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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 [Tumor necrosis factor] antagonist therapy.

AMEVIVE RAPTIVA

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®
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 16 years or older.

Prescriber Restrictions

N/A

Coverage Duration

Indefinite.

Other Criteria

Gender must be male.

ARANESP PROCRIT EPOGEN

Affected Drugs

ARANESP®

EPOGEN®

PROCRIT®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Aranesp will also be covered for anemia associated with Zidovudine therapy in HIV infected patients and in anemic patients scheduled to undergo surgery to reduce the need for allogenic blood transfusion. All medications will be covered for anemia related to Multiple Myeloma, Refractory Anemia related to Myelodysplastic Syndrome, and 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 greater and an endogenous serum EPO level greater than 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 anemia related to chemotherapy must have received chemotherapy in past 8 weeks and will be receiving chemo for a minimum of 2 months. For anemia of chronic disease if the member has been transfusion dependent for at least 3 months. 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.

ARCALYST

Affected Drugs

ARCALYST®

Covered Uses

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

Exclusion Criteria

Active or chronic infection including Hepatitis B, Hepatitis C, Tuberculosis. Strong history of neoplasm. Active SLE [Systemic lupus erythematosus]. Concomitant use of other interleukin-1 antagonist or TNF [Tumor necrosis factor] agents.

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®
AZASAN®
AZATHIOPRINE
AZATHIOPRINE SODIUM
CARIMUNE NF NANOFILTERED®
CELLCEPT®
CESAMET®
CYCLOPHOSPHAMIDE
CYCLOSPORINE
CYCLOSPORINE MODIFIED
DRONABINOL
EMEND®
FLEBOGAMMA®
GAMMAGARD LIQUID®
GAMUNEX®
GENGRAF
GRANISETRON HCL
GRANISOL
IMURAN®
KYTRIL®
MARINOL®
MEDROXYPROGESTERONE ACETATE
METHOTREXATE
MYCOPHENOLATE MOFETIL
MYFORTIC®
NEORAL®
OCTAGAM®
ONDANSETRON HCL
ONDANSETRON ODT
POLYGAM S-D®
PRIVIGEN®
PROGRAF®
PROVERA®
RAPAMUNE®
RHEUMATREX®
SANDIMMUNE®
TACROLIMUS
TREXALL®

ZOFRAN ODT®
ZOFRAN®

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®

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

N/A

Required Medical Information

Diagnosis must be moderate to severe chronic Crohn's Disease or moderate to severe Rheumatoid Arthritis.

Age Restrictions

N/A

Prescriber Restrictions

Gastroenterologist. Rheumatologist.

Coverage Duration

Indefinite.

Other Criteria

For Rheumatoid Arthritis, must first try and have an inadequate response or be intolerant to two other conventional therapies, including one each of a DMARD [Disease-modifying antirheumatic drug] (methotrexate, hydroxychloroquine, azathioprine, sulfasalazine) and another Anti-Tumor Necrosis Factor (Enbrel, Humira, Remicade). For Crohn's Disease, must try and fail one other Anti-Tumor Necrosis Factor (Humira, Remicade). Must be up to date and received all recommended vaccines, or must receive all recommended vaccines prior to initiation of therapy.

ENBREL

Affected Drugs

ENBREL®

Covered Uses

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

Exclusion Criteria

Chronic infection including Hepatitis B, Hepatitis C, Tuberculosis. Strong history of neoplasm. Active SLE [Systemic lupus erythematosus].

Required Medical Information

Polyarticular disease requires that the disease must be active. Ankylosing Spondylitis requires presence of active disease for at least 4 weeks defined by a BASDAI Index of at least 4. For plaque psoriasis, diagnosis must be moderate to severe.

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 fail injectable methotrexate with at least one other DMARD [Disease-modifying antirheumatic drug], or must fail at least two other DMARDs [Disease-modifying antirheumatic drugs] if intolerant to/contraindicated to MTX [methotrexate]. Failure from first line approaches is defined as inadequate improvement in joint symptoms and inflammation, and can also be defined as inability to taper off or down to a minimum of 10mg prednisone equivalent per day. For non axial forms of Ankylosing Spondylitis, must first try and fail any two of the following conventional therapies: NSAIDs [Non-steroidal anti-inflammatory drugs], intraarticular steroids, injectable methotrexate, DMARDs [Disease-modifying antirheumatic drugs] (failure is defined as improvement of less than 50% or 2 units, on a 0-10 scale, of the BASDAI scale). For plaque psoriasis or psoriasis with anthropathy, must try and fail

topical therapy, and must also try and fail one of the following: Methotrexate, Oral retinoids, cyclosporine, phototherapy.

GROWTH HORMONE

Affected Drugs

GENOTROPIN®
HUMATROPE®
NORDITROPIN NORDIFLEX®
NORDITROPIN®
NUTROPIN AQ®
NUTROPIN®
OMNITROPE®
SAIZEN®
TEV-TROPIN®

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Short children born small for gestational age or with intrauterine growth retardation including those with Silver-Russell syndrome. Patients who have undergone brain radiation. Congenital hypopituitarism. Children who have had a hypophysectomy.

Exclusion Criteria

For Adult growth hormone deficiency, other causes of low serum IGF-I must be excluded before using IGF-I as a marker of growth hormone deficiency, such as excluding malnutrition, prolonged fasting, poorly controlled diabetes mellitus, hypothyroidism, hepatic insufficiency, oral estrogen therapy. For short children born small for gestational age, exclude from coverage if age is greater than 8 and child is clearly pubertal. Other exclusions include: Constitutional delay of growth and puberty, familial (normal) short stature, Down's syndrome, corticosteroid induced short stature, renal transplant (children) with functional renal allograft, liver or cardiac transplant, bone marrow transplant without total body (cranial) radiation, congenital adrenal hyperplasia, bony dysplasias (achondroplasia, hypochondroplasia), osteogenesis imperfecta, x-linked hypophosphatemic rickets, myelomeningocele, dilated cardiomyopathy and heart failure, athletic ability enhancement, aging, somatopause, to improve functional status in elderly, infertility, acute critical illness due to surgery complications or multiple accidental trauma or with acute respiratory failure, osteoporosis (postmenopausal or idiopathic in men), adults with ESRD on hemodialysis, HIV infected patients with alterations in body fat distribution, Crohn's disease, chronic fatigue syndrome, fibromyalgia, cystic fibrosis, familial dysautonomia, children with severe burn injury.

Required Medical Information

Growth hormone deficiency(children), brain radiation history(children), congenital hypopituitarism(children) require provocative growth hormone testing with diminished

serum growth hormone response to stimulation testing of less than 10ng/ml, supported by at least 1 stimulation test. Growth hormone deficiency(children), nongrowth hormone deficient short stature(idiopathic short stature), short children small for gestational age, Noonan Syndrome require baseline height less than 3rd% (greater than 2 SD below the mean for gender/age). Growth hormone deficiency(children), nongrowth hormone deficient short stature(idiopathic short stature), children with brain radiation history require pretreatment growth rate less than 7cm/year for age less than 3 or rate less than 4cm/year for age 3 or greater. Nongrowth hormone deficient short stature(idiopathic short stature), MD must certify by bone-age xray a predicted adult height less than 3rd%. Growth hormone deficiency(adult) and brain radiation history(adult) must have documented diagnosis of growth hormone deficiency of adult or childhood onset. Adult onset deficiency may be due to growth hormone deficiency alone or multiple hormone deficiencies, or childhood onset deficiency resulting from childhood growth hormone deficiency. Growth hormone deficiency(adult) requires negative response to 1 standard stimulation test (max peak 5ng/ml or less by radioimmunoassay or less than 2. 5ng/ml by immunoradiometric assay) or documentation of 2 or more pituitary hormone deficiencies and serum IGF-I less than 84ug/L by Esoterix Endocrinology competitive binding RIA. Turner Syndrome, SHOX deficiency must be demonstrated by chromosome analysis. Short children born small for gestational age require birth weight and/or length greater than 2 SD below the mean for gestational age/gender without catchup growth by age 2.

Age Restrictions

Pediatrics/children are defined as 17 or less, adults as 18 or greater. For short children born small for gestational age: age must be greater than/equal to 2 and less than/equal to 8, or if greater than 8 must be prepubertal. For short bowel syndrome, must be adult 18 years or greater.

Prescriber Restrictions

Pediatric endocrinologist, Adult endocrinologist, nephrologist.

Coverage Duration

Idiopathic short stature 6 mo. Short Bowel Syndrome 1x4 week course/year. All others 1 year.

Other Criteria

Accepted growth hormone deficiency stimulation tests for children are levodopa, insulin induced hypoglycemia, arginine, clonidine, glucagon. Accepted growth hormone deficiency stimulation tests for adults include insulin tolerance, arginine, growth hormone releasing hormone, combination of arginine/GHRH [growth hormone releasing

hormone], combination of GHRH [growth hormone releasing hormone]/growth hormone releasing peptide, glucagon. Nongrowth hormone deficient short stature(idiopathic short stature), authorization of continued therapy is based on an adequate clinical response defined as an annualized growth rate that doubles compared to the previous year. Nongrowth hormone deficient short stature(idiopathic short stature), a pediatric endocrinologist must certify that ability to participate in basic activities of daily living is limited by the short stature, the degree of growth retardation is considered medically significant, and the child has a condition for which growth hormone will possibly be effective. Adult onset growth hormone deficiency defines multiple hormone deficiencies (hypopituitarism) as resulting from pituitary disease, hypothalamic disease, surgery, radiation or trauma, and childhood onset growth hormone deficiency defines growth hormone deficiency during childhood as a result of congenital, genetic, acquired, or idiopathic causes. Adults with childhood onset growth hormone deficiency are excluded from growth hormone stimulation tests if they have known mutations, embryopathic lesions, irreversible structural lesions/damage. For adult onset growth hormone deficiency pituitary hormone deficiencies are defined as thyroid stimulating hormone deficiency, ACTH deficiency, gonadotropin deficiency (Leutinizing hormone and/or FHS deficiency considered one deficiency) and arginine vasopressin deficiency. Chronic renal insufficiency(children) is approved up to time of kidney transplantation or if chronic renal insufficiency develops after kidney transplant. For Turner Syndrome gender must be female. Nongrowth hormone deficient short stature(idiopathic short stature) in children and SHOX, epiphyses must remain open. Short bowel syndrome, must be receiving specialized nutritional support defined as high carbohydrate, low fat diet adjusted for individual patient requirements and preferences. For infants and children with congenital hypopituitarism growth hormone stimulation testing is not required in patients with pituitary stalk agenesis, empty sella , sellar or supra-sellar mass lesion, or ectopic posterior pituitary bright spot on magnetic resonance image or computed tomography.

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 [Immune thrombocytopenic purpura] is defined as greater than 6 months. Baseline platelet count must be less than 30, 000/mm³, OR baseline platelet count must be 30, 000-50, 000/mm³ AND in the presence of clinically significant mucous membrane bleeding.

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 [Intravenous Immune Globulin], or anti-D immunoglobulins. For continuation of therapy, a clinically positive response is either a platelet count with a positive increase to greater than 50, 000/mm³ OR a clinically significant improvement in bleeding status if platelet count remains less than 50, 000/mm³. If the platelet count does not increase after 4 weeks at maximum dose, then therapy will not be reauthorized.

HUMIRA

Affected Drugs

HUMIRA®

Covered Uses

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

Exclusion Criteria

Chronic infection including Hepatitis B, Hepatitis C, Tuberculosis. Strong history of neoplasm. Active SLE [Systemic lupus erythematosus].

Required Medical Information

Polyarticular disease requires that the disease must be active. Ankylosing Spondylitis requires presence of active disease for at least 4 weeks defined by both a BASDAI Index of at least 4 and expert opinion based on clinical features, acute phase reactants, and imaging modalities. For plaque psoriasis or psoriasis with arthropathy, diagnosis must be severe. For Crohn's, the disease must be moderate to severe.

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 fail injectable methotrexate with at least one other DMARD [Disease-modifying antirheumatic drug], or must fail at least two other DMARDs [Disease-modifying antirheumatic drugs] if intolerant to/contraindicated to MTX [methotrexate]. Failure from first line approaches is defined as inadequate improvement in joint symptoms and inflammation, and can also be defined as inability to taper off or down to a minimum of 10mg prednisone equivalent per day. For non axial forms of Ankylosing Spondylitis, must try and fail at least 2 NSAIDs [Non-steroidal anti-inflammatory drugs] during a single 3 month period, fail intraarticular steroids if indicated, and fail injectable methotrexate with at least 1 other DMARD [Disease-modifying antirheumatic drug] (failure is defined as improvement of less than 50% or 2 units, on a 0-10 scale, of the BASDAI scale). For plaque psoriasis or psoriasis with

anthropathy, must try and fail topical therapy, and must try and fail or be intolerant to two of the following: Methotrexate, Oral retinoids, Cyclosporine, Phototherapy. For Crohn's, must try and fail with an inadequate response or be intolerant to corticosteroids and azathioprine/mercaptopurine, or have tried Remicade with an inadequate response.

KINERET

Affected Drugs

KINERET®

Covered Uses

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

Exclusion Criteria

Chronic infection including Hepatitis B, Hepatitis C, Tuberculosis. Strong history of neoplasm. Active SLE [Systemic lupus erythematosus].

Required Medical Information

Polyarticular disease requires the disease must be active.

Age Restrictions

N/A

Prescriber Restrictions

Rheumatologist.

Coverage Duration

Indefinite.

Other Criteria

For rheumatoid arthritis, must first fail injectable methotrexate with at least one other DMARD [Disease-modifying antirheumatic drug], or must fail at least two other DMARDs [Disease-modifying antirheumatic drugs] if intolerant to/contraindicated to MTX [methotrexate]. Failure from first line approaches is defined as inadequate improvement in joint symptoms and inflammation, and can also be defined as inability to taper off or down to a minimum of 10mg prednisone equivalent per day.

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.

LAMISIL

Affected Drugs

LAMISIL®
TERBINAFINE HCL

Covered Uses

All FDA-approved indications not otherwise excluded from Part D. Other Tinea type infections including Capitis, Barbae, Cruris, Faciei, Manuum, Pedis (non plantar type or non moccasin type dry chronic), Imbricata, Corporis. Black Piedra. Plantar type or Moccasin type dry chronic Tinea Pedis. Cutaneous Candidiasis. Chronic Mucocutaneous Candidiasis. Eumycetoma/mycetoma.

Exclusion Criteria

Systemic Fungal Infections, Tinea Versicolor (Pityriasis Versicolor), Oral, Esophageal, or Vaginal candidiasis, Other superficial fungal infections.

Required Medical Information

Onychomycosis must be medically significant, causing impaired mobility, discomfort, or in the presence of diabetes mellitus.

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

Twelve weeks.

Other Criteria

Tinea Capitis and Barbae require failure of one trial of griseofulvin or ketoconazole. Tinea Cruris, Faciei, Manuum, Pedis (non plantar type or non moccasin type dry chronic) and Imbricata require failure of one trial of topical antifungal agent. Tinea Corporis requires failure of one trial of topical antifungal agent. Cutaneous candidiasis requires failure of one trial including both a topical antifungal agent and an azole antibiotic (ketoconazole, fluconazole, or itraconazole). Chronic mucocutaneous candidiasis requires failure of one trial of oral fluconazole. For Tinea Capitis and Barbae and Chronic mucocutaneous candidiasis pediatric patients less than or equal to 10 years are exempt from trial of oral agent and may receive Lamisil Granules. For cutaneous candidiasis pediatric patients less than or equal to 10 years are excluded

from a trial of an azole antibiotic and may receive Lamisil granules after only a failure of a topical antifungal agent.

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 fluid restriction, and /or 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 [Non-steroidal anti-inflammatory drugs], interferon alpha and gamma, amiodarone, ciprofloxacin, and opiates).

SEROSTIM

Affected Drugs

SEROSTIM®

Covered Uses

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

Exclusion Criteria

HIV infected patients with alterations in body fat distribution such as increased abdominal girth or buffalo hump.

Required Medical Information

Must be HIV positive. Adults must have wasting or cachexia, children must have failure to thrive. Adults must have documented unintentional weight loss of greater than/equal to 10% from baseline, weight less than 90% of the lower limit of ideal body weight, or body mass index less than/equal to 20kg/m².

Age Restrictions

N/A

Prescriber Restrictions

N/A

Coverage Duration

1 year in children. 12 weeks in adults, may repeat 12 week if off treatment x 1 mo and meets criteria.

Other Criteria

Must be able to consume or be fed through parenteral or enteral feedings 75% or more of maintenance energy requirements based on current body weight. Must have been on antiretroviral therapy for 30 days or more prior to the beginning of therapy and will continue antiretroviral therapy throughout the course of treatment.

SIMPONI

Affected Drugs

SIMPONI®

Covered Uses

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

Exclusion Criteria

Chronic infection including invasive fungal infection, Hepatitis B, Hepatitis C, Tuberculosis. Strong history of neoplasm. Active SLE [Systemic lupus erythematosus]. Concomitant use of other Interleukin-1 antagonist or TNF [Tumor necrosis factor] agent.

Required Medical Information

For Rheumatoid Arthritis, diagnosis must be moderate to severe, and disease must be active. Ankylosing Spondylitis requires presence of active disease for at least 4 weeks defined by both a BASDAI Index of at least 4 and expert opinion based on clinical features, acute phase reactants, and imaging modalities. For psoriasis with arthropathy, diagnosis must be active.

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 fail injectable methotrexate with at least one other DMARD [Disease-modifying antirheumatic drug] (failure is an inadequate improvement in joint symptoms and inflammation from first line approaches, or defined as inability to taper off or down to a minimum of 10mg prednisone equivalent per day). For non axial forms of Ankylosing Spondylitis, must first try and fail any two of the following conventional therapies: NSAIDs [Non-steroidal anti-inflammatory drugs], intraarticular steroids, injectable methotrexate, DMARDs [Disease-modifying antirheumatic drugs] (failure is defined as improvement of 50% or 2 units or less on BASDAI scale). For psoriasis with arthropathy, must try and fail topical therapy, and must also try and fail one of the following: Methotrexate, Oral retinoids, Cyclosporine, Phototherapy.

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 must be moderate to severe plaque psoriasis as made by a dermatologist and 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.

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 3 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.

ZORBTIVE

Affected Drugs

ZORBTIVE®

Covered Uses

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

Exclusion Criteria

N/A

Required Medical Information

N/A

Age Restrictions

18 years or greater.

Prescriber Restrictions

N/A

Coverage Duration

One 4-week course per year.

Other Criteria

Patient must be receiving specialized nutritional support, defined as high carbohydrate, low fat diet that is adjusted for individual patient requirements and preferences.

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