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## **ACTEMRA**

### **Affected Drugs**

ACTEMRA®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

The diagnosis is moderate to severe rheumatoid arthritis as made by a rheumatologist and the disease must be active.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Rheumatologist.

### **Coverage Duration**

Indefinite.

### **Other Criteria**

Must have failed and had an inadequate response to a 2 month trial of one other TNF antagonist therapy.

## **AMEVIVE**

### **Affected Drugs**

AMEVIVE®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Dermatologist.

### **Coverage Duration**

Indefinite.

### **Other Criteria**

Must try and fail topical therapy first and must also try and fail one of the following: Methotrexate, Oral retinoids, Cyclosporine, Phototherapy. Topical therapy is defined as an agent applied directly to the skin, and includes potent corticosteroids (clobetasol), retinoids (tazarotene), Vitamin D analogs (calcipotriene), or combination products (betamethasone/calcipotriene).

## **AMPYRA**

### **Affected Drugs**

AMPYRA®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Neurologist.

### **Coverage Duration**

Indefinite.

### **Other Criteria**

N/A

## **ANDROGEL**

### **Affected Drugs**

ANDRODERM®  
ANDROGEL®  
AXIRON®  
FORTESTA®  
STRIANT®  
TESTIM®

### **Covered Uses**

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

### **Exclusion Criteria**

Erectile dysfunction. Decreased Libido.

### **Required Medical Information**

Patient must be symptomatic with a total testosterone level of less than 300ng/dl.

### **Age Restrictions**

Aged 15 years or older.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Indefinite.

### **Other Criteria**

Gender must be male.

## **ARANESP PROCIT EPOGEN**

### **Affected Drugs**

ARANESP®

EPOGEN®

PROCIT®

### **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. All agents will also be covered for anemia related to Multiple Myeloma, Refractory Anemia related to Myelodysplastic Syndrome. Procrit and Epogen only will be covered for anemia related to chronic disease.

### **Exclusion Criteria**

Refractory anemia related to Myelodysplastic Syndrome must be an EPO insufficiency that cannot be assigned to a specific vitamin or mineral deficiency. Uncontrolled hypertension. Anemic patients willing to donate autologous blood. Improvement of symptomatic anemia to improve quality of life, fatigue, or well being. Anemia due to factors other than diagnoses noted (iron or folate deficiency, hemolysis, GI bleeding). Patients receiving hormonal agents, therapeutic biological products, or radiotherapy UNLESS also receiving concomitant myelosuppressive chemotherapy. For immediate anemia correction or as a substitute for emergency transfusion. Prophylactic use to prevent chemotherapy included anemia.

### **Required Medical Information**

Chronic renal failure patients not on dialysis must have symptomatic anemia with a HGB of 10g/dl or less. HIV-infected Zidovudine use requires a Zidovudine dose of 4200mg/week or less and an endogenous serum EPO level less than or equal to 500mUnits/ml. Non myeloid malignancy chemotherapy induced anemia must have HCT of 30% or less or HBC of 10g/dl or less in past 30 days. Multiple myeloma anemia must have HCT of 30% or less or HGB of 10g/dl or less in past 30 days. For Myelodysplastic Syndrome refractory anemia diagnosis must include excess blasts, or excess blasts in transformation to leukemia when, for medical reasons, the patient is not a candidate for active treatment of active leukemia. For Myelodysplastic Syndrome the patient must have a HCT of 30% or less or HGB of 10g/dl or less, and endogenous EPO serum level less than 500mu/ml. Anemia of chronic disease must have pretreatment HCT of 30% or less and pretreatment EPO level of 100mu/ml or less. Anemia patients scheduled to undergo elective surgery require hemoglobin greater than 10 but 13 or less.

### **Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

Indefinite.

**Other Criteria**

For all agents, For anemia related to chemotherapy must have received chemotherapy in past 8 weeks and will be receiving chemo for a minimum of 2 months. For Procrit and Epogen only, For anemia of chronic disease if the member has been transfusion dependent for at least 2 months. For Procrit and Epogen only, In anemic patients scheduled to undergo surgery, the surgery must be elective, noncardiac and nonvascular, or in patients at high risk for perioperative transfusion with significant anticipated blood loss who are receiving anticoagulant prophylaxis. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.

## **ARCALYST**

### **Affected Drugs**

ARCALYST®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

12 years or greater.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Indefinite.

### **Other Criteria**

Must be up to date and have received all recommended vaccines, or must receive all recommended vaccinations prior to initiation of therapy.

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

### **Affected Drugs**

ANZEMET®  
AREDIA®  
ATGAM®  
AZASAN®  
AZATHIOPRINE  
AZATHIOPRINE SODIUM  
BONIVA®  
CALCIJEX®  
CALCITRIOL  
CARIMUNE NF NANOFILTERED®  
CARNITOR®  
CELLCEPT®  
CESAMET®  
CUBICIN®  
CYCLOPHOSPHAMIDE  
CYCLOSPORINE  
CYCLOSPORINE MODIFIED  
DRONABINOL  
EMEND®  
GAMMAGARD LIQUID®  
GAMMAPLEX®  
GAMUNEX®  
GENGRAF  
GRANISETRON HCL  
GRANISOL  
HECTOROL®  
HEPARIN SODIUM  
HEPARIN SODIUM IN 0.45% NACL  
HEPARIN SODIUM IN 0.9% NACL  
HEPARIN SODIUM IN 5% DEXTROSE  
IMURAN®  
KYTRIL®  
LEVOCARNITINE  
MARINOL®  
METHOTREXATE  
MIACALCIN®  
MITOXANTRONE HCL  
MYCOPHENOLATE MOFETIL

MYFORTIC®  
NEORAL®  
NOVANTRONE®  
ONDANSETRON HCL  
ONDANSETRON ODT  
ORTHOCLONE OKT-3®  
PAMIDRONATE DISODIUM  
PRIVIGEN®  
PROGRAF®  
RAPAMUNE®  
RHEUMATREX®  
ROCALTROL®  
SANDIMMUNE®  
SIMULECT®  
TACROLIMUS  
THYMOGLOBULIN®  
Trexall®  
VANCOMYCIN HCL  
ZEMPLAR®  
ZOFRAN ODT®  
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.

# **BOTOX**

## **Affected Drugs**

BOTOX®

XEOMIN®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Tics of organic origin, Idiopathic torsion dystonia, Symptomatic torsion dystonia, Oral facial dyskinesia, Organic writer's cramp, Fragments of torsion dystonia (other), Hereditary spastic paraplegia, Multiple Sclerosis, Neuromyelitis optica, Schilder's disease, Other demyelinating diseases of central nervous system, Demyelinating disease of central nervous system (unspecified), Spastic hemiplegia affecting unspecified site, Spastic hemiplegia affecting dominant side, Spastic hemiplegia affecting nondominant side, Infantile cerebral palsy, Other specified infantile cerebral palsy, Infantile cerebral palsy unspecified, Quadriplegia and quadriplegia, Paraplegia, Diplegia of upper limbs, Monoplegia of lower limb, Monoplegia of upper limb, Other facial nerve disorders, Spastic ectropion, Esotropia, Exotropia, Intermittent heterotropia, Other and unspecified heterotropia, Heterophoria, Heterophoria, Other disorders of binocular eye movements, Unspecified disorder of eye movements, Late effect of cerebrovascular disease, Monoplegia of upper limb affecting dominant side, Monoplegia of upper limb affecting nondominant side, Monoplegia of lower limb affecting dominant side, Monoplegia of lower limb affecting nondominant side, Paralysis of vocal cords unspecified, Paralysis of vocal cords unilateral partial, Paralysis of vocal cords unilateral complete, Paralysis of vocal cords bilateral partial, Paralysis of vocal cords bilateral complete, Laryngeal spasm, Disturbance of salivary secretion, Achalasia and cardiospasm, Anal spasm, Anal fissure, Spasm of muscle, Torticollis unspecified, Other musculoskeletal symptoms, Congenital deformity of sternomastoid muscle-torticollis wryneck contracture, Abnormal involuntary movements, Voice disturbance unspecified, Aphonia, Other voice disturbance, Other speech disturbance.

## **Exclusion Criteria**

N/A

## **Required Medical Information**

N/A

## **Age Restrictions**

N/A

**Prescriber Restrictions**

N/A

**Coverage Duration**

One year.

**Other Criteria**

Diagnosis of severe primary axillary hyperhidrosis requires inadequate disease management with topical agents first.

## **CIMZIA**

### **Affected Drugs**

CIMZIA®

### **Covered Uses**

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

### **Exclusion Criteria**

Concomitant use of other Interleukin-1 antagonist or TNF agent.

### **Required Medical Information**

For Rheumatoid Arthritis, the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis as made by a rheumatologist and the disease must be active. For Crohn's Disease, the member must have a confirmed diagnosis of moderate to severe Crohn's Disease as made by a gastroenterologist.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Rheumatologist, Gastroenterologist.

### **Coverage Duration**

Indefinite.

### **Other Criteria**

For Rheumatoid Arthritis, must first try and fail or have an inadequate response to a 2-month trial of injectable methotrexate, OR if the member has a contraindication to methotrexate, then must fail at least two other DMARDs for at least 2 months. For Crohn's Disease, must first try and fail or have an inadequate response to either Corticosteroids AND one of Azathioprine or Mercaptopurine, OR Remicade or Humira. Must be up to date and received all recommended vaccines, or must receive all recommended vaccines prior to initiation of therapy.

## **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.

### **Exclusion Criteria**

N/A

### **Required Medical Information**

For Rheumatoid Arthritis the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis as made by a rheumatologist and the disease must be active. For Juvenile Idiopathic Arthritis, the member must have a confirmed diagnosis of moderate to severe Juvenile Idiopathic Arthritis as made by a rheumatologist and the disease must be active. For Ankylosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as made by a rheumatologist as defined by presence of active disease for at least 4 weeks defined by a BASDAI Index of at least 4 and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Psoriasis with Arthropathy, the member must have a confirmed diagnosis of Psoriasis with Arthropathy as made by a rheumatologist or dermatologist. For Plaque Psoriasis, the member must have a confirmed diagnosis of chronic and moderate to severe Plaque Psoriasis, as made by a dermatologist and defined as a minimum body surface area involvement of greater than or equal to 5%.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Rheumatologist, Dermatologist.

### **Coverage Duration**

Indefinite. For Ankylosing Spondylitis, 12wk trial initially, with positive response then ok x 1yr.

### **Other Criteria**

For Rheumatoid Arthritis, must first try and fail or have an inadequate response to a 2-month trial of injectable methotrexate, OR if the member has a contraindication to methotrexate, then must fail at least two other DMARDs for at least 2 months. For Juvenile Idiopathic Arthritis and Psoriasis with Arthropathy, must first try and fail

methotrexate for at least two months, OR if the member has an absolute contraindication to methotrexate, then Enbrel will be approved. For non axial forms of Ankylosing Spondylitis, the member must first try and fail any two of the following conventional therapies over a three month period: NSAIDs, intraarticular steroids, injectable methotrexate, DMARDs (failure is defined as improvement of less than 50% or 2 units, on a 0-10 scale, of the BASDAI scale). For Plaque Psoriasis, the member must first try and fail over a three month period, both one topical therapy AND one of the following: Methotrexate, Oral retinoids, cyclosporine, phototherapy.

## **GROWTH HORMONE**

### **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. Non-GH deficient short stature (idiopathic short stature). Turner's syndrome. SHOX (short stature homeobox-containing gene) deficiency. Chronic renal insufficiency. Prader-Willi syndrome. Short child born small for gestational age (SGA) or with intrauterine growth retardation (IUGR) including those with Silver-Russell syndrome. Noonan syndrome. Short bowel syndrome. HIV infection with wasting or cachexia (Serostim only). HIV-associated failure to thrive (Serostim only).

### **Exclusion Criteria**

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

## **Required Medical Information**

Child/adolesc w/GH DF (initial tx), eval by a pediatric endocrinologist (PE), documented GH stim test (levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon) w/GH response of less than 10 ng/mL AND baseline height (Ht) less than the 3rd percentile 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 of any age GR less than the 10th percentile for age/gender based on at least 6 mos of data. Child w/brain radiation does not have to meet baseline Ht criteria. Congenital hypopituitarism does not have to meet Ht or GR criteria. Child w/hypophysectomy, approve. Child/adolesc w/GH 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 pts GR annually (does not apply to hypopituitarism). Adoles/young adults who completed linear growth (GR less than 2 cm/yr), review for txment of adult GH DF. Greater than 18 yrs, auth not allowed if mid-parental ht attained. Non-GH DF short stature (ISS) child w/open epiphyses. 6 mo trial. Baseline Ht less than 3rd percentile (greater than 2 SD below mean for gender/age) AND 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 of any age GR less than the 10th percentile for age/gender based on at least 6 mos of data AND PE certifies child's basic activities of daily living limited by short stature and has condition for which GH is effective (or may be effective during tx trial) AND PE certifies vis bone-age x-ray, predicted adult Ht less than 3rd percentile. Authorization 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 MR Y per MD AND epiphyses open (older than 12 yrs). Greater than 18 yrs, auth not allowed if mid-parental ht attained.

## **Age Restrictions**

Turner' syndrome, children. SHOX/CRI, children/adolescents. SGA, 2 to 8 yrs. Noonan, 17 yrs or younger. HIV failure to thrive, less than 17 yrs. SBS/HIV cachexia, adults.

## **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**

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

## Other Criteria

Adult GH def (start) AND 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 childhood-onset AND negative response to 1 GH stimulation test (insulin tolerance [peak less than 5 mcg/L], or glucagon [peak less than 3 mcg/L]) [GHRH plus arginine may be used if available], transition 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. Turners, initial tx, female, and has short stature. Cont tx, GR increased by 2.5 cm/yr or more in most recent yr AND epiphyses open. SHOX, start, open epiphyses. Cont tx, GR increased by 2.5 cm/yr or more in most recent yr AND epiphyses open. CRI, start, approve. Cont tx, GR increased by 2.5 cm/yr or more in most recent yr AND epiphyses open. Prader-Willi, initial tx, approve. Cont tx, GR increased by 2.5 cm/yr or more in most recent yr AND epiphyses open. SGA/IUGR, initial tx, 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. Noonan syndrome, initial tx, baseline ht less than 3rd percentile. Cont tx, GR increased by 2.5 cm/yr or more in most recent yr AND epiphyses open. HIV infection w/wasting or cachexia, HIV-positive AND have 1 of the following, documented unintentional wt loss of greater than or equal to 10% from baseline OR wt less than 90% of the lower limit of ideal body wt OR BMI less than or equal to 20 kg/m<sup>2</sup> AND able to consume or be fed via parenteral or enteral feedings 75% or more of maintenance energy requirements based on current body weight AND on antiretroviral 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 pts eval on case-by-case basis for more than one 4-wk course per yr.

## **HEMATOPOIETIC GROWTH FACTOR**

### **Affected Drugs**

PROMACTA®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Chronic ITP is defined as greater than 6 months. Baseline platelet count must be less than 30,000/mm<sup>3</sup>, OR baseline platelet count must be 30,000-50,000/mm<sup>3</sup> AND in the presence of clinically significant mucous membrane bleeding. For continuation of therapy, a clinically positive response is either a platelet count with a positive increase to greater than 50,000/mm<sup>3</sup> OR a clinically significant improvement in bleeding status if platelet count remains less than 50,000/mm<sup>3</sup>. If the platelet count does not increase after 4 weeks at maximum dose, then therapy will not be reauthorized.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

90 day initial trial, then 1 year with positive clinical response.

### **Other Criteria**

Must try and have insufficient response to or be intolerant to both of the following: Corticosteroids AND one of either splenectomy, IVIG, or anti-D immunoglobulins.

## **HIGH RISK FIRST GENERATION ANTIHISTAMINES**

### **Affected Drugs**

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

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **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.

## **HIGH RISK SKELETAL MUSCLE RELAXANTS**

### **Affected Drugs**

AMRIX®  
CARISOPRODOL  
CARISOPRODOL COMPOUND  
CARISOPRODOL COMPOUND-CODEINE  
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 1 month.

**Other Criteria**

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

# **HUMIRA**

## **Affected Drugs**

HUMIRA®

## **Covered Uses**

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

## **Exclusion Criteria**

N/A

## **Required Medical Information**

For Rheumatoid Arthritis the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis as made by a rheumatologist and the disease must be active. For Juvenile Idiopathic Arthritis, the member must have a confirmed diagnosis of Juvenile Idiopathic Arthritis as made by a rheumatologist and the disease must be active. For Ankylosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as made by a rheumatologist as defined by presence of active disease for at least 4 weeks defined by a BASDAI Index of at least 4 and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Psoriasis with Arthropathy, the member must have a confirmed diagnosis of Psoriasis with Arthropathy as made by a rheumatologist or dermatologist. For Plaque Psoriasis, the member must have a confirmed diagnosis of chronic and moderate to severe Plaque Psoriasis, as made by a dermatologist and defined as a minimum body surface area involvement of greater than or equal to 5%. For Crohn's Disease, the member must have a confirmed diagnosis of moderate to severe Crohn's Disease as made by a gastroenterologist.

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

Rheumatologist, Dermatologist, Gastroenterologist.

## **Coverage Duration**

Indefinite. For Ankylosing Spondylitis, 12wk trial initially, with positive response then ok x 1yr.

## **Other Criteria**

For Rheumatoid Arthritis, must first try and fail or have an inadequate response to a 2-month trial of injectable methotrexate, OR if the member has a contraindication to

methotrexate, then must fail at least two other DMARDs for at least 2 months. For Juvenile Idiopathic Arthritis and Psoriasis with Arthropathy, must first try and fail methotrexate for at least two months, OR if the member has an absolute contraindication to methotrexate, then Humira will be approved. For non axial forms of Ankylosing Spondylitis, the member must first try and fail any two of the following conventional therapies over a three month period: NSAIDs, intraarticular steroids, injectable methotrexate, DMARDs (failure is defined as improvement of less than 50% or 2 units, on a 0-10 scale, of the BASDAI scale). For Plaque Psoriasis, the member must first try and fail over a three month period, both topical therapy AND one of the following: Methotrexate, Oral retinoids, cyclosporine, phototherapy. For Crohn's Disease, must first try and fail or have an inadequate response to either Corticosteroids AND one of Azathioprine or Mercaptopurine, OR Remicade or Cimzia.

## **KINERET**

### **Affected Drugs**

KINERET®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

The member must have a confirmed diagnosis of Rheumatoid Arthritis as made by a rheumatologist and the disease must be active.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Rheumatologist.

### **Coverage Duration**

Indefinite.

### **Other Criteria**

For Rheumatoid Arthritis, must first try and fail or have an inadequate response to a 2-month trial of injectable methotrexate, OR if the member has a contraindication to methotrexate, then must fail at least two other DMARDs for at least 2 months.

## **KUVAN**

### **Affected Drugs**

KUVAN®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Initial 2 months, if positive response, then indefinite. In pregnancy, through term.

### **Other Criteria**

Patient must continue to receive a specialized phenylalanine restricted diet in conjunction with Kuvan. For continuation of therapy, a positive response is defined as showing a 30% or greater reduction in blood phenylalanine level after initial 2 months of therapy.

## **PANRETIN**

### **Affected Drugs**

PANRETIN®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Indefinite.

### **Other Criteria**

N/A

## **PROLEUKIN**

### **Affected Drugs**

PROLEUKIN®

### **Covered Uses**

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

### **Exclusion Criteria**

Kaposi's Sarcoma, Colorectal Cancer, Non-Hodgkin's Lymphoma.

### **Required Medical Information**

N/A

### **Age Restrictions**

18 years or greater.

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Indefinite.

### **Other Criteria**

N/A

## **REVATIO**

### **Affected Drugs**

ADCIRCA®  
REVATIO®

### **Covered Uses**

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

### **Exclusion Criteria**

Erectile dysfunction.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Indefinite.

### **Other Criteria**

N/A

## **RILUTEK**

### **Affected Drugs**

RILUTEK®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Neurologist.

### **Coverage Duration**

Indefinite.

### **Other Criteria**

Requires documentation of exclusion of other diagnoses by neurologist.

# **SAMSCA**

## **Affected Drugs**

SAMSCA®

## **Covered Uses**

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

## **Exclusion Criteria**

Patients requiring urgent intervention to raise serum sodium acutely. Patients unable to sense or appropriately respond to thirst. Patients with hypovolemic hyponatremia. Concomitant use of strong CYP 3A inhibitors. Patients who are anuric.

## **Required Medical Information**

The diagnosis must be clinically significant hyponatremia, hypervolemic or euvolemic, defined as serum sodium less than 125meq/l or less, and the patient must be symptomatic (symptoms may include nausea/vomiting, headache, confusion, lethargy, fatigue, loss of appetite, restlessness and irritability, muscle weakness, spasm, cramps, seizures, decreased consciousness, or coma), including patients with heart failure, cirrhosis, and SIADH.

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

4 days initially, if positive response then 6 months.

## **Other Criteria**

Therapy must be initiated or re-initiated in a hospital setting. The patient must have failed or resisted correction with both fluid restriction and one other means of treatment, such as loop diuretics, hypertonic saline, or salt tablets. The patient has been discontinued from any other possible causes of drug-induced hyponatremia or SIADH (such as carbamazepine, oxcarbazepine, chlorpropamide, fluoxetine, sertraline, vincristine, vinblastine, cisplatin, cyclophosphamide, thiothixene, thioridazine, haloperidol, amitriptyline, MAO inhibitors, methotrexate, NSAIDs, interferon alpha and gamma, amiodarone, ciprofloxacin, and opiates).

# **SIMPONI**

## **Affected Drugs**

SIMPONI®

## **Covered Uses**

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

## **Exclusion Criteria**

N/A

## **Required Medical Information**

For Rheumatoid Arthritis, the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis as made by a rheumatologist and the disease must be active. For Ankylosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as made by a rheumatologist as defined by presence of active disease for at least 4 weeks defined by a BASDAI Index of at least 4 and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Psoriasis with Arthropathy, the member must have a confirmed diagnosis of Psoriasis with Arthropathy as made by a rheumatologist or dermatologist.

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

Rheumatologist, Dermatologist.

## **Coverage Duration**

Indefinite. In Ankylosing Spondylitis, 12wk trial initially, if positive response then indefinite.

## **Other Criteria**

For Rheumatoid Arthritis, must first try and fail or have an inadequate response to a 2-month trial of injectable methotrexate, OR if the member has an intolerance/contraindication to injectable methotrexate, then must fail at least two other DMARDs for at least 2 months, AND the member will also be receiving methotrexate concurrently with Simponi. For non axial forms of Ankylosing Spondylitis, the member must first try and fail any two of the following conventional therapies over a three month period: NSAIDs, intraarticular steroids, injectable methotrexate, DMARDs (failure is defined as improvement of less than 50% or 2 units, on a 0-10 scale, of the BASDAI scale). For Psoriasis with Arthropathy, must first try and fail methotrexate for at least two

months, OR if the member has an absolute contraindication to methotrexate, then Simponi will be approved.

# **SPORANOX**

## **Affected Drugs**

ITRACONAZOLE  
SPORANOX®

## **Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Onychomycosis. Other Tinea type infections including Versicolor, Capitis, Barbae, Crurus, Faciei, Manuum, Imbricata, Pedis (non moccasin or non chronic type), Corporis. Plantar type or Moccasin type dry chronic Tinea Pedis. Vaginal Candidiases. Prevention of recurrent vulvovaginal or vaginal candidiasis. Pityriasis versicolor. Other superficial and systemic mycosis. Oral and esophageal candidiasis.

## **Exclusion Criteria**

Vaginal candidiasis hypersensitivity syndrome.

## **Required Medical Information**

Onychomycosis must be due to dermatophytes, and treatment must not be solely for cosmetic purposes as cosmetic use is excluded under Medicare Part D.

## **Age Restrictions**

N/A

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Twelve weeks.

## **Other Criteria**

Tinea or Pityriasis Versicolor requires one trial and failure of ketoconazole or a topical antifungal agent first. Tinea Capitis and Barbae require failure of one trial of griseofulvin or ketoconazole first. Tinea Cruris, Faciei, Manuum, Imbricata and Pedis (non moccasin or chronic type) require failure of one topical antifungal agent. Tinea Corporis requires failure of one topical antifungal agent first, except when condition is considered extensive. Vaginal Candidiases requires failure of both one topical antifungal regimen and one trial of oral fluconazole (patients of age less than 16 years are excluded from a trial of a topical vaginal antifungal preparation). For oral and esophageal candidiasis, must try and fail ketoconazole or fluconazole first. For febrile neutropenia, must be intolerant of or refractory to amphotericin B therapy. For Aspergillosis, must be

intolerant of or refractory to Amphotericin B. Itraconazole may be covered for other systemic infection if used for continuation of itraconazole therapy that has already been started and stabilized.

## **STELARA**

### **Affected Drugs**

STELARA®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

Diagnosis of moderate to severe plaque psoriasis must be made by a dermatologist and is defined as a minimum body surface area (BSA) involvement of greater than or equal to 5 percent.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

Dermatologist.

### **Coverage Duration**

Indefinite.

### **Other Criteria**

Patient must have tried and failed over a three month period a trial of both topical therapy AND one of the following: methotrexate, oral retinoids, cyclosporine, or phototherapy.

## **TAZORAC**

### **Affected Drugs**

TAZORAC®

### **Covered Uses**

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

### **Exclusion Criteria**

Pregnancy.

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Indefinite.

### **Other Criteria**

Diagnosis of acne vulgaris requires failure on at least two other formulary anti-acne preparations. Dermatologists may prescribe Tazorac without prior authorization.

## **TOPICAL RETINOID PRODUCTS**

### **Affected Drugs**

ATRALIN®  
AVITA®  
RETIN-A MICRO®  
RETIN-A®  
TRETINOIN  
TRETIN-X®

### **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).

### **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). Use for the treatment of psoriasis.

### **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.

## **XENAZINE**

### **Affected Drugs**

XENAZINE®

### **Covered Uses**

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

### **Exclusion Criteria**

Impaired hepatic function, Concomitant use of MAOIs or Reserpine, Non-Huntington's related chorea, other hyperkinetic movement disorders including tardive dyskinesia or tics associated with Tourette Syndrome.

### **Required Medical Information**

Diagnosis must be chorea associated with Huntington's Disease.

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Indefinite.

### **Other Criteria**

N/A

# **XOLAIR**

## **Affected Drugs**

XOLAIR®

## **Covered Uses**

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

## **Exclusion Criteria**

N/A

## **Required Medical Information**

Diagnosis must be moderate to severe persistent asthma. Must have a positive skin test or in vitro testing (blood test for allergen-specific IgE antibodies such as RAST) for one or more perennial aeroallergens or for one or more seasonal aeroallergens.

## **Age Restrictions**

12 years or greater.

## **Prescriber Restrictions**

N/A

## **Coverage Duration**

Indefinite.

## **Other Criteria**

Requires trial and failure to control symptoms by inhaled moderate to high dose corticosteroids after at least 2 months of therapy. Failure is demonstrated by hospitalization for asthma, requirement for systemic (oral or parenteral) corticosteroids to control exacerbations of asthma, increasing need (usually greater than once per day) for short-acting inhaled beta2 agonist for symptom control (excluding preventive use of exercise induced asthma).

## **XOPENEX**

### **Affected Drugs**

XOPENEX HFA®

### **Covered Uses**

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

### **Exclusion Criteria**

N/A

### **Required Medical Information**

N/A

### **Age Restrictions**

N/A

### **Prescriber Restrictions**

N/A

### **Coverage Duration**

Indefinite.

### **Other Criteria**

Must have tried and failed, or be intolerant to albuterol secondary to clinically significant adverse cardiovascular effects, such as increased pulse rate, increased blood pressure, and/or other sympathetic nervous system symptoms.

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