hb exceeds 12.0 g/dL. Anemia due to myelosuppressive chemotx, Hb immediately prior start/maintenance of Aranesp is 10.0 g/dL or less (hematocrit [Hct] is 30% or less). Maintenance of Aranesp is the starting dose if the Hb remains 10.0 g/dL or less (or Hct remains 30% or less) 4 wks after therapy start and the rise in Hb is 1.0 g/dL or more (or Hct rise is 3% or more). Pts whose Hb rises less than 1.0 g/dL (Hct rise less than 3%) compared to pretx baseline over 4 wks of tx and whose Hb remains less than 10.0 g/dL after the 4 wks of treatment (or the Hct is less than 30%), the recommended FDA starting dose may be increased once by 25%. Continued Aranesp is not reasonable or necessary if the Hb rises less than 1.0 g/dL (Hct rise less than 3%) compared to pretx baseline by 8 wks 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 wks 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, approve tx if Hb is 12.0 g/dL or less. Aranesp tx is not recommended if Hb is more than 12.0 g/dL in any situation. If the pt has previously been receiving Aranesp or EA, approve only if Hb is 12.0 g/dL or less. Anemia in HF, approve in pts with New York Heart Association (NYHA) functional class III or IV w/ Hb of 10.0 g/dL or less and according to the MD underlying causes of anemia persist despite transfusions or pt has contraindications to transfusions. Addtl tx allowed if pt has Hb of 12.0 g/dL or less. Aranesp is not recommended if Hb is more than 12.0 g/dL. If pt had previously been receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

### **Coverage Duration**

Chemo course +8 wk after last chemo dose. CRF=12 mos. MDS=6 mos. HF=6 mos. Addtl 6 mos, Hb 12.0 or less.

### **Other Criteria**

Anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Pts 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 wks 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.

## **ARCALYST**

### **Affected Drugs**

ARCALYST®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

Greater than or equal to 12 years of age.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **AVONEX**

### **Affected Drugs**

AVONEX ADMINISTRATION PACK®  
AVONEX®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Prescribed by or after consultation with a neurologist or an MS specialist.

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

N/A

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

### **Affected Drugs**

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

### **Covered Uses**

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

## **BETASERON**

### **Affected Drugs**

BETASERON®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Prescribed by or after consultation with a neurologist or an MS specialist.

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

# **BOTOX**

## **Affected Drugs**

BOTOX®

## **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

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

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

## **BYETTA**

### **Affected Drugs**

BYETTA®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

# **CEREZYME**

## **Affected Drugs**

CEREZYME®

## **Covered Uses**

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

## **Exclusion Criteria**

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

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

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

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

N/A

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

### **Affected Drugs**

ADVAIR DISKUS®

ADVAIR HFA®

SYMBICORT®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus COPD. Chronic bronchitis. Emphysema.

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **COPAXONE**

### **Affected Drugs**

COPAXONE®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Prescribed by or after consultation with a neurologist or an MS specialist.

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

N/A

## **DIFLUCAN (FLUCONAZOLE)**

### **Affected Drugs**

FLUCONAZOLE

### **Covered Uses**

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

### **Coverage Duration**

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

### **Other Criteria**

Criteria only applies to the 50, 100 and 200 mg tablets (not the 150-mg tablet) and oral suspension. Tinea corporis and tinea versicolor after a trial of a topical antifungal agent, except for extensive conditions. Tinea cruris, manuum, pedis, and faciei after a trial of a topical antifungal agent. Onychomycosis. Approve fluconazole tablets or oral suspension for if the patient has tried terbinafine tablets or itraconazole capsules unless the patients has a medical condition or other clinical reason to not utilize these agents (e.g., drug-drug interactions, heart failure).

## **ENBREL**

### **Affected Drugs**

ENBREL®

### **Covered Uses**

### **Exclusion Criteria**

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Plaque psoriasis. Prescribed by a dermatologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

## **EPOETIN/PROCRIT**

### **Affected Drugs**

PROCRIT®

### **Covered Uses**

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

### **Exclusion Criteria**

Anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis. Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), 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. To treat orthostatic hypotension in patients with anemia. To treat thalassemia-related anemia. As an adjunct to bone marrow transplantation (BMT) for donors. Use as an adjunct to blood donation for autologous use. Treatment of anemia associated with epidermolysis bullosa. Treatment of anemia in systemic lupus erythematosus. Treatment of anemia in rheumatoid arthritis. Treatment of anemia in inflammatory bowel disease (eg, ulcerative colitis, Crohn's disease). Treatment of anemia in diabetes mellitus. Hemochromatosis. Anemia in patients due to acute blood loss. Non-anemic pts (Hb more than 13.0 g/dL) prior to surgery. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

CRF anemia. Hemoglobin (Hb) of less than or equal to 11.0 g/dL to start. Hb less than or equal to 12.0 g/dL if previously on epoetin alfa (EA) or Aranesp. Anemia w/myelosuppressive chemotx. Hb immediately prior to EA is 10.0 g/dL or less (or hematocrit [Hct] is 30% or less). EA maintenance is starting dose if Hb level remains 10.0 g/dL or less (or Hct remains 30% or less) 4 wks after start and Hb rise is 1.0 g/dL or more (Hct rise is 3% or more). Pts w/Hb rises less than 1.0 g/dL (Hct rise less than 3%) vs pretx baseline over 4 wks of tx and Hb is less than 10.0 g/dL after 4 wks of tx (Hct is less than 30%), the recommended FDA starting dose may be increased once by 25%. Continued use is not reasonable/necessary if Hb rises less than 1.0 g/dL (Hct rise less than 3%) vs pretx baseline by 8 wks of tx. 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 wks of tx 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, approve if Hb is 12.0 g/dL or less. Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HF, approve for New York Heart Association functional class III or IV pts w/Hb 10.0 g/dL or less and per MD underlying anemia causes persist despite transfusions or pt has contraindications to transfusions. Addtl tx allowed if pt has Hb of 12.0 g/dL or less. Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV (+/- zidovudine), Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 units/mL or less at tx start. Previously on EA approve if Hb is 12.0 g/dL or less. Anemia due to ribavirin for Hep C, Hb is 10.0 g/dL or less at tx start. Aplastic anemia, Hb is 12.0 g/dL or less. Previously on EA approve if Hb is 12.0 g/dL or less. All conds, deny if Hb exceeds 12.0 g/dL.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

### **Coverage Duration**

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

### **Other Criteria**

Anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Pts 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 wks therapy, the recommended FDA dose may be increased once by 25%. Continued epoetin alfa use is not reasonable or necessary if the Hb rise is less than 1.0 g/dL (or Hct is less than 3%)

compared to pretreatment baseline by 8 weeks of treatment. Continued epoetin alfa administration is not reasonable and necessary if there is a rapid rise in Hb or more than 1.0 g/dL (or Hct more than 3%) over 2 weeks of treatment unless the Hb remains below or subsequently falls to less than 10.0 g/dL (or Hct less than 30%). Continuation and reinstatement of epoetin alfa must include a dose reduction of 25% from the previously administered dose.

## **FABRAZYME**

### **Affected Drugs**

FABRAZYME®

### **Covered Uses**

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

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

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

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

# **FORTEO**

## **Affected Drugs**

FORTEO®

## **Covered Uses**

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

## **Exclusion Criteria**

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

## **Required Medical Information**

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

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

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

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

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

# **GROWTH HORMONES**

## **Affected Drugs**

OMNITROPE®

TEV-TROPIN®

## **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

Child w/acquired GH deficiency (DF). 1 documented GH stimulation test (levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon) shows diminished serum GH response of less than 10 ng/mL AND baseline height (Ht) less than the 3rd percentile for gender/age AND pretx Ht velocity (VEL) in child less than 3 yrs of less than 7 cm/yr and in child greater than or equal to 3 yrs of less than 4 cm/yr OR child of any age growth VEL less than the 10th percentile for age/gender based on at least 6 mos of data. Child had brain radiation does not have to meet baseline Ht criteria. Congenital hypopituitarism does not have to meet Ht or growth VEL criteria. Child w/hypophysectomy does not have to meet any criteria. Adolescents (diagnosed as child with GH DF or with idiopathic short stature [ISS]) with prior GH use and aged 16 yrs or older, growth rate (GR) must be at least 2.5 cm/yr in recent yr. Review pts annually for

this GR(does not apply to documented hypopituitarism).Further approval is not recommended if GR is less than 2.5 cm/yr.Adolescents, young adults with ISS who completed linear growth (GR less than 2 cm/year), review for txment of adult GH DF.Non-GH deficient short stature (ISS) child w/open epiphyses.6 mo trial.Baseline Ht less than 3rd percentile (ie, greater than 2 SD below the mean for gender/age AND pretx Ht VEL in child less than 3 yrs of less than 7 cm/yr and in child greater than or equal to 3 yrs of less than 4 cm/yr OR child of any age growth VEL less than the 10th percentile for age/gender based on at least 6 mos of data AND pediatric endocrinologist (PE) must certify child's basic activities of daily living is limited by short stature and child has a condition for which GH is effective (or may be effective during the initial trial of tx) AND PE must certify based on bone-age x-ray, predicted adult Ht is less than 3rd percentile.Authorization for cont tx based on adequate clinical response (an annualized GR that doubles in comparison to previous yr).

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

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

### **Coverage Duration**

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

### **Other Criteria**

Therapy should be discontinued if there is no significant increase in growth rate during the first year. Adult GH deficiency. 1 of the following diagnoses Adult onset (GH alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage) OR Childhood-onset AND must have a negative response to 1 standard GH stimulation test as follows, 1 of the following stimulation tests must be used (insulin tolerance, glucagon, GH releasing hormone (GHRH) plus arginine, or GHRH plus GH releasing peptide (GHRP-6).Arginine alone may be used in non-obese adolescents with childhood onset. Cutoff values for GH peak for each test are For the insulin tolerance or glucagon peak less than 3 mcg/L, For GHRH plus arginine, peak less than 11 mcg/L with BMI less than 25 kg/m<sup>2</sup> or less than Patients will be evaluated by a pharmacist and/or a physician on a case-by-case basis for more than 4 wks of therapy or more than one 4-wk course per yr. Adults with HIV infection with wasting or cachexia.All of the following, HIV-positive and have wasting or

cachexia AND have 1 of the following, documented unintentional weight loss of greater than or equal to 10% from baseline OR weight less than 90% of the lower limit of ideal body weight OR BMI less than or equal to 20 kg/m<sup>2</sup> AND must be able to consume or be fed through parenteral or enteral feedings greater than or equal to 75% of maintenance energy requirements based on current body weight AND must have been on antiretroviral therapy for greater than or equal to 30 days prior to beginning GH therapy and will continue antiretroviral therapy throughout the course of GH treatment AND Therapy with GH is limited to 24 weeks. Repeat 12 or 24-week courses of GH may be authorized in patients who have received a previous 12 or 24-week course of GH for HIV infection with wasting or cachexia provided that they have been off GH for at least 1 month and meet all of the previous criteria. HIV-associated failure to thrive. Child less than 17 yrs AND must be able to consume or be fed through parenteral or enteral feedings greater than or equal to 75% of maintenance energy requirements based on current body weight AND has been on antiretroviral therapy for greater than or equal to 30 days prior to beginning GH therapy and will continue antiretroviral tx.

# **HUMIRA**

## **Affected Drugs**

HUMIRA®

## **Covered Uses**

## **Exclusion Criteria**

## **Required Medical Information**

N/A

## **Age Restrictions**

## **Prescriber Restrictions**

Plaque psoriasis. Prescribed by a dermatologist.

## **Coverage Duration**

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

## **Other Criteria**

Adults with RA, approve if the patient has tried 1 DMARD or is concurrently receiving MTX. Adults with Crohn's disease to induce remission. Approve if patient has tried corticosteroids or if corticosteroids are contraindicated or if patient currently on corticosteroids. Adults with Crohn's disease to maintain remission. Patient has received 2 doses or 12 wks of adalimumab and has responded or if has not received adalimumab for induction of remission then authorize if patient has tried azathioprine, 6-mercaptopurine, or MTX or if patient has tried infliximab or certolizumab pegol. Plaque psoriasis in patients without psoriatic arthritis. Pt has chronic (greater than or equal to 1 year) plaque psoriasis AND pt has tried a systemic therapy (e.g., MTX, azathioprine, cyclosporine, Soriatane, Prograf, Enbrel, Raptiva, Amevive, Remicade, Cellcept, 6-thioguanine, sulfasalazine, hydroxyurea, propylthiouracil, UVB, OR oral methoxsalen plus UVA light [PUVA]) for psoriasis. Rarely, a pt may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA if they have plaque psoriasis of palms, soles, head and neck, nails, intertriginous areas or genitalia. Patient has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with

less than 5% BSA if they have had an inadequate response to either topical therapy OR localized phototherapy, and had an inadequate response to systemic therapy, and had significant disability or impairment in physical or mental functioning according to the treating physician. JIA or JRA, polyarticular course. Approve if the patient has tried MTX or will be starting on Humira concurrently with MTX. Approve without trying MTX if the patient has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias).

## **INCRELEX**

### **Affected Drugs**

INCRELEX®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

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

### **Age Restrictions**

Children age not specified.

### **Prescriber Restrictions**

pediatric endocrinologist or after consultation with pediatric endocrinologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

# **KINERET**

## **Affected Drugs**

KINERET®

## **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

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

### **Other Criteria**

Adults with RA. Approve if the patient has tried Humira, Enbrel, or Remicade for at least 2 months. JIA, JRA (regardless of onset), approve if pt has tried Enbrel, Humira, or Orencia. Systemic onset of JIA, approve if pt has tried a systemic corticosteroid. Ankylosing spondylitis, approve if the pt has tried Enbrel, Remicade, or Humira. Adult with Still's disease, approve if pt has tried one DMART or is currently receiving MTX. MWS, approve if pt has tried two other drugs (Arcalyst, colchicine, corticosteroids, chlorambucil, antihistamines, dapsone, azathioprine, CellCept). FCAS, approve if pt has tried two other drugs (eg, colchicine, corticosteroids, antihistamines, azathioprine, Cellcept, Arcalyst). Schnitzler's syndrome, approve if pt has tried one other prescriber medication used in Schnitzler's syndrome. Acute gout, pt has tried 2 standard therapies for acute gout (eg, NSAIDs, colchicine, corticosteroid) or pt cannot tolerate or has contraindications to standard therapies. FMF, approve in pts who have tried colchicine. TRAPS, approve in patients who have tried colchicine.

## **LAMISIL**

### **Affected Drugs**

LAMISIL®  
TERBINAFINE HCL

### **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Physician must consider onychomycosis to be medically significant.

### **Coverage Duration**

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

### **Other Criteria**

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

## **LEUPROLIDE (LONG ACTING)**

### **Affected Drugs**

ELIGARD®

LUPRON DEPOT®

LUPRON DEPOT-PED®

### **Covered Uses**

### **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 mos.

### **Other Criteria**

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

## **LIDODERM**

### **Affected Drugs**

LIDODERM®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

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

## **NEULASTA**

### **Affected Drugs**

NEULASTA®

### **Covered Uses**

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

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **NEUPOGEN**

### **Affected Drugs**

NEUPOGEN®

### **Covered Uses**

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

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

# **ORENCIA**

## **Affected Drugs**

ORENCIA®

## **Covered Uses**

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

## **Exclusion Criteria**

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

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

Adults with rheumatoid arthritis approve if the patient has tried one DMARD (oral or injectable) for at least 2 months, [this includes patients who have tried other biologic DMARDs for at least 2 months] OR approve if the patients is concurrently receiving MTX. Juvenile idiopathic arthritis (JIA) [or JRA], polyarticular course approve if the patient has tried MTX or will be starting on abatacept concurrently with MTX, approve without trying MTX if the patient has an absolute contraindication to MTX.

## **PEGYLATED INTERFERONS**

### **Affected Drugs**

PEGASYS®

### **Covered Uses**

#### **Exclusion Criteria**

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

#### **Required Medical Information**

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

#### **Age Restrictions**

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

#### **Prescriber Restrictions**

#### **Coverage Duration**

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

#### **Other Criteria**

A. Patient not previously treated for hep C with interferon/peginterferon alfa. Obtain Hep C genotype and HCV RNA titer before starting therapy (HCV RNA not required for

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

## **PENLAC**

### **Affected Drugs**

CICLOPIROX

### **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

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

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Physician must consider onychomycosis to be medically significant.

### **Coverage Duration**

Authorization will be for up to 48 weeks.

### **Other Criteria**

N/A

# **PROVIGIL**

## **Affected Drugs**

PROVIGIL®

## **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

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

### **Age Restrictions**

Adjunctive augmentation treatment for depression must be in adults.

### **Prescriber Restrictions**

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

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

Excessive sleepiness due to OSAHS if the patient has tried CPAP. Excessive sleepiness due to SWSD if the patient is working at least 5 overnight shifts per month. ADHD/ADD for patients who have tried two alternative medication for ADHD/ADD from two different classes as follows: methylphenidate products (e.g., methylphenidate, dexamethylphenidate), amphetamines (e.g., mixed amphetamine salts, dextroamphetamine), atomoxetine, bupropion or tricyclic antidepressants (TCAs e.g.,

imipramine, desipramine). Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression. Idiopathic hypersomnia if the diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center). Spasticity due to cerebral palsy, approve if patient has tried one other agent for spasticity (eg, benzos, baclofen, dantrolene, tizanidine, or botulinum toxin).

## **REBIF**

### **Affected Drugs**

REBIF®

### **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Prescribed by or after consultation with a neurologist or an MS specialist.

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

# **REGRANEX**

## **Affected Drugs**

REGRANEX®

## **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

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

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

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

## **REMICADE**

### **Affected Drugs**

REMICADE®

### **Covered Uses**

#### **Exclusion Criteria**

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

#### **Required Medical Information**

N/A

#### **Age Restrictions**

N/A

#### **Prescriber Restrictions**

Plaque psoriasis. Prescribed by a dermatologist.

#### **Coverage Duration**

CD (w/ or w/out fistulas)=12 wks for induction. All other conds=12mos.

#### **Other Criteria**

## **REVATIO**

### **Affected Drugs**

REVATIO®

### **Covered Uses**

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

### **Exclusion Criteria**

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

## **RITUXAN**

### **Affected Drugs**

RITUXAN®

### **Covered Uses**

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Adult with RA. Prescribed by a rheumatologist or in consultation with a rheumatologist.

### **Coverage Duration**

RA.Approve 2 doses.6 mos or more after, approve 2 more doses if response per MD.Other conds=12 mos.

### **Other Criteria**

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

## **SOMAVERT**

### **Affected Drugs**

SOMAVERT®

### **Covered Uses**

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

### **Exclusion Criteria**

Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

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

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

## **SPORANOX**

### **Affected Drugs**

ITRACONAZOLE

### **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

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

### **Other Criteria**

Tinea corporis after a trial of a topical antifungal agent, except for extensive conditions. Tinea cruris, faciei, manuum, imbricata, and pedis (nonmoccasin or chronic type) after a trial of a topical antifungal agent. Tinea or pityriasis versicolor after trial of a topical antifungal agent, except for extensive conditions. Treatment of vaginal candidiasis after a trial of oral fluconazole.

## **SYMLIN**

### **Affected Drugs**

SYMLIN®

SYMLINPEN 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**

#### **Exclusion Criteria**

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

#### **Required Medical Information**

N/A

#### **Age Restrictions**

N/A

#### **Prescriber Restrictions**

N/A

#### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

#### **Other Criteria**

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

## **TOPAMAX/ZONEGRAN**

### **Affected Drugs**

TOPIRAMATE  
ZONISAMIDE

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **TOPICAL TRETINOIN PRODUCTS**

### **Affected Drugs**

TRETINOIN

### **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

For the treatment of other non-cosmetic conditions exceptions can be made if the patient has tried at least 1 other therapy (eg, dermatitis/eczema, folliculitis, milia, keratosis pilaris, sebaceous hyperplasia/cyst, basal cell carcinoma [skin cancer], confluent and reticulated papillomatosis). Coverage of the combination clindamycin plus tretinoin (Ziana) is recommended for acne vulgaris ONLY and all other indications are not recommended.

# **TYSABRI**

## **Affected Drugs**

TYSABRI®

## **Covered Uses**

All FDA approved indications not otherwise excluded from Part D.

## **Exclusion Criteria**

Concurrent use of another immunomodulator (eg, Rebif, Betaseron, Copaxone or Avonex) in MS patients. MS patients with chronic progressive MS. Concurrent use with immunosuppressants (eg, 6MP, azathioprine, CSA, MTX) or TNF alfa inhibitors (eg, Remicade, Humira, Cimzia) in CD patients. Ulcerative colitis. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

N/A

## **Age Restrictions**

Adults.

## **Prescriber Restrictions**

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

## **Coverage Duration**

Authorization will be for 12 months.

## **Other Criteria**

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

## **VFEND**

### **Affected Drugs**

VFEND®

### **Covered Uses**

#### **Exclusion Criteria**

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

#### **Required Medical Information**

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

#### **Age Restrictions**

N/A

#### **Prescriber Restrictions**

N/A

#### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

#### **Other Criteria**

N/A

# **XOLAIR**

## **Affected Drugs**

XOLAIR®

## **Covered Uses**

### **Exclusion Criteria**

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

### **Required Medical Information**

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

### **Age Restrictions**

Moderate to severe persistent asthma, patient is at least 6 y/o. SAR/PAR, patient is at least 12 y/o.

### **Prescriber Restrictions**

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

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

Pts with moderate to severe persistent asthma must meet all criteria prescribed by or in consultation with an allergist, immunologist, or pulmonologist AND baseline IgE of at least 30 IU/mL AND pt has a positive skin test or in vitro testing AND/OR for 1 or

more seasonal aeroallergens AND patient's asthma symptoms have not been adequately controlled by inhaled corticosteroids AND patient is at least 6 y/o. Pts with SAR/PAR must meet the following criteria prescribed by an allergist, immunologist, or pulmonologist AND baseline IgE level at least 30 IU/mL AND pt has positive skin testing and/or positive in vitro testing (ie, a blood test for allergen-specific IgE antibodies) for 1 or more relevant allergens AND the patient is at least 12 y/o.

## **ZYVOX**

### **Affected Drugs**

ZYVOX®

### **Covered Uses**

#### **Exclusion Criteria**

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

#### **Required Medical Information**

VRE, cultures must be done. Methicillin-resistant Staphylococcus, cultures must be done.

#### **Age Restrictions**

N/A

#### **Prescriber Restrictions**

N/A

#### **Coverage Duration**

Authorization will be for one fill up to one month.

#### **Other Criteria**

N/A

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