



## **UCARE FOR SENIORS (HMO-POS) 2010 PA CRITERIA**

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

ADCIRCA <sup>®</sup> .....	3
ALDARA <sup>®</sup> .....	4
ARANESP <sup>®</sup> .....	5
AVONEX <sup>®</sup> .....	7
B VERSUS D COVERAGE .....	8
BANZEL <sup>®</sup> .....	10
BETASERON <sup>®</sup> .....	11
BYETTA <sup>®</sup> .....	12
CIMZIA <sup>®</sup> .....	13
COPAXONE <sup>®</sup> .....	14
ENBREL <sup>®</sup> .....	15
EPOGEN <sup>®</sup> /PROCRIT <sup>®</sup> .....	17
FENTANYL .....	20
FORTEO <sup>®</sup> .....	21
GROWTH HORMONES .....	22
HUMIRA <sup>®</sup> .....	25
KINERET <sup>®</sup> .....	27

LOTRONEX® .....	29
NUVIGIL® .....	30
ORENCIA® .....	32
PROVIGIL® .....	33
QUALAQUIN® .....	35
REBIF® .....	36
REGRANEX® .....	37
RESTASIS® .....	38
REVATIO® .....	39
SAMSCA® .....	40
SANCUSO® .....	41
SIMPONI® .....	42
TAZORAC® .....	43
TOPICAL TESTOSTERONE PRODUCTS.....	44
TOPICAL TRETINOIN PRODUCTS.....	45
TYSABRI® .....	47
VFEND® .....	48
XENAZINE® .....	49
XOLAIR® .....	50
ZYVOX® .....	52
INDEX .....	53

## **ADCIRCA**

### **Affected Drugs**

ADCIRCA®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

## **ALDARA**

### **Affected Drugs**

ALDARA®

### **Covered Uses**

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

### **Exclusion Criteria**

Treatment of urethral, intravaginal, cervical, rectal, or anal human papilloma virus (HPV) growths. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

Treatment of AK limited to adults. Treatment of warts limited to patients 12 years of age and older.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

4 months.

### **Other Criteria**

N/A

## **ARANESP**

### **Affected Drugs**

ARANESP®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

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

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

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

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

### **Other Criteria**

Anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Pts with Hb rise of less than 1.0 g/dL (or Hct 3% or less) and Hb levels is less than 10.0 g/dL after 4 wks therapy, the recommended FDA dose may be increased once by 25%. Continued Aranesp use is not reasonable or necessary if the Hb rise is less than 1.0 g/dL (or Hct is less than 3%) compared to pretreatment baseline by 8 weeks of treatment. Continued Aranesp administration is not reasonable and necessary if there is a rapid rise in Hb or more than 1.0 g/dL (or Hct more than 3%) over 2 weeks of treatment unless the Hb remains below or subsequently falls to less than 10.0 g/dL (or Hct less than 30%). Continuation and reinstatement of Aranesp must include a dose reduction of 25% from the previously administered dose.

## **AVONEX**

### **Affected Drugs**

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

## PART B VERSUS PART D COVERAGE

### Affected Drugs

ANZEMET<sup>®</sup>  
AZASAN<sup>®</sup>  
AZATHIOPRINE  
CARIMUNE NF<sup>®</sup>  
CELLCEPT<sup>®</sup>  
CYCLOPHOSPHAMIDE  
CYCLOSPORINE  
DRONABINOL  
EMEND<sup>®</sup>  
ENGERIX-B<sup>®</sup>  
FLEBOGAMMA<sup>®</sup>  
GAMASTAN S-D<sup>®</sup>  
GAMMAGARD<sup>®</sup>  
GAMUNEX<sup>®</sup>  
GENGRAF  
GRANISETRON  
GRANISOL  
IMURAN<sup>®</sup>  
KYTRIL<sup>®</sup>  
MARINOL<sup>®</sup>  
METHOTREXATE  
MITOXANTRONE  
MYCOPHENOLATE MOFETIL  
MYFORTIC<sup>®</sup>  
NEORAL<sup>®</sup>  
NOVANTRONE<sup>®</sup>  
OCTAGAM<sup>®</sup>  
ONDANSETRON  
ORTHOCLONE OKT-3<sup>®</sup>  
POLYGAM S-D<sup>®</sup>  
PROGRAF<sup>®</sup>  
RAPAMUNE<sup>®</sup>  
RECOMBIVAX HB<sup>®</sup>  
SANDIMMUNE<sup>®</sup>  
SIMULECT<sup>®</sup>  
TREXALL<sup>®</sup>  
ZOFRAN<sup>®</sup>

**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**

### **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**

N/A

## **BYETTA**

### **Affected Drugs**

BYETTA®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **CIMZIA**

### **Affected Drugs**

CIMZIA®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D plus patients already started on certolizumab pegol for Crohn's disease.

### **Exclusion Criteria**

Combination with anakinra. Plaque psoriasis. Children with Crohn's disease. Coverage not recommended for anything not listed.

### **Required Medical Information**

N/A

### **Age Restrictions**

Adults.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 weeks to induce remission. 12 months to maintain remission.

### **Other Criteria**

Adults with Crohn's disease to induce remission. Approve if patient has tried corticosteroids or if corticosteroids are contraindicated or if patient currently on corticosteroids. Adults with Crohn's disease to maintain remission. Patient has received 3 doses of certolizumab pegol and has responded or if has not received certolizumab pegol for induction of remission then authorize if patients has tried azathioprine, 6-mercaptopurine, or MTX or if patient has tried infliximab or adalimumab.

## **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

## **ENBREL**

### **Affected Drugs**

ENBREL®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Plaque psoriasis. Prescribed by a dermatologist.

### **Coverage Duration**

12 months.

### **Other Criteria**

Adults with RA, approve if patient has tried 1 DMARD for at least 2 months or is concurrently receiving MTX. JIA or JRA, polyarticular course, approve if the patient has tried MTX or will be starting on Enbrel concurrently with MTX. Approve without trying MTX if the patient has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias). Plaque psoriasis. Patient has chronic (greater than or equal to 1 year) plaque psoriasis AND

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

# **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 pts. Preoperative use in pts undergoing major surgery utilizing hemodilution intraoperatively. Treatment of aplastic anemia. Anemia in heart failure (HF).

## **Exclusion Criteria**

Anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis. Anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers. Anemia of cancer not related to cancer treatment. Any anemia associated only with radiotherapy. Prophylactic use to prevent chemotherapy-induced anemia. Prophylactic use to reduce tumor hypoxia. Use in patients with erythropoietin-type resistance due to neutralizing antibodies. Anemia due to cancer treatment if patients have uncontrolled hypertension. To enhance athletic performance. To treat orthostatic hypotension in patients with anemia. To treat thalassemia-related anemia. As an adjunct to bone marrow transplantation (BMT) for donors. Use as an adjunct to blood donation for autologous use. Treatment of anemia associated with epidermolysis bullosa. Treatment of anemia in systemic lupus erythematosus. Treatment of anemia in rheumatoid arthritis. Treatment of anemia in inflammatory bowel disease (eg, ulcerative colitis, Crohn's disease). Treatment of anemia in diabetes mellitus. Hemochromatosis. Anemia in patients due to acute blood loss. Non-anemic pts (Hb more than 13.0 g/dL) prior to surgery. Coverage not recommended for anything not listed under Covered Uses.

## **Required Medical Information**

CRF anemia. Hemoglobin (Hb) of less than or equal to 11.0 g/dL to start. Hb less than or equal to 12.0 g/dL if previously on epoetin alfa (EA) or Aranesp. Anemia w/myelosuppressive chemotx. Hb immediately prior to EA is 10.0 g/dL or less (or hematocrit [Hct] is 30% or less). EA maintenance is starting dose if Hb level remains 10.0 g/dL or less (or Hct remains 30% or less) 4 wks after start and Hb rise is 1.0 g/dL or more (Hct rise is 3% or more). Pts w/Hb rises less than 1.0 g/dL (Hct rise less than 3%) vs pretx baseline over 4 wks of tx and Hb is less than 10.0 g/dL after 4 wks of tx (Hct is less than 30%), the recommended FDA starting dose may be increased once by 25%. Continued use is not reasonable/necessary if Hb rises less than 1.0 g/dL (Hct rise less than 3%) vs pretx baseline by 8 wks of tx. Continued EA is not reasonable/necessary if there is a rapid Hb rise more than 1.0 g/dL (Hct more than 3%) over 2 wks of tx unless Hb remains below or subsequently falls to less than 10.0 g/dL (or Hct is less than 30%). Continuation/reinstitution of EA must have dose reduction of 25% of previous dose. MDS, approve if Hb is 12.0 g/dL or less. Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HF, approve for New York Heart Association functional class III or IV pts w/Hb 10.0 g/dL or less and per MD underlying anemia causes persist despite transfusions or pt has contraindications to transfusions. Addtl tx allowed if pt has Hb of 12.0 g/dL or less. Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV (+/- zidovudine), Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 units/mL or less at tx start. Previously on EA approve if Hb is 12.0 g/dL or less. Anemia due to ribavirin for Hep C, Hb is 10.0 g/dL or less at tx start. Aplastic anemia, Hb is 12.0 g/dL or less. Previously on EA approve if Hb is 12.0 g/dL or less. All conds, deny if Hb exceeds 12.0 g/dL.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

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

### **Coverage Duration**

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

### **Other Criteria**

Anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Pts with Hb rise of less than 1.0 g/dL (or Hct 3% or less) and Hb levels is less than 10.0 g/dL after 4 wks therapy, the recommended FDA dose may be increased once by 25%. Continued epoetin alfa use is not reasonable or necessary if the Hb rise is less than 1.0 g/dL (or Hct is less than 3%)

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

## **FENTANYL**

### **Affected Drugs**

ACTIQ®  
FENTANYL CITRATE  
FENTORA®

### **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).

# **FORTEO**

## **Affected Drugs**

FORTEO®

## **Covered Uses**

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

## **Exclusion Criteria**

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

## **Required Medical Information**

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

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

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

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

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

## **GROWTH HORMONES**

### **Affected Drugs**

GENOTROPIN<sup>®</sup>  
HUMATROPE<sup>®</sup>  
NORDITROPIN<sup>®</sup>  
NUTROPIN AQ<sup>®</sup>  
NUTROPIN<sup>®</sup>  
OMNITROPE<sup>®</sup>  
SAIZEN<sup>®</sup>  
SEROSTIM<sup>®</sup>  
TEV-TROPIN<sup>®</sup>  
ZORBTIVE<sup>®</sup>

### **Covered Uses**

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

### **Exclusion Criteria**

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

## **Required Medical Information**

Child w/acquired GH deficiency (DF). 1 documented GH stimulation test (levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon) shows diminished serum GH response of less than 10 ng/mL AND baseline height (Ht) less than the 3rd percentile for gender/age AND pretx Ht velocity (VEL) in child less than 3 yrs of less than 7 cm/yr and in child greater than or equal to 3 yrs of less than 4 cm/yr OR child of any age growth VEL less than the 10th percentile for age/gender based on at least 6 mos of data. Child had brain radiation does not have to meet baseline Ht criteria. Congenital hypopituitarism does not have to meet Ht or growth VEL criteria. Child w/hypophysectomy does not have to meet any criteria. Adolescents (diagnosed as child with GH DF or with idiopathic short stature [ISS]) with prior GH use and aged 16 yrs or older, growth rate (GR) must be at least 2.5 cm/yr in recent yr. Review pts annually for this GR (does not apply to documented hypopituitarism). Further approval is not recommended if GR is less than 2.5 cm/yr. Adolescents, young adults with ISS who completed linear growth (GR less than 2 cm/year), review for txment of adult GH DF. Non-GH deficient short stature (ISS) child w/open epiphyses. 6 mo trial. Baseline Ht less than 3rd percentile (ie, greater than 2 SD below the mean for gender/age AND pretx Ht VEL in child less than 3 yrs of less than 7 cm/yr and in child greater than or equal to 3 yrs of less than 4 cm/yr OR child of any age growth VEL less than the 10th percentile for age/gender based on at least 6 mos of data AND pediatric endocrinologist (PE) must certify child's basic activities of daily living is limited by short stature and child has a condition for which GH is effective (or may be effective during the initial trial of tx) AND PE must certify based on bone-age x-ray, predicted adult Ht is less than 3rd percentile. Authorization for cont tx based on adequate clinical response (an annualized GR that doubles in comparison to previous yr).

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

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

## **Coverage Duration**

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

## **Other Criteria**

Therapy should be discontinued if there is no significant increase in growth rate during the first year. Adult GH deficiency. 1 of the following diagnoses Adult onset (GH

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

# **HUMIRA**

## **Affected Drugs**

HUMIRA®

## **Covered Uses**

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

## **Exclusion Criteria**

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

## **Required Medical Information**

N/A

## **Age Restrictions**

Crohn's disease adults and adolescents aged 15 to up to 18 yrs. Uveitis or other systemic manifestations of Behcet's disease in adults. No age range specified.

## **Prescriber Restrictions**

Plaque psoriasis. Prescribed by a dermatologist.

## **Coverage Duration**

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

## **Other Criteria**

Adults with RA, approve if the patient has tried 1 DMARD or is concurrently receiving MTX. Adults with Crohn's disease to induce remission. Approve if patient has tried corticosteroids or if corticosteroids are contraindicated or if patient currently on corticosteroids. Adults with Crohn's disease to maintain remission. Patient has received 2 doses or 12 wks of adalimumab and has responded or if has not received adalimumab for induction of remission then authorize if patient has tried azathioprine, 6-mercaptopurine, or MTX or if patient has tried infliximab or certolizumab pegol. Plaque psoriasis in patients without psoriatic arthritis. Pt has chronic (greater than or equal to 1

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

# **KINERET**

## **Affected Drugs**

KINERET®

## **Covered Uses**

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

## **Exclusion Criteria**

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

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

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

## **Other Criteria**

Adults with RA. Approve if the patient has tried Humira, Enbrel, or Remicade for at least 2 months. JIA, JRA (regardless of onset), approve if pt has tried Enbrel, Humira, or Orencia. Systemic onset of JIA, approve if pt has tried a systemic corticosteroid. Ankylosing spondylitis, approve if the pt has tried Enbrel, Remicade, or Humira. Adult with Still's disease, approve if pt has tried one DMART or is currently receiving MTX. MWS, approve if pt has tried two other drugs (Arcalyst, colchicine, corticosteroids, chlorambucil, antihistamines, dapsone, azathioprine, CellCept). FCAS, approve if pt has

tried two other drugs (eg, colchicine, corticosteroids, antihistamines, azathioprine, Cellcept, Arcalyst). Schnitzler's syndrome, approve if pt has tried one other prescripon medication used in Schnitzler's syndrome. Acute gout, pt has tried 2 standard therapies for acute gout (eg, NSAIDs, colchicine, corticosteroid) or pt cannot tolerate or has contraindications to standard therapies. FMF, approve in pts who have tried colchicine. TRAPS, approve in patientst who have tried colchicine.

## **LOTRONEX**

**Affected Drugs**  
LOTRONEX<sup>®</sup>

### **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

## **NUVIGIL**

### **Affected Drugs**

NUVIGIL®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Fatigue associated with MS [Multiple Sclerosis]. Excessive daytime sleepiness (EDS) due to myotonic dystrophy. ADHD [Attention Deficit Hyperactive Disorder] and ADD [Attention Deficit Disorder] in patients less than 18 years. Adjunctive/augmentation for treatment of depression in adults. EDS [Excessive daytime sleepiness] in Parkinson's. Idiopathic hypersomnia. Cancer-related fatigue.

### **Exclusion Criteria**

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

### **Required Medical Information**

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

### **Age Restrictions**

ADHD [Attention Deficit Hyperactive Disorder] or ADD [Attention Deficit Disorder] in patients less than 18 years. Adjunctive augmentation treatment for depression must be in adults.

### **Prescriber Restrictions**

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

### **Coverage Duration**

Authorization will be for 12 months.

**Other Criteria**

Excessive sleepiness due to OSAHS [Obstructive sleep apnea/hypoapnea syndrome] if the patient has tried CPAP [Continuous positive airway pressure]. Excessive sleepiness due to SWSD [Shift work sleep disorder] if the patient is working at least 5 overnight shifts per month. ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder] for patients less than 18 years who have tried two alternative medication for ADHD [Attention Deficit Hyperactive Disorder]/ADD [Attention Deficit Disorder] from two different classes as follows: methylphenidate products (e. g. , methylphenidate, dexamethylphenidate), amphetamines (e. g. , mixed amphetamine salts, dextroamphetamine), atomoxetine, bupropion or tricyclic antidepressants (TCAs e. g. , imipramine, desipramine). Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression. Idiopathic hypersomnia if the diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i. e. , sleep center).

# **ORENCIA**

## **Affected Drugs**

ORENCIA®

## **Covered Uses**

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

## **Exclusion Criteria**

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

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

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

# **PROVIGIL**

## **Affected Drugs**

PROVIGIL<sup>®</sup>

## **Covered Uses**

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

## **Exclusion Criteria**

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

## **Required Medical Information**

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

## **Age Restrictions**

Adjunctive augmentation treatment for depression must be in adults.

## **Prescriber Restrictions**

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

## **Coverage Duration**

Authorization will be for 12 months.

## **Other Criteria**

Excessive sleepiness due to OSAHS if the patient has tried CPAP. Excessive sleepiness due to SWSD if the patient is working at least 5 overnight shifts per month.

ADHD/ADD for patients who have tried two alternative medication for ADHD/ADD from two different classes as follows: methylphenidate products (e.g., methylphenidate, dextromethylphenidate), amphetamines (e.g., mixed amphetamine salts, dextroamphetamine), atomoxetine, bupropion or tricyclic antidepressants (TCAs e.g., imipramine, desipramine). Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression. Idiopathic hypersomnia if the diagnosis is confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders (i.e., sleep center). Spasticity due to cerebral palsy, approve if patient has tried one other agent for spasticity (eg, benzos, baclofen, dantrolene, tizanidine, or botulinum toxin).

## **QUALAQUIN**

### **Affected Drugs**

QUALAQUIN®

### **Covered Uses**

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

### **Exclusion Criteria**

Leg cramps. Coverage is not recommended for circumstances not listed in Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 1 month.

### **Other Criteria**

N/A

## **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.

## **Exclusion Criteria**

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

## **Required Medical Information**

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

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

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

## **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

## **REVATIO**

### **Affected Drugs**

REVATIO®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

12 months.

### **Other Criteria**

N/A

## **SAMSCA**

### **Affected Drugs**

SAMSCA®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

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

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months.

### **Other Criteria**

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

## **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.

## **SIMPONI**

### **Affected Drugs**

SIMPONI®

### **Covered Uses**

All FDA approved indications not otherwise excluded from Part D.

### **Exclusion Criteria**

Simponi should not be given in combination with a TNF antagonist (e.g., adalimumab, certolizumab pegol, etanercept, infliximab), with anakinra, with rituximab, or with abatacept. Plaque psoriasis without psoriatic arthritis. Asthma. Ulcerative colitis. Coverage not recommended for anything not listed under Covered Uses.

### **Required Medical Information**

N/A

### **Age Restrictions**

Adults.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

Adults with rheumatoid arthritis (RA), approve if the patient has tried one disease-modifying antirheumatic drug [DMARD] (brand or generic, oral or injectable) for at least 2 months, [this includes patients who have tried other biologic DMARDs for at least 2 months] AND the patient will be receiving methotrexate (MTX) in combination with Simponi. Adult RA patients are not required to use MTX concurrently with Simponi if there are contraindications to MTX or the patient has a history of intolerance to MTX.

## **TAZORAC**

### **Affected Drugs**

TAZORAC®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

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

## **TOPICAL TESTOSTERONE PRODUCTS**

### **Affected Drugs**

ANDRODERM®

ANDROGEL®

TESTIM®

### **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**

N/A

## TOPICAL TRETINOIN PRODUCTS

### Affected Drugs

ATRALIN<sup>®</sup>  
AVITA<sup>®</sup>  
RETIN-A MICRO<sup>®</sup>  
RETIN-A<sup>®</sup>  
TRETINOIN  
TRETIN-X<sup>®</sup>  
ZIANA<sup>®</sup>

### Covered Uses

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

### Exclusion Criteria

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

### Required Medical Information

N/A

### Age Restrictions

N/A

### Prescriber Restrictions

N/A

### Coverage Duration

Authorization will be for 12 months.

**Other Criteria**

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

# **TYSABRI**

## **Affected Drugs**

TYSABRI®

## **Covered Uses**

All FDA approved indications not otherwise excluded from Part D.

## **Exclusion Criteria**

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

## **Required Medical Information**

N/A

## **Age Restrictions**

Adults.

## **Prescriber Restrictions**

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

## **Coverage Duration**

Authorization will be for 12 months.

## **Other Criteria**

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

## **VFEND**

### **Affected Drugs**

VFEND®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D worded as invasive aspergillosis, esophageal candidiasis, treatment of fungal infections caused by *Scedosporium apiospermum* and *Fusarium* spp., and treatment of candidemia in nonneutropenic patients and the following *Candida* infections: disseminated infections in skin and infections in the abdomen, kidney, bladder wall, and wounds.

Treatment/prevention of other serious systemic or suspected systemic fungal infections. Continuation therapy for patients started/stabilized on IV or oral voriconazole for a systemic infection.

### **Exclusion Criteria**

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

### **Required Medical Information**

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

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

### **Other Criteria**

N/A

## **XENAXINE**

### **Affected Drugs**

XENAZINE®

### **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**

N/A

# **XOLAIR**

## **Affected Drugs**

XOLAIR®

## **Covered Uses**

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

## **Exclusion Criteria**

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

## **Required Medical Information**

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

## **Age Restrictions**

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

## **Prescriber Restrictions**

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

## **Coverage Duration**

Authorization will be for 12 months, unless otherwise specified.

## **Other Criteria**

Pts with moderate to severe persistent asthma must meet all criteria prescribed by or in consultation with an allergist, immunologist, or pulmonologist AND baseline IgE of

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

## **ZYVOX**

### **Affected Drugs**

ZYVOX®

### **Covered Uses**

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

### **Exclusion Criteria**

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

### **Required Medical Information**

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

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Authorization will be for one fill up to one month.

### **Other Criteria**

N/A

## Index

ACTIQ<sup>®</sup> 20  
ADCIRCA<sup>®</sup> 3  
ALDARA<sup>®</sup> 4  
ANDRODERM<sup>®</sup> 44  
ANDROGEL<sup>®</sup> 44  
ANZEMET<sup>®</sup> 8  
ARANESP<sup>®</sup> 5  
ATRALIN<sup>®</sup> 45  
AVITA<sup>®</sup> 45  
AVONEX<sup>®</sup> 7  
AZASAN<sup>®</sup> 8  
AZATHIOPRINE 8  
BANZEL<sup>®</sup> 10  
BETASERON<sup>®</sup> 11  
BYETTA<sup>®</sup> 12  
CARIMUNE NF<sup>®</sup> 8  
CELLCEPT<sup>®</sup> 8  
CIMZIA<sup>®</sup> 13  
COPAXONE<sup>®</sup> 14  
CYCLOPHOSPHAMIDE 8  
CYCLOSPORINE 8  
DRONABINOL 8  
EMEND<sup>®</sup> 8  
ENGERIX-B<sup>®</sup> 8  
EPOGEN<sup>®</sup> 17  
EXTAVIA<sup>®</sup> 11  
FENTANYL CITRATE 20  
FENTORA<sup>®</sup> 20  
FLEBOGAMMA<sup>®</sup> 8  
FORTEO<sup>®</sup> 21  
GAMASTAN S-D<sup>®</sup> 8  
GAMMAGARD<sup>®</sup> 8  
GAMUNEX<sup>®</sup> 8  
GENGRAF 8  
GENOTROPIN<sup>®</sup> 22  
GRANISETRON 8  
GRANISOL 8  
HUMATROPE<sup>®</sup> 22  
HUMIRA<sup>®</sup> 25  
IMURAN<sup>®</sup> 8  
KINERET<sup>®</sup> 27  
KYTRIL<sup>®</sup> 8  
LOTRONEX<sup>®</sup> 29  
MARINOL<sup>®</sup> 8  
METHOTREXATE 8  
MITOXANTRONE 8  
MYCOPHENOLATE MOFETIL 8  
MYFORTIC<sup>®</sup> 8  
NEORAL<sup>®</sup> 8  
NORDITROPIN<sup>®</sup> 22  
NOVANTRONE<sup>®</sup> 8  
NUTROPIN AQ<sup>®</sup> 22  
NUTROPIN<sup>®</sup> 22  
NUVIGIL<sup>®</sup> 30  
OCTAGAM<sup>®</sup> 8  
OMNITROPE<sup>®</sup> 22  
ONDANSETRON 8  
ORENCIA<sup>®</sup> 32  
ORTHOCLONE OKT-3<sup>®</sup> 8  
POLYGAM S-D<sup>®</sup> 8  
PROCRIPT<sup>®</sup> 17  
PROGRAF<sup>®</sup> 8  
PROVIGIL<sup>®</sup> 33  
QUALAQUIN<sup>®</sup> 35  
RAPAMUNE<sup>®</sup> 8  
REBIF<sup>®</sup> 36  
RECOMBIVAX HB<sup>®</sup> 8  
REGRANEX<sup>®</sup> 37  
RESTASIS<sup>®</sup> 38  
RETIN-A<sup>®</sup> 45  
REVATIO<sup>®</sup> 39  
SAIZEN<sup>®</sup> 22  
SAMSCA<sup>®</sup> 40  
SANCUSO<sup>®</sup> 41  
SANDIMMUNE<sup>®</sup> 8  
SEROSTIM<sup>®</sup> 22

SIMPONI® 42  
SIMULECT® 8  
TAZORAC® 43  
TESTIM® 44  
TEV-TROPIN® 22  
TRETINOIN 45  
TRETIN-X® 45  
TREXALL® 8

TYSABRI® 47  
VFEND® 48  
XENAZINE® 49  
XOLAIR® 50  
ZIANA® 45  
ZOFRAN® 13  
ZORBTIVE® 22  
ZYVOX® 52

