



## **UCARE FOR SENIORS STANDARD D (HMO-POS) 2012 PA CRITERIA**

*UCare* requires your physician to get prior authorization for certain drugs. This means that you will need to get approval from *UCare* before you fill your prescriptions. If you don't get approval, *UCare* may not cover the drug.

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## **ACTEMRA**

### **Affected Drugs**

ACTEMRA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Systemic-onset juvenile idiopathic arthritis (JIA). Castleman's disease. Still's disease. Plus patients already started on tocilizumab for a Covered Use.

### **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 types other than systemic onset, and Crohn's disease. Coverage is not recommended for circumstances not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

For indication of systemic-onset JIA, may approve for children and adolescents 18 years of age or younger. For indication of rheumatoid arthritis (RA) and Still's disease, approve for adults.

### **Prescriber Restrictions**

For adults with RA, tocilizumab is to be prescribed by a rheumatologist or in consultation with a rheumatologist. For systemic-onset JIA, tocilizumab is to be prescribed by a rheumatologist. For Castleman's disease, approve if patient is under the care of an oncologist or hematologist.

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

Adults with RA, approve for patients who have tried for at least 2 months or who were intolerant to one of the following TNF antagonists , adalimumab, certolizumab pegol, etanercept, golimumab, or infliximab. Systemic-onset JIA, approve for patients who have tried a systemic corticosteroid, and either MTX or sulfasalazine or another DMARD such as etanercept. Adult with Still's disease, approve for patients who tried a

corticosteroid and had an inadequate response to one non-biologic DMARD, such as methotrexate, after at least a 2 month trial or was intolerant to the non-biologic DMARD.

## **ADCIRCA/REVATIO**

### **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 pulmonary arterial hypertension (PAH), approve if patient has had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. For patients currently receiving sildenafil or tadalafil, approve if patient has a diagnosis of PAH.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

For PAH, 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

## **ALPHA-1 PROTEINASE INHIBITORS**

### **Affected Drugs**

ARALAST NP®  
GLASSIA®  
PROLASTIN C®  
PROLASTIN®  
ZEMAIRA®

### **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 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 if patient is a smoker and continues to smoke while on alpha-1 proteinase inhibitor or for anything not listed under Covered Uses.

### **Required Medical Information**

For AAT deficiency with emphysema (or COPD), 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 deficiency with emphysema (or COPD), 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, 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**

For indication of 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**

For PP/PsA/LP, approval is for 12 weeks. For Hand/Foot Psoriasis, approval is for 16 weeks. Approvable for 2nd course (exc LP), if off Amevive for 12 or 16 weeks, 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 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. LP, patient has tried two other systemic therapies (photochemotherapy, acitretin, oral corticosteroid, mycophenolate mofetil, azathioprine, cyclosporine, oral tacrolimus, or MTX).

## **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**

For MS, dalfampridine is to be prescribed by, or in consultation with, an MS specialist.

### **Coverage Duration**

Initial approval for MS is for 90 days. Subsequent authorization for 12 months if patient had a response.

### **Other Criteria**

For initial approval for MS, authorize for 90 days. After up to 90 days of dalfampridine extended-release therapy, if MS 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®

OXANDRIN®

OXANDROLONE

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus oxandrolone for inclusion body myositis sporadic form, ALS 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**

For indication of Turners' Syndrome or Ullrich-Turner Syndrome, may approve for girls aged 8 years and older.

### **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). Anemia in heart failure (HF). Anemia of chronic disease/anemia of chronic inflammation (eg, anemia in inflammatory bowel disease [ulcerative colitis, Crohn's disease], rheumatoid arthritis, systemic lupus erythematosus).

### **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), or erythroid cancers. Anemia of cancer not related to cancer treatment. Any anemia associated only with radiotherapy. Prophylactic use to prevent chemotherapy-induced anemia. Prophylactic use to reduce tumor hypoxia. Use in patients with erythropoietin-type resistance due to neutralizing antibodies. Anemia due to cancer treatment if patients have uncontrolled hypertension. To enhance athletic performance. Anemia in patients due to acute blood loss. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Anemia w/CRF. 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 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. 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 Hep 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**

For chemotherapy, approval is for chemotherapy treatment + 8 weeks after last chemotherapy treatment. For ribavirin therapy and CRF, approval is for 12 months. For MDS, approval is for 6 months. For HF, initial approval is for 2 months. For chronic disease, initial approval is for 3 months.

### **Other Criteria**

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. 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. Anemia in HF, approve initial trial of up to 2 months for patients with more severe HF, Hb of 10.0 g/dL or less, anemia persists despite transfusions or pt has contraindications to transfusions. Deny if

Hb is more than 12.0 g/dL. Further approval after initial course will be determined on a case-by-case basis after evaluation by a pharmacist and/or physician. Anemia of chronic disease, approve initial trial of 3 months for patients with symptomatic anemia of 10.0 g/dL or less, anemia persists despite transfusions or cannot tolerate or undergo transfusions, and/or low erythropoietin levels or failure of other treatment modalities (eg, iron supplementation). Other causes of anemia have been ruled out. Deny if Hb is more than 12.0 g/dL. Further approval after initial course will be determined on a case-by-case basis after evaluation by a pharmacist and/or physician.

## **ARCALYST**

### **Affected Drugs**

ARCALYST®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus patient already started on rilonacept 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). Rilonacept 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**

For MSW/FCAS, initial approval is for 2 months with subsequent authorization for 12 months if patient had a response.

### **Other Criteria**

Patients already started on rilonacept for MWS/FCAS may receive 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. Plus patients with a diagnosis of secondary progressive MS and currently on Avonex.

### **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**

N/A

### **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**

ANZEMET®  
AREDIA®  
ATGAM®  
AZASAN®  
AZATHIOPRINE  
CALCIJEX®  
CALCITRIOL  
CARIMUNE NF®  
CARNITOR®  
CELLCEPT®  
CESAMET®  
CUBICIN®  
CYCLOPHOSPHAMIDE  
CYCLOSPORINE  
CYCLOSPORINE MODIFIED  
DRONABINOL  
EMEND®  
ENGERIX-B®  
GAMMAGARD LIQUID®  
GAMUNEX®  
GENGRAF  
GRANISETRON HCL  
GRANISOL  
HECTOROL®  
HEPARIN SODIUM  
MURAN®  
LEVOCARNITINE  
MARINOL®  
MIACALCIN®  
MITOXANTRONE  
MYCOPHENOLATE MOFETIL  
MYFORTIC®  
NEORAL®  
NOVANTRONE®  
ONDANSETRON  
ORTHOCLONE OKT-3®  
PAMIDRONATE DISODIUM

PRIVIGEN®  
PROGRAF®  
PULMOZYME®  
RAPAMUNE®  
RECOMBIVAX HB®  
ROCALTROL®  
SANDIMMUNE®  
SIMULECT®  
TACROLIMUS  
TOBI®  
VANCOMYCIN HCL  
ZEMPLAR®  
ZOFRAN®  
ZORTRESS®  
ZUPLENZ®

**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.

## **BANZEL**

### **Affected Drugs**

BANZEL®

### **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**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

Previous trial or concurrent use of felbamate, lamotrigine, or topiramate with an inadequate response.

## **BETASERON/EXTAVIA**

### **Affected Drugs**

BETASERON®  
EXTAVIA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus patients with a diagnosis of secondary progressive MS and currently on Betaseron.

### **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**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

For patients requesting Extavia, approve if the patient has previously tried Betaseron.

## **BYETTA/VICTOZA**

### **Affected Drugs**

BYETTA®  
VICTOZA®

### **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

## **CHORIONIC GONADOTROPINS (HCG)**

### **Affected Drugs**

CHORIONIC GONADOTROPIN  
NOVAREL  
PREGNYL®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Preoperative use in male infants/toddlers with hypospadias and chordee OR with total epispadias and bladder exstrophy.

### **Exclusion Criteria**

Use in the management of infertility (diagnosis or treatment) in males or females, obesity, prevention of recurrent or habitual miscarriage, or treatment or prevention of breast cancer. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

For indication of prepubertal cryptorchidism, approve for child or adolescent. For indication of hypospadias or epispadias, approve for infant or toddler.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless noted otherwise.

### **Other Criteria**

Hypogonadotropic hypogonadism in males. Preoperative use for hypospadias and chordee OR total epispadias and bladder exstrophy in male infants or toddlers.

## **CINRYZE**

### **Affected Drugs**

CINRYZE®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus for the acute treatment of Hereditary Angioedema (HAE).

### **Exclusion Criteria**

Coverage is not recommended for circumstances not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Must be prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

N/A

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

### **Affected Drugs**

ADVAIR DISKUS®  
ADVAIR HFA®  
DULERA®  
SYMBICORT®

### **Covered Uses**

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

### **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**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **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 spondyloarthropathy (JS). Undifferentiated spondyloarthritis (undifferentiated arthritis)(US/UA). Reactive arthritis (Reiter's disease). Still's disease (SD). Uveitis (noninfectious). Scleritis or sterile corneal ulceration (SCU). Chronic inflammatory demyelinating polyneuropathy (CIDP). Myasthenia gravis (MG). Graft versus host disease (GVHD). Behcet's disease. Giant cell arteritis (GCA). Polymyalgia rheumatica (PMR). Pyoderma gangrenosum (PG). Autoimmune mucocutaneous blistering diseases (pemphigus vulgaris, mucous membrane pemphigoid [cicatricial pemphigoid]) (AMBD). Systemic sclerosis (scleroderma) with inflammatory joint involvement. Tumor necrosis factor receptor-associated periodic syndrome (TRAPS).

### **Exclusion Criteria**

Concurrent use with adalimumab, alefacept, anakinra, abatacept, certolizumab pegol, ustekinumab, infliximab, rituximab, golimumab, or tocilizumab. 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 indication of Still's disease and rheumatoid arthritis (RA), approve for adults. For uveitis (non-infectious), approve for children aged less than 18 years. For juvenile idiopathic arthritis (JIA) 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, Tried 1 DMARD for 2 mos (includes other biologic DMARDs for at least 2 mos), or is concurrently receiving methotrexate (MTX). JIA/JRA, polyarticular course, tried MTX or will be starting on etanercept concurrently with MTX. Approve without trying MTX if pt has an absolute contraindication to MTX. Plaque psoriasis (PP). Pt has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5% BSA if they have PP of palms, soles, head and neck, nails, intertriginous areas or genitalia. Pt has a minimum BSA of 5% or more, exceptions allowed for patients with less than 5% BSA if they have had an inadequate response to a 2-mo trial of either topical therapy (tx) OR localized phototherapy (ultraviolet B [UVB] or oral methoxsalen plus UVA light [PUVA]), and had inadequate response to 2-mo trial of systemic tx (with one of the following- MTX, cyclosporine (CSA), acitretin, 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. Pt has tried a systemic tx (MTX, CSA, acitretin, adalimumab, alefacept, infliximab, or ustekinumab) or phototherapy (UVB or PUVA) for 2 mos. Rarely, a pt may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. JS. Tried 1 other DMARD. Reactive arthritis. Tried an NSAID and 1 DMARD. SD. Tried a corticosteroid (CS) and had inadequate response to 1 of these txs: periocular, intraocular or a systemic CS, immunosuppressant (eg, MTX, mycophenolate mofetil (MM), azathioprine (AZA), cyclophosphamide (CPM), or CSA), or adalimumab or infliximab for this condition. Scleritis/SCU. Tried one other tx (eg, oral, topical/ophthalmic or IV CS, MTX, topical/ophthalmic NSAID, CSA, CPM) for these conditions. CIDP. Tried two of the following- IVIG, systemic CS, plasmapheresis, AZA, CSA, CPM, interferon alfa. MG. Approve if receiving CS and have received 1 other immunosuppressant (eg, AZA, CSA, CPM, MM). GVHD. Tried or currently is receiving with etanercept 1 conventional GVHD tx (high-dose SC, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Behcet's. Have not responded to at least 1 conventional tx (eg, CS, immunosuppressant, interferon alfa, etc) or adalimumab or infliximab. GCA. Tried CS but are unable to withdraw systemic CS tx. PMR. Tried CS but unable to reduce dose or withdraw CS tx. PG. Tried 1 other systemic tx (eg, systemic CS or immunosuppressant (AZA, 6-mercaptopurine, CSA, CPM, chlorambucil), infliximab, adalimumab) for at least 2 mos or a 2-mo trial of intralesional CS injections or CSA for localized PG. AMBD.

Tried conventional tx (systemic CS AND immunosuppressant (eg, AZA, CPM, dapsone, MTX, CSA, MM) or has contraindications to conventional tx. Systemic sclerosis. Tried an NSAID AND at least one DMARD. TRAPS. Tried CS.

## **EPOGEN/PROCRIT**

### **Affected Drugs**

EPOGEN®  
PROCRIT®

### **Covered Uses**

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

### **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), 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 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 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 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. An additional 6 months allowed after first 6 months if Hb is 12.0 g/dL or less. Anemia in HIV (with or without 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. All conds, deny if Hb exceeds 12.0 g/dL.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

For AA, epoetin alfa is to be prescribed by a hematologist.

### **Coverage Duration**

For chemotherapy, approval is for chemotherapy treatment + 8 weeks after last chemotherapy treatment. For ribavirin therapy and CRF, approval is for 12 months. For MDS, approval is for 6 months. For HF, initial approval is for 2 months. For chronic disease, initial approval is for 3 months. For AA, approval is for 1 month. For other, approval is for 12 months.

### **Other Criteria**

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. 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. Continuation and reinstatement of Aranesp must include a dose reduction of 25% from the previously administered dose. Anemia in HF, approve initial trial of up to 2 months for patients with more severe HF, Hb of 10.0 g/dL or less, anemia persists despite transfusions or pt has contraindications to transfusions. Deny if Hb is more than 12.0 g/dL. Further approval after initial course will be determined on a case-by-case basis after evaluation by a pharmacist and/or physician. Anemia of chronic disease, approve initial trial of 3 months for patients with symptomatic anemia of 10.0 g/dL or less, anemia persists despite transfusions or cannot tolerate or undergo transfusions, and/or low erythropoietin levels or failure of other treatment modalities (eg, iron supplementation). Other causes of anemia have been ruled out. Deny if Hb is more than 12.0 g/dL. Further approval after initial course will be determined on a case-by-case basis after evaluation by a pharmacist and/or physician. Treatment of AA, approve initial trial of up to 1 month for patients with symptomatic anemia of less than 11.0 g/dL. Deny if Hb is more than 12.0 g/dL. Further approval after initial course will be determined on a case-by-case basis after evaluation by a pharmacist and/or physician.

## **FENTANYL**

### **Affected Drugs**

ABSTRAL®  
ACTIQ®  
FENTANYL CITRATE  
FENTORA®  
ONSOLIS®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

Breakthrough pain in patients with cancer or other terminal pain AND Patient is opioid tolerant (has been on morphine 60mg/day, fentanyl patch 25mcg/hr, oxycodone 30mg/day, hydromorphone 8mg/day or an equianalgesic dose fo another opioid for a week or longer).

## **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.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Prescribed by a neurologist or an MS specialist.

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

For use in MS, patient has a relapsing form of MS 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 and have a relapsing form of MS will receive authorization, they are not required to try an interferon beta product or glatiramer acetate.

## **GROWTH HORMONES**

### **Affected Drugs**

GENOTROPIN®  
HUMATROPE®  
NORDITROPIN FLEXPRO®  
NORDITROPIN NORDIFLEX®  
NUTROPIN AQ NUSPIN®  
NUTROPIN AQ®  
NUTROPIN®  
OMNITROPE®  
SAIZEN®  
SEROSTIM®  
TEV-TROPIN®  
ZORBTIVE®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Growth hormone (GH) deficiency (DF) (except Serostim and Zorbtive). Non-GH deficient short stature (idiopathic short stature, ISS) (except Serostim and Zorbtiv). Turner's syndrome (TS) (except Serostim and Zorbtive). SHOX (short stature homeobox-containing gene) deficiency (except Serostim and Zorbtive). Chronic renal insufficiency (CRI) (except Serostim and Zorbtive). Prader-Willi syndrome (PW) (except Serostim and Zorbtive). Short child born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) including those with Silver-Russell syndrome (except Serostim and Zorbtive). Noonan syndrome (NS) (except Serostim and Zorbtive). Short bowel syndrome (SBS) (except Serostim). Human Immunodeficiency Virus (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, bone marrow transplant (BMT) 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 BMT, Crohn's disease, cystic fibrosis, dilated cardiomyopathy/heart failure, end-stage renal disease 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 GH DF initial tx, eval by pediatric endocrinologist (PE), documented GH stim test (levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon) w/GH response less than 10 ng/mL AND baseline height (Ht) less than the 3rd percentile (pct) for gender/age AND pretx Ht growth rate (GR) child less than 3 yrs of less than 7 cm/yr and child greater than or equal to 3 yrs of less than 4 cm/yr OR child any age GR less than the 10th pct for age/gender based on min 6 mos of data. Child w/brain radiation does not have to meet baseline Ht crit. Congenital hypopituitarism does not have to meet Ht or GR crit. Child w/hypophysectomy, approve. Child/adolesc GH DF cont tx, GR increased by 2.5 cm/yr or more in most recent yr (MRY) per MD AND epiphyses open (older than 12 yrs), both crit exclude adolesc w/hypopituitarism. Review GR annually (not applied to hypopituitarism). Adoles/young adult w/completed linear growth (GR less than 2 cm/yr), review for adult GH DF. Greater than 18 yrs, auth not allowed if midparental ht attained. ISS child w/open epiphyses, 6 mo trial if baseline Ht less than 3rd pct (greater than 2 SD below mean for gender/age) AND pretx GR child less than 3 yrs of less than 7 cm/yr and child greater than or equal to 3 yrs of less than 4 cm/yr OR child any age GR less than the 10th pct for age/gender based on min 6 mos of data AND PE certifies child's basic activities of daily living limited by SS and has condition which GH is/may be effective AND PE certifies via bone-age x-ray, predicted adult Ht less than 3rd pct. Auth after initial tx (auth for 12 mos) based on adequate clinical response (annualized GR doubles). Cont tx (after 12 to 18 mos), GR increased by 2.5 cm/yr or more in MRY per MD AND epiphyses open (older than 12 yrs). Greater than 18 yrs, auth not allowed if midparental ht attained. Adult GH DF or PW/trans adoles, eval by or in consultation w/endocrinologist (start and annually). NS/SGA/SHOW/child PW, eval by PE. CRI, eval by PE or nephrologist.

### **Age Restrictions**

For indication of TS, children. For indication of SHOX/CRI/NS, children/adolescents. For indication of SGA, children aged 2 to 8. For HIV failure to thrive, children less than 17. For SBS/HIV cachexia/wasting, adults.

### **Prescriber Restrictions**

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

## Coverage Duration

For GH DF, approval is for 12 months. For SBS, approval is for 4 weeks per year. For Non-GH DF ISS, approval is for 6 months. For HIV cachexia/wasting, approval is for 24 weeks. For HIV failure to thrive, approval is for 12 weeks.

## Other Criteria

Adult GH DF (start), document diagnosis of GH DF due to adult-onset (GH alone or multiple hormone deficiencies/hypopituitarism from pituitary dz, hypothalamic dz, surgery, cranial radiation tx, tumor txment, traumatic brain injury, or subarachnoid hemorrhage) or due to childhood-onset (GH not rec in adults who had GH tx as child for uses not due to GH DF) AND negative response to 1 GH stim 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] (exclude stim test for childhood-onset due to mutations, lesions, congenital defects), transition adoles 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. TS start, female and has short stature (SS). SHOX start, open epiphyses. CRI w/growth failure (GF), start, approve. Child PW w/GF or adult PW, approve. NS start, baseline ht less than 3rd percentile. TS/SHOX/CRI/child PW/NS, cont tx, GR increased by 2.5 cm/yr or more in most recent yr (MRY) AND epiphyses open. SGA/IUGR start, born SGA AND no sufficient catch-up growth before age 4 yr, AND age 2 to 8 yrs, if older than 8 yrs, approve 1 yr trial if prepubertal, AND baseline ht less than 3rd percentile for gender/age. Cont tx, GR increased by 2.5 cm/yr or more in most recent, if aged 2 to 8 yrs, or by 3 or more cm/yr if older than 8 yrs and prepubertal. HIV 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 tx greater than or equal to 30 days prior to beginning GH tx and will continue antiretroviral tx throughout GH txment. Repeat 12 or 24-wk courses of GH may be authorized after initial 12 or 24-wk GH course for HIV infection w/wasting or cachexia provided that they are off GH for at least 1 mo and meet all of previous HIV criteria. HIV-assoc 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 tx for greater than or equal to 30 days prior to beginning GH tx and will continue antiretroviral tx. SBS, receiving specialized nutritional support. SBS pts eval on case-by-case basis for more than one 4-wk course per yr.

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

### **Affected Drugs**

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

### **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**

AMRIX®  
CARISOPRODOL  
CHLORZOXAZONE  
CYCLOBENZAPRINE HCL  
FEXMID®  
FLEXERIL®  
METHOCARBAMOL  
ORPHENADRINE CITRATE  
ORPHENADRINE COMPOUND  
ORPHENADRINE COMPOUND FORTE  
PARAFON FORTE DSC®  
ROBAXIN®  
SKELAXIN®  
SOMA®

### **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.

### **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 covered uses. Crohn's disease (CD) patients already on adalimumab. Undifferentiated spondylarthritis (undifferentiated arthritis) (US/UA). CD (induction/remission) in adolescents (15 up to 18 yrs). Uveitis (noninfectious). Behcet's disease. Sarcoidosis. Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS).

### **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**

For rheumatoid arthritis (RA), adults. For CD, adults and adolescents 15 years of age and older.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

CD=12 wks for induction.All other conds=12mos.

### **Other Criteria**

RA, Tried 1 DMARD (brand or generic, oral or injectable) for 2 mos (this includes patients who have tried other biologic DMARDs for 2 mos), or pt is concurrently receiving methotrexate (MTX). JIA/JRA polyarticular course. Tried MTX or will be starting on adalimumab concurrently with MTX. Approve without trying MTX if pt has absolute contraindication to MTX. Plaque psoriasis (PP). Pt has a minimum body surface area (BSA) of 5% or more, exceptions allowed for patients with less than 5%

BSA if they have PP of palms, soles, head and neck, nails, intertriginous areas or genitalia. Pt has a minimum BSA of 5% or more, exceptions allowed for patients with less than 5% BSA if they have had an inadequate response to a 2-mo trial of either topical therapy OR localized phototherapy (ultraviolet B [UVB] or oral methoxsalen plus UVA light [PUVA]), and had inadequate response to a 2-mo trial of systemic therapy (with one of the following- MTX, 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. Pt has tried a systemic therapy (MTX, CSA, acritretin, etanercept, alefacept, infliximab, or ustekinumab) for 2 mos or phototherapy (UVB or PUVA) for 2 months. Rarely, pt may have contraindications to nearly all of these other therapies and exceptions can be made on a case-by-case basis. CD, induce remission. Tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs (adolescents with CD must also have tried infliximab). CD, maintain remission. Pt 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 pt tried azathioprine (AZA), 6-mercaptopurine (6MP), or MTX or has tried infliximab (or certolizumab pegol for adults). Uveitis (non-infectious). Tried 1 of the following therapies: periocular/intraocular CS, immunosuppressants (eg, MTX, mycophenolate mofetil (MM), AZA, cyclophosphamide (CPM), CSA), or etanercept or infliximab. Behcet's. Pt has not responded to at least 1 conventional tx (eg, systemic CSs, immunosuppressants (eg, AZA, MTX, MM, tacrolimus, chlorambucil, CPM, CSA), interferon alfa, etanercept, or infliximab). Sarcoidosis. Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or infliximab, or chloroquine, or thalidomide. PG. Tried 1 other systemic therapy (eg, systemic CSs, immunosuppressives (eg, AZA, 6MP, CSA, CPM, chlorambucil), infliximab, or etanercept) for at least 2 mos or intralesional CS or CSA for localized PG for 2 mos. HS. Tried one other therapy (eg, intralesional/oral CSs, topical or systemic antibiotics, isotretinoin).

## **IMIQUIMOD**

### **Affected Drugs**

ALDARA®  
IMIQUIMOD  
ZYCLARA®

### **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**

For the treatment of AK, adults. For the treatment of warts, 12 years of age and older.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 4 months for 5% creams and 6 weeks for 3% cream.

### **Other Criteria**

Previous trial of Zyclara required prior to approval of 5% creams for an AK diagnosis.

## **INCIVEK**

### **Affected Drugs**

INCIVEK®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus patients with Hepatitis B virus (HBV)/chronic Hepatitis C virus (HCV) genotype 1 co-infection.

### **Exclusion Criteria**

Patients with non-genotype 1 chronic HCV infection. Patients with chronic HCV and human immune deficiency (HIV) co-infection. Patients with recurrent hepatitis C after liver (or other organ) transplantation. For use as monotherapy. In patients less than 18 years of age. Patients who have failed therapy with Incivek or another NS3/4A protease inhibitor (e.g., Victrelis) for HCV. Coverage is not recommended for circumstances not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

Adults

### **Prescriber Restrictions**

Must be prescribed by or in consultation with a gastroenterologist or infectious disease physician.

### **Coverage Duration**

Authorization will be for 3 months.

### **Other Criteria**

Must be prescribed in combination with peginterferon alfa and ribavirin.

## **KINERET**

### **Affected Drugs**

KINERET®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus patient already started on anakinra for a covered use. Juvenile idiopathic arthritis (JIA) or juvenile rheumatoid arthritis (JRA), polyarticular course (regardless of type of onset). Systemic onset JIA. Ankylosing spondylitis. Still's disease (SD). 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 (FMF). 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 blocking agents (etanercept, adalimumab, infliximab, certolizumab pegol, and golimumab), or abatacept, rituximab, or tocilizumab. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

For treatment of rheumatoid arthritis (RA) and Still's disease, adults.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

For acute gout, approval is for 3 doses. For all other uses, approval is for 12 months.

### **Other Criteria**

Adults with RA. Tried adalimumab, certolizumab pegol, golimumab, etanercept, or infliximab for at least 2 months or was intolerant to one of these therapies. JIA/JRA (regardless of onset), approve if patient has tried etanercept, adalimumab, infliximab, or abatacept for at least 2 months or was intolerant to one of these therapies. Systemic onset of JIA, approve if patient has tried a systemic corticosteroid (CS). Ankylosing spondylitis, approve if the patient has tried etanercept, infliximab, golimumab, or

adalimumab for at least 2 months or was intolerant to one of these therapies. SD, approve if patient has tried a CS and has had an inadequate response to 1 non-biologic DMARD (eg, methotrexate) for at least 2 months or was intolerant to this therapy. MWS, approve if patient has tried two other drugs (rilonacept, canakinumab, colchicine, CS, chlorambucil, antihistamines, dapsone, azathioprine, mycophenolate mofetil) for MWS. FCAS, approve if patient has tried two other drugs (eg, colchicine, CS, 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, antihistamines, colchicine, CS, immunosuppressive drugs). Acute gout, patient has tried 2 standard therapies for acute gout (eg, NSAIDs, colchicine, CS) or patient cannot tolerate or has contraindications to standard therapies. FMF, approve in patients who have tried colchicine. TRAPS, approve in patients who have tried CS.

## **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 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.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

For PAH, 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). Additionally - For patients requesting Letairis, approve if the patient has previously tried Tracleer.

## **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 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, 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).

## **LOTRONEX**

### **Affected Drugs**

LOTRONEX®

### **Covered Uses**

All FDA-approved indication 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**

Prescribing physician must be enrolled in GSK Prescribing Program for Lotronex.

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **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**

NUVIGIL®

PROVIGIL®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Fatigue associated with multiple sclerosis (MS). Excessive daytime sleepiness (EDS) due to myotonic dystrophy. Attention-deficit hyperactivity disorder (ADHD) and attention-deficit disorder (ADD) in patients less than 18 years. Adjunctive/augmentation for treatment of depression in adults. EDS in Parkinson's. Idiopathic hypersomnia. Fatigue associated with human immunodeficiency virus (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 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 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 excessive sleepiness due to obstructive sleep apnea/hypoapnea syndrome (OSAHS) patients must have tried continuous positive airway pressure (CPAP). For the FDA-approved indication of excessive sleepiness due to shift-work sleep disorder (SWSD), patients must be working at least 5 overnight shifts per month.

### **Age Restrictions**

For indication of ADHD or ADD, may approve in patients less than 18 years of age. For indication of adjunctive augmentation treatment for depression, may approve for adults.

### **Prescriber Restrictions**

For idiopathic hypersomnia, the diagnosis must be 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 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 less than 18 years who have tried two alternative medications 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. 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).

## **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 for a covered use.

### **Exclusion Criteria**

Concurrent use with a tumor necrosis factor (TNF) alpha antagonist (e.g., etanercept, adalimumab, certolizumab pegol, golimumab, or infliximab) or with anakinra, rituximab, or tocilizumab. 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**

For indication of rheumatoid arthritis (RA) may approve for adults.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

RA, approve if the patient has tried one of the following biologic DMARDs, adalimumab, etanercept, certolizumab pegol, golimumab, or infliximab for at least 2 months, or was intolerant to one of these therapies. Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], polyarticular course, approve if the patient has tried one of the following biologic DMARDs, adalimumab, etanercept, or infliximab for at least 2 months or was intolerant to one of these therapies.

## **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).

## **PROMACTA**

### **Affected Drugs**

PROMACTA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D.  
Thrombocytopenia due to hepatitis C virus (HCV)-related cirrhosis.

### **Exclusion Criteria**

Use in the management of thrombocytopenia in myelodysplastic syndrome (MDS).  
Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria.

### **Required Medical Information**

Cause of thrombocytopenia.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

For thrombocytopenia due to chronic immune (idiopathic) thrombocytopenic purpura (ITP), approve if prescribed by, or after consultation with, a hematologist. For thrombocytopenia due to HCV-related cirrhosis, approve if prescribed by, or after consultation with, either a gastroenterologist or a physician who specializes in infectious disease.

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

For treatment of thrombocytopenia due to HCV-related cirrhosis, approve to allow for initiation of antiviral therapy.

## **REBIF**

### **Affected Drugs**

REBIF®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus patients with a diagnosis of secondary progressive MS and currently on Rebif..

### **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**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **REGRANEX**

### **Affected Drugs**

REGRANEX®

### **Covered Uses**

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

### **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 [collagenase]) 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 covered uses. Crohn's disease (CD) patients already on infliximab (IFB) and continuing therapy for maintenance of remission (MR). Undifferentiated spondyloarthritis/spondyloarthritis (undifferentiated arthritis). Juvenile rheumatoid arthritis (JRA) or juvenile idiopathic arthritis (JIA), polyarticular course. Behcet's disease (BD). Still's disease (SD). Uveitis (UV). Sarcoidosis (Sarc). Pyoderma gangrenosum (PG). Hidradenitis suppurativa (HS). Graft-versus-host disease (GVHD). Indeterminate colitis (IC). Enterovesical fistulas (EF) in patients with Crohn's disease. Macular edema (ME) in type 2 diabetes. Orbital myositis (OM, chronic idiopathic orbital inflammation). SAPHO (synovitis, acne, pustulosis, hyperostosis, osteitis) syndrome. Cogan's syndrome (CGS). Crohn's disease after ileocolonic resection, to reduce the chance of recurrence. Pouchitis (PC). 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, chronic obstructive pulmonary disease (COPD), 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, alefacept, rituximab, ustekinumab, certolizumab pegol, etanercept, adalimumab, golimumab, or tocilizumab. Intra-articular injection of IFB. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

Pouchitis, patient has active disease.

### **Age Restrictions**

For rheumatoid arthritis (RA) and SD, may approve for adults.

### **Prescriber Restrictions**

N/A

## Coverage Duration

For CD (w/ or w/out fistulas) approval is for 12 weeks for induction of remission. All other conditions, approval is for 12 months.

## Other Criteria

RA, Tried 1 DMARD for 2 mos or concurrently receiving methotrexate (MTX). CD IR. Tried corticosteroid (CS) or if CSs contraindicated or if currently on CS. CD MR. Got 3 IFB doses and responded, or not received IFB for IR then if tried azathioprine (AZA), 6-mercaptopurine (6MP), MTX, adalimumab, or certolizumab pegol. Fistulizing CD (FCD) IR, approve. FCD MR. Got 3 doses of IFB and responded. Plaque psoriasis (PP). A minimum body surface area (BSA) of 5% or more, exceptions for less than 5% BSA if PP of palms, soles, head/neck, nails, intertriginous areas or genitalia. A minimum BSA of 5% or more, exceptions for less than 5% BSA if inadequate response to 2-mo trial of topical therapy (tx) OR localized phototx (ultraviolet B [UVB] or oral methoxsalen plus UVA light [PUVA]), and inadequate response to 2-mo trial of systemic tx (w/ one of- MTX, cyclosporine (CSA), acritretin, adalimumab, alefacept, etanercept, or ustekinumab) or contraindications to all, and significant disability or impairment in physical or mental functioning according to treating physician (MD). Tried systemic tx (MTX, CSA, acritretin, etanercept, alefacept, adalimumab, or ustekinumab) for 2 mos or phototx (UVB or PUVA) for 2 mos. If contraindications to nearly all other txs, exceptions to be evaluated by pharmacist and/or MD on case-by-case basis. Ulcerative colitis (UC). Tried 2-mo trial of systemic CS, 6-MP, AZA, CSA or tacrolimus. JIA/JRA, tried MTX or starting on IFB concurrently w/MTX. BD. Pt has not responded to 1 conventional tx (eg, systemic CS, immunosuppressant (eg, AZA, MTX, mycophenolate mofetil (MM), CSA, tacrolimus, chlorambucil, cyclophosphamide (CPM), or interferon alfa), etanercept or adalimumab. SD. Tried CS AND inadequate response to 1 non-biologic DMARD (eg, MTX) for 2 mos, or was intolerant. UV. Tried periocular/intraocular CS, systemic CS, immunosuppressant (eg, MTX, MM, CSA, AZA, CPM), etanercept, adalimumab. Sarc. Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide. PG. Tried 1 systemic tx (eg, systemic CS, immunosuppressant (eg, AZA, 6MP, CSA, CPM, chlorambucil), etanercept or adalimumab) for 2 mos, or 2-mo trial of intralesional CS or CSA for localized PG. HS. Tried 1 tx (eg, intralesional/oral CS, topical or systemic antibiotic, isotretinoin). GVHD. Tried 1 tx (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.) or receiving IFB concurrently. IC. Tried systemic CS AND inadequate response to mesalamine, AND either AZA or 6-MP. CD EF. Tried 1 tx (eg, AZA, 6-MP, MM, CSA, tacrolimus). ME. Refractory to laser therapy. OM. Tried systemic CS, immunosuppressant (eg, MTX, AZA, 6MP, CPM, CSA), or radiotherapy. SAPHO. Tried NSAID and MTX, systemic CS, sulfasalazine, or CSA. CGS. Tried CSs and an immunosuppressant (eg, AZA, MTX, CPM). PC. Tried

antibiotic (metronidazole, ciprofloxacin), probiotic, CS or mesalamine enema. Scleritis/SCU. Tried 1 tx (eg, oral NSAID, oral, topical/ophthalmic or IV CSs, MTX, CSA, or other immunosuppressant).

## **REMODULIN**

### **Affected Drugs**

REMODULIN®

### **Covered Uses**

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

### **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 Remodulin are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. For the FDA-approved indication of pulmonary arterial hypertension, patients currently on Remodulin may continue therapy if they have a diagnosis of PAH.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

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

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

N/A

## **RESTASIS**

### **Affected Drugs**

RESTASIS®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Diagnosis of keratoconjunctivitis sicca (dry eye disease).

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **RITUXAN**

### **Affected Drugs**

RITUXAN®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D. Patients already started on Rituxan for rheumatoid arthritis (RA).

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

For RA, may approve for adults.

### **Prescriber Restrictions**

For RA (initial and repeat courses). Rituxan is to be prescribed by a rheumatologist or in consultation with a rheumatologist. For Non-RA indications, if prescribed by or in consultation with an oncologist, hematologist, neurologist, multiple sclerosis (MS) specialist, rheumatologist, dermatologist, or immunologist, or who are being managed by a transplant center.

### **Coverage Duration**

For RA, approval is for 2 doses. After 16 or more weeks, may be approved for 2 more doses if response per doctor. All others, approval is for 1 year.

### **Other Criteria**

Adult with RA (initial course), approve if patient has tried at least 1 of the following biologic DMARDs, etanercept, certolizumab pegol, golimumab, infliximab, or adalimumab, for at least 2 months. Adult with RA (repeat course), approve if 16 weeks or more 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.

## **SANCUSO**

### **Affected Drugs**

SANCUSO®

### **Covered Uses**

All FDA-approved indication 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**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

Previous trial of oral or injectible forms of granisetron with an inadequate response.

## **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).

## **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 (eg, actinic keratoses, skin neoplasms, warts, dermatitis/eczema, folliculitis, acne rosacea, cystic acne, comedonal acne) exceptions can be made if the patient has tried at least 1 other therapy.

## TOPICAL RETINOID PRODUCTS

### Affected Drugs

ADAPALENE  
ATRALIN®  
AVITA®  
DIFFERIN®  
EPIDUO®  
RETIN-A MICRO®  
RETIN-A®  
TRETINOIN  
TRETIN-X®  
ZIANA®

### 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**

ANDRODERM®  
ANDROGEL®  
AXIRON®  
FORTESTA®  
STRIANT®  
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, may approve for males 12 years of age and 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) or fingolimod (Gilenya) in multiple sclerosis (MS) patients. Use in MS patients with chronic progressive MS. 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. Patient has a relapsing form of MS. Adults with CD. Patient has moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein).

### **Age Restrictions**

Adults.

### **Prescriber Restrictions**

For MS, Tysabri is to be prescribed by a neurologist or an MS specialist registered with the TOUCH prescribing program. For CD, Tysabri is to be 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. Patient has a relapsing form of MS and has had an inadequate response to, or is unable to tolerate, therapy with at least two of the following MS medications: interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone), or fingolimod (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. Patient has moderately to severely active CD 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 antagonists for CD for at least 2 months each, adalimumab, certolizumab pegol, or infliximab, and had an inadequate response or was intolerant to the TNF antagonists. Exception to the CD 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 intravenous (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.

## **VICTRELIS**

### **Affected Drugs**

VICTRELIS®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus adult patients with Hepatitis B virus (HBV)/chronic HCV genotype 1 co-infection.

### **Exclusion Criteria**

Use in the management of non-genotype 1 chronic HCV infection, chronic HCV and human immune deficiency (HIV) co-infection, ecurrent hepatitis C after liver (or other organ) transplantation, use as monotherapy, in pediatric patients (age less than 18 years), in patients who have failed therapy with boceprevir or another NS3/4A protease inhibitor for HCV (e.g., telaprevir). Coverage is not recommended for circumstances not listed in the Covered Uses.

### **Required Medical Information**

HCV RNA titers. Tx-naïve pts with chronic HCV-1 mono-infection without cirrhosis and re-tx of pts with chronic HCV-1 mono-infection who have been previously treated with interferon/peginterferon alfa without cirrhosis, greater or equal to 1 log<sub>10</sub> reduction in HCV RNA at TW 4 required, TW 12 if HCV RNA less than 100= addl 12wks if HCV RNA greater or equal to 100=no addl, TW 24 if early responder with undetectable HCV RNA and pt non-black and for tx-naïve pt with chronic HCV-1 mono-infection without cirrhosis= addl 4wks, TW 24 if early responder with undetectable HCV RNA and pt non-black and for re-tx in pt with chronic HCV-1 mono-infection previously treated for HCV with interferon/peginterferon alfa without cirrhosis= addl 12wks, TW 24 if early responder with undetectable HCV RNA and pt black= addl 24wks, TW 24 if late responder with undetectable HCV RNA and pt non-black= addl 12wks if pt black= addl 24wks, TW 24 if early or late responder with detectable HCV RNA=no addl. Retx in pts with chronic HCV-1 mono-infection previously treated with interferon/peginterferon alfa without cirrhosis null-responder documentation required, TW 12 if HCV RNA less than 100= addl 12wks if HCV RNA greater or equal to 100=no addl, TW 24 if HCV RNA undetectable= addl 24wks if HCV RNA detectable=no addl. Poor interferon response with chronic HCV-1 mono-infection and less than 1 log<sub>10</sub> reduction HCV RNA after TW 4 without cirrhosis, TW 12 if HCV RNA less than 100= addl 12wks if HCV RNA greater or equal to 100=no addl, TW 24 if HCV RNA undetectable= addl 24wks if HCV RNA detectable=no addl. Chronic HCV-1 mono-infection and advanced fibrosis/compensated cirrhosis, TW 12 if HCV RNA less than 100= addl 12 wks if HCV RNA greater or equal to 100=no addl, TW 24 if HCV RNA undetectable= addl 24wks if HCV RNA detectable=no addl.

**Age Restrictions**

Adults

**Prescriber Restrictions**

All FDA-approved indications. Prescribed by or in consultation with a gastroenterologist or infectious disease physician.

**Coverage Duration**

FDA-approved indications, authorization=8wks with TW 12, 24 assessment.  
Other=12mo.

**Other Criteria**

HCV RNA titers not available but sent approve until available. For all FDA-approved indications, patient must have completed or will be completing a 4-week lead-in with peginterferon alfa and ribavirin prior to initiating boceprevir and boceprevir must be prescribed in combination as triple-drug therapy with peginterferon alfa and ribavirin.

# **XALKORI**

## **Affected Drugs**

XALKORI®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Plus, patients with non-small cell lung cancer (NSCLC) already started on crizotinib.

## **Exclusion Criteria**

Patients with anaplastic lymphoma kinase (ALK)-negative NSCLC not already started on crizotinib. Patients with NSCLC initiating therapy whose ALK status is unknown. Coverage is not recommended for circumstances not listed in Covered Uses.

## **Required Medical Information**

For the FDA-approved indication of NSCLC for patients new to therapy, ALK status required.

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Authorization will be for 12 months.

## **Other Criteria**

NSCLC, patient new to therapy must be ALK-positive for approval.

## **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 is to be prescribed by or after consultation with a neurologist. For TD, Xenazine is to 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 (SAR or PAR). 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/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/EC, diagnosis confirmed by biopsy with at least 15 eosinophils/HPF.

### **Age Restrictions**

May be approved for patients aged 12 years and older. May be approved for asthma patients aged 6 to 12 years, if already started and stabilized on Xolair.

### **Prescriber Restrictions**

For moderate to severe persistent asthma, Xolair is to be prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. For SAR/PAR, Xolair is to be prescribed by an allergist, immunologist, or pulmonologist. For EG/EE/EC, Xolair is to be 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) or LABA alternative, if LABA contraindicated or pt has intolerance then alternatives include sustained-release theophylline or a leukotriene modifier (eg, montelukast), 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/PAR must meet the following criteria - pt 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 pt has tried at least one drug from all 3 of these classes during one allergy season AND pt has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy, AND for pts 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.

# ZELBORAF

## Affected Drugs

ZELBORAFI®

## Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Plus, patients with melanoma already started on vemurafenib.

## Exclusion Criteria

Patients with melanoma with wild-type BRAF (ie, no detected BRAFV600E mutation) not already started on vemurafenib. Patients with melanoma initiating therapy with vemurafenib whose BRAFV600E status is unknown. Coverage is not recommended for circumstances not listed in Covered Uses.

## Required Medical Information

For the FDA-approved indication of melanoma, for patients new to therapy, BRAFV600E status required.

## Age Restrictions

N/A

## Prescriber Restrictions

N/A

## Coverage Duration

Authorization will be for 12 months.

## Other Criteria

Melanoma, patient new to therapy must have BRAFV600E mutation for approval.

## **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**

For indication of vancomycin-resistant enterococcus (VRE) infection, cultures must be done to confirm. Methicillin-resistant Staphylococcus, cultures must be done to confirm. 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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