Prior Authorization
Medical Coverage Drug List

Actemra®

Coverage is provided for the treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, or Giant Cell arthritis when prescribed by a rheumatologist.

For a diagnosis of RA: Treatment with one disease-modifying antirheumatic drug (DMARD) (must be methotrexate) and a trial and failure of one of the following agents when requesting the IV formulation: Simponi Aria® or Remicade®/Renflexis™/Inflectra™.

For a diagnosis of polyarticular juvenile idiopathic arthritis or systemic juvenile idiopathic arthritis, treatment with one disease-modifying antirheumatic drug (DMARD) and a trial and failure of one of the following agents when requesting the IV formulation: Humira® or Remicade®.

Coverage is also provided for a diagnosis of severe or life-threatening cytokine release syndrome (CRS) associated with chimeric antigen receptor (CAR) T cell therapy, when prescribed by or in consultation with an oncologist.

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Actemra®.

Acthar® Gel (H.P. Acthar® Gel)

Coverage is provided for the treatment of infantile spasms in children younger than 2 years old.

Medical record notes must be provided to support all requests for Acthar®.

Alpha-1 Proteinase Inhibitors
(Aralast™, Glassia™, Prolastin®-C/Liquid, Zemaira®)

Coverage is provided for the treatment of alpha-1 antitrypsin deficiency (AATD).

Diagnosis of AATD must be confirmed by an alpha-1 antitrypsin level of less than 80mg/dl, which is consistent with AATD. Patient must have symptoms of emphysema and worsening lung function. Patient must be a non-smoker.

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Alpha-1 Proteinase Inhibitors.

Benlysta®

Coverage is provided for the treatment of systemic lupus erythematosus (SLE) in patients who have tested positive for serum antibodies.

Patients must have active disease as indicated by a score of at least 6 on the Safety of Estrogens in Lupus Erythematosus National Assessment modification on the SLE Disease Activity Index (SELENA-SLEDAI).

Patient must not have severe lupus nephritis, active nephritis or central nervous system lupus.

Patient must be currently receiving, and will continue to receive, a stable standard of care regimen including antimalarials, corticosteroids or nonbiologic immunosuppressives.

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Benlysta®.
Prior Authorization
Medical Coverage Drug List

**Berinert®, Firazyr®, Kalbitor®, Ruconest®**

Coverage is provided for the treatment of type 1 or type 2 hereditary angioedema (HAE) when prescribed by an immunologist, allergist, or hematologist; the requested medication is being used for the treatment of acute HAE attacks; and the patient has tried and failed preferred agents as age appropriate.

Diagnosis of HAE must be confirmed by genetic testing or with all the following laboratory findings:

1. Normal C1q levels
2. C4 levels below the limits of the laboratory's normal reference range
3. C1-INH levels (antigenic or functional) below the limits of the laboratory's normal reference range

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Berinert®, Firazyr®, Kalbitor® and Ruconest®.

**Botox® (also Dysport® and Xeomin®)**

Coverage is provided for the treatment of spasticity or dystonia associated with the following conditions when unresponsive to other treatments and when causing functional impairment:

- Cervical dystonia
- Spasmodic torticollis
- Blepharospasm
- Strabismus
- Cerebral palsy
- Spastic paraplegia
- Facial nerve VII disorders
- Laryngeal spasm
- Upper limb spasticity
- Lower limb spasticity

Coverage is provided for chronic migraines when documentation supports the patient has recurring debilitating headaches 15 or more days per month with the migraine headache lasting for four hours a day or longer. The patient must have been evaluated by a neurologist, with rebound headache being ruled out. Any other conditions or aggravating factors that are contributing to the development of chronic migraine headaches must be treated.

The patient must also have tried at least two preventative medication classes for at least 2 months (such as beta-blockers, tricyclic antidepressants, calcium channel blockers, anticonvulsants, ACE (angiotensin-converting enzyme) inhibitor/angiotensin II receptor blockers, or venlafaxine).

Coverage is provided for primary axillary hyperhidrosis which results in functional impairment or medical complications, when a prior therapy was tried and failed, and when other medical conditions and drugs have been eliminated as a cause of hyperhidrosis.

Coverage is provided for urinary incontinence associated with a neurologic condition or overactive bladder when an anticholinergic medication or Myrbetriq was tried and failed.

Coverage is provided for excessive saliva (sialorrhea) associated with Parkinson’s disease.

Coverage is provided for pelvic floor spasms (pelvic pain caused by a disorder in both the muscles and skeleton) after trial and failure with at least 2 other therapeutic alternatives, such as muscle relaxants and benzodiazepines.

Medical record notes must be provided to support all requests for Botox®, Dysport® and Xeomin®.

**Cimzia®**

Coverage is provided for the treatment of Crohn’s disease, rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis when prescribed by a specialist.

For a diagnosis of Crohn’s disease when prescribed by a gastroenterologist: One of the following criteria must be met:

- Treatment with an adequate course of systemic corticosteroids must have been ineffective or contraindicated,
Prior Authorization
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- The patient has been unable to reduce the dose of systemic corticosteroids without experiencing worsening of disease, or
- The patient is experiencing breakthrough disease (for example, active disease flares) while stabilized for at least 2 months on immunomodulatory medication (such as azathioprine, mercaptopurine, cyclosporine, or methotrexate), unless contraindicated

For a diagnosis of rheumatoid arthritis when prescribed by a rheumatologist: Treatment with methotrexate has been ineffective or contraindicated.

For a diagnosis of psoriatic arthritis when prescribed by a rheumatologist or dermatologist: Treatment with one DMARD (disease-modifying antirheumatic drug, such as methotrexate, sulfasalazine, azathioprine, hydroxychloroquine/chloroquine, cyclosporine, gold, or penicillamine) has been ineffective or contraindicated.

For a diagnosis of plaque psoriasis when prescribed by a dermatologist: Plaque psoriasis must involve at least 10% of the patient’s body surface area or be causing significant functional disability. Patient must have had a previous trial with phototherapy. Patient must have also had treatment with at least one generic oral systemic agent, such as cyclosporine, methotrexate, or acitretin, that was ineffective or contraindicated.

For a diagnosis of ankylosing spondylitis when prescribed by a rheumatologist.

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Cimzia®.

Cinqair®

Coverage is provided for add-on maintenance treatment of patients with severe asthma aged 18 years and older, and with an eosinophilic phenotype.

Diagnosis of eosinophilic asthma must be confirmed by appropriate lab tests.

Documentation of a consultation with an allergist, immunologist, or pulmonologist prior to initiation of therapy must be provided.

Patient must have tried and failed chronic administration of systemic corticosteroids or high dose inhaled corticosteroids in combination with a long acting inhaled beta2 agonist or leukotriene receptor antagonist for at least 3 months.

Cinqair® cannot be used in combination with other biologics for asthma such as Nucala® and/or Xolair®. Medical record notes must be provided to support all requests for Cinqair®.

Starting 01/01/2019, treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Cinryze®

Coverage is provided for the treatment of type 1 or type 2 hereditary angioedema (HAE) when prescribed by an immunologist, allergist, or hematologist.

Diagnosis of HAE must be confirmed by genetic testing or with all the following laboratory findings:
1. Normal C1q levels
2. C4 levels below the limits of the laboratory’s normal reference range
3. C1-INH levels (antigenic or functional) below the limits of the laboratory’s normal reference range

The requested medication must be used for the treatment of one of the following:
- Short-term prophylaxis for patients scheduled to undergo dental work, invasive medical procedures, or surgical procedures.
  OR
- Long-term prophylaxis: Patient must have a history of at least 2 HAE attacks per month or a history of attacks that are considered severe with swelling of the face, throat or gastrointestinal tract.
Patient must have tried and failed preferred agents as age appropriate. Medical record notes must be provided to support all requests for Cinryze®.

**Crysvita®**
Coverage is provided for patients 18 to 65 years of age for the treatment of the underlying cause of X-linked hypophosphatemia (XLH) when prescribed by an endocrinologist, and when the diagnosis is confirmed by laboratory findings. Medical record notes must be provided to support all requests for Crysvita®.

**Dysport®**
See Botox®.

**Entyvio™**
Coverage is provided for the diagnosis of moderately to severely active ulcerative colitis (UC) or Crohn’s disease (CD).

For a diagnosis of UC or CD, the medication must be prescribed by, or in consultation with, a gastroenterologist. Conventional therapy (such as corticosteroids or an immunomodulator) must be tried and ineffective or contraindicated/not tolerated based on clinical documentation.

Treatment coverage will be provided in your home, in a physician's office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Entyvio™.

**Enzyme Replacement Therapy**

Coverage is provided for Cerezyme®, Elelyso™, and VPRIV® for Type 1 Gaucher disease when diagnosis has been confirmed by a geneticist or metabolic specialist and laboratory testing. Symptoms such as enlarged spleen or low hemoglobin must be present.

Coverage is provided for Brineura™ for the diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2, a genetic disorder that leads to a decline in motor and language development) when patient is age 3 years and older, and when it is prescribed by a specialist. Diagnosis must be confirmed by laboratory or genetic test. Patient must be able to walk at start of treatment and will receive standard of care treatment for CLN2 (such as seizure management, nutritional support, and physical therapy).

Coverage is provided for Aldurazyme®, Elaprase®, Naglazyme®, and Vimizim™ when diagnosis of the correct form of mucopolysaccharidosis has been made by a geneticist or metabolic specialist and confirmed with laboratory testing.

Coverage is provided for Fabrazyme® when the diagnosis of Fabry disease has been made by a geneticist or metabolic specialist and confirmed by laboratory testing. All other diseases must be ruled out, patient must show symptoms of active disease, and goals of therapy must be provided.

Coverage is provided for Lumizyme® when the diagnosis of either infantile or late onset Pompe disease has been made by a geneticist or metabolic specialist and confirmed by laboratory testing. All other diseases must be ruled out.

Coverage is provided for Adagan® when the diagnosis of adenosine deaminase deficiency has been made by an immune specialist and confirmed by laboratory testing. Patient must have tried and failed, or not be a candidate for, bone marrow transplantation. Patient must not have extremely low platelet counts.

Coverage is provided for Kanuma™ when the diagnosis of lysosomal acid lipase deficiency has been made by a geneticist or metabolic specialist and confirmed by laboratory testing. Patient must show symptoms such as elevated liver enzymes or coronary artery disease.
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Medical Coverage Drug List

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Enzyme Replacement Therapy.

Exondys 51™
Coverage of Exondys 51™ is considered investigational/experimental for all indications and will not be provided.

Fasenra™
Coverage is provided as an add-on maintenance treatment for patients 12 years of age or older with a diagnosis of severe eosinophilic asthma (a subtype of asthma which is a condition where a person’s airways become inflamed, narrow, and swell, and produce extra mucus, which makes it difficult to breathe) when prescribed by an allergist/immunologist or pulmonologist.

Diagnosis of eosinophilic asthma must be confirmed by appropriate laboratory tests.

Patient must have tried and failed chronic administration of oral corticosteroids or high dose inhaled corticosteroids in combination with long acting beta-agonists or a leukotriene modifier for at least 3 months.

Patient must continue to receive standard of care regimen while on Fasenra, have tried and failed all preferred products, and its use cannot be combined with other biologics for asthma.

Medical record notes must be provided to support all requests for Fasenra™.

Ilaris®
Coverage is provided for the treatment of cryopyrin-associated periodic syndromes (CAPS), tumor necrosis factor receptor associated periodic syndrome (TRAPS), hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD), Familial Mediterranean Fever (FMF), or systemic juvenile idiopathic arthritis (SJIA) when prescribed by a rheumatologist.

Diagnosis of CAPS must be confirmed by either genetic testing or through physical assessment of symptoms. Patient must have significant functional impairment which limits activities of daily living. Patient must be experiencing one or more of the following classic syndromes of CAPS: familial cold auto-inflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), and/or neonatal-onset multisystem inflammatory disease (NOMID)/chronic infantile neurologic cutaneous articular syndrome (CINCA).

For diagnosis of SJIA: patient must have tried and failed at least one oral drug from a class called DMARD (Disease-Modifying Antirheumatic Drug, for example, methotrexate). Patient must have also tried and failed Enbrel, Remicade, and Actemra.

For a diagnosis of FMF, the patient must have tried and failed colchicine.

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Ilaris®.

Illumya™
Coverage is provided for patients 18 years of age or older for the treatment of severe plaque psoriasis when prescribed by a dermatologist.

Patient must have tried and failed treatment with phototherapy or photochemotherapy, at least 3 months of topical steroids, one generic oral systemic agent (such as methotrexate cyclosporine, or acitretin), and all preferred drugs unless contraindicated.

The use of Illumya™ cannot be combined with other biologics.

Medical record notes must be provided to support all requests for Illumya™.
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Immune Globulin Replacement Therapy

Drug names: Bivigam™, Carimune® NF, Cuvitru™, Flebogamma® DIF, Gammagard® Liquid or S/D, Gammaked®, Gammaplex®, Gamunex®, Hizentra®, HyQvia®, Octagam®, Privigen®

Coverage is provided for multiple diseases including common variable immunodeficiency, immune thrombocytopenia purpura, and hypogammaglobulinemia.

Diagnosis of disease must be confirmed by standard testing. Patient must try and fail common therapies such as systemic steroids or immunosuppressants. Patient must have significant functional impairment which limits activities of daily living.

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Immune Globulin Replacement Therapy.

Inflectra™

Coverage is provided in patients with the following diagnoses:

- Ulcerative colitis diagnosed by a gastroenterologist when treatment with a systemic corticosteroid was ineffective, or the patient was not able to decrease the dose of steroids without experiencing worsening of disease, or the patient is experiencing active flares while stabilized on immunomodulatory medication (such as azathioprine, cyclosporine, or methotrexate)
- Pediatric ulcerative colitis diagnosed by a gastroenterologist when the patient has a poor response to conventional therapy
- Rheumatoid arthritis diagnosed by a rheumatologist when clinical documentation shows that oral disease-modifying anti-rheumatic drugs (DMARD, e.g. methotrexate, sulfasalazine, azathioprine, hydroxychloroquine/chloroquine, cyclosporine, gold and penicillamine) were not effective after an adequate trial and Inflectra™ is prescribed with methotrexate
- Psoriatic arthritis diagnosed by a dermatologist or rheumatologist
- Plaque psoriasis diagnosed by a dermatologist or rheumatologist with documentation that psoriasis is affecting at least 10% of the patient’s body surface area or causing significant functional disability. Treatment with phototherapy or photochemotherapy must have been ineffective. At least one oral systemic agent must have been ineffective. Examples of systemic agents include, but are not limited to, cyclosporine, methotrexate, and acitretin
- Ankylosing spondylitis diagnosed by a rheumatologist

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.
Medical record notes must be provided to support all requests for Inflectra™.

**Krystexxa®**

Coverage is provided for the treatment of chronic gout. Patient must be experiencing two or more of the following: three or more gouty flares in an 18 month period, presence of one or more tophi, and/or chronic gouty arthritis. Patient must not have a known G6PD deficiency.

Treatment with maximum appropriate doses of standard therapy (allopurinol and Uloric [feboxostat]) must have been ineffective, not tolerated or contraindicated. Patient must have a serum uric acid level of at least 8mg/dL.

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for **Krystexxa®**.

**Kymriah™**

Coverage is provided for the treatment of patients from ages 1 up to 25 years with a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL, cancer of a particular type of cell in the blood) that is not responding to treatment or has worsened after two or more treatments, and when it is prescribed by an oncologist.

Patient must also meet all of the following criteria:

- Documentation of CD 19 tumor expression (a protein found on the surface of white blood cells)
- Patient’s bone marrow (BM) did not recover after stem cell transplant (SCT) or patient can’t receive a stem cell transplant

**AND**

For a diagnosis of ALL, patient must have tried 2 cycles of a standard chemotherapy and did not respond to treatment **OR** patient did not achieve a response after 1 cycle of standard chemotherapy for leukemia that had previously responded to treatment.

- Burkitt’s lymphoma (a type of blood cancer)
- Active hepatitis B, C, or any uncontrolled infection
- Grade 2 to 4 graft-versus-host disease (a reaction between patient’s cells and the cells received from a donor)
- Existing genetic syndrome, with the exception of Down’s syndrome
- Has received prior treatment with Kymriah™ or any other gene therapy

Documentation showing patient’s response to Kymriah™ must be provided within 3 months of treatment. Medical record notes must be provided to support all requests for **Kymriah™**.

**Luxturna™**

Coverage is provided for the treatment of Leber congenital amaurosis (LCA, a rare inherited eye disease that appears at birth or in the first few months of life) and retinitis pigmentosa (RP, an eye disease in which the retina, back wall of the eye, is damaged), when an ophthalmologist (eye doctor) confirms the diagnosis and gives the medication.

Patient must have all the following:

- A test confirming a biallelic RPE65 gene mutation (abnormal changes to your genes).
- Visual acuity (a number that shows the sharpness or clarity of vision) of 20/60 or worse in both eyes **OR** vision where both eyes work together with a visual field (total area in which objects can be seen) of less than 20 degrees
- Retinal thickness (thickness of the back wall of the eye) of greater than 100 microns

Medical record notes must be provided to support all requests for **Luxturna™**.
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Medical Coverage Drug List

Makena™
Coverage is provided for patients who are pregnant with one baby, who had a previous spontaneous preterm delivery (less than 37 weeks gestation), who will start treatment between 16 weeks 0 days and 20 weeks 6 days, and have no known fetal abnormality and no known risk factors for preterm delivery.
Medical record notes must be provided to support all requests for Makena™.

Mepsevii™
Coverage is provided for pediatric and adult patients for the treatment of mucopolysaccharidosis VII (MPS VII or Sly syndrome, a condition that causes a deficiency in a type of enzyme and leads to the body not growing) when prescribed by a geneticist or metabolic specialist.
Diagnosis of MPS VII must be confirmed by appropriate laboratory tests and documentation supporting signs of disease. In addition, documentation stating disease level status prior to treatment must be submitted.
Medical record notes must be provided to support all requests for Mepsevii™.

Myobloc®
Coverage is provided for cervical dystonia, spasmodic torticollis, sialorrhea with Parkinson’s disease, amyotrophic lateral sclerosis or cerebral palsy.
Medical record notes must be provided to support all requests for Myobloc®.

Nplate®
Coverage is provided for the treatment of chronic immune thrombocytopenia purpura (ITP), when diagnosis is confirmed by, or made in consultation with, a hematologist.
Patient must have a persistent platelet count below 100,000 mcL for more than 3 months. Patient must also have either a current platelet count below 20,000 mcL, or a current platelet count below 30,000 mcL with symptoms of active bleeding.
Patient must have had an inadequate response to, or not be a candidate for, therapy with Promacta®. Patient must have had an inadequate response to therapy with corticosteroids, immunoglobulins, or splenectomy.
Medical record notes must be provided to support all requests for Nplate®.

Nucala®
Coverage is provided as an add-on maintenance treatment for patients 12 years of age or older with a diagnosis of severe uncontrolled eosinophilic asthma as confirmed by appropriate lab tests. The patient must have tried and failed chronic administration of systemic corticosteroids or high dose inhaled corticosteroids in combination with a long acting inhaled beta2 agonist or leukotriene receptor antagonist for at least 3 months.

OR
Coverage is provided for patients 18 years of age or older with a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) with a history or presence of asthma and when two of the following criteria are met:

1. Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
2. Neuropathy
3. Pulmonary infiltrates
4. Allergic rhinitis and nasal polyps
5. Cardiomyopathy
6. Glomerulonephritis
7. Alveolar hemorrhage
8. Palpable purpura
9. Antineutrophil cytoplasmic antibody (ANCA) positivity

Documentation of a consultation with an allergist, immunologist, or pulmonologist prior to initiation of therapy must be provided.
Nucala® cannot be used in combination with other biologics for asthma such as Cinqair® and/or Xolair®.
Medical record notes must be provided to support all requests for Nucala®.
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Starting 01/01/2019, treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Onpattro™
Coverage is provided for the treatment of peripheral nerve diseases caused by hereditary transthyretin-mediated amyloidosis (hATTR) in adults. Documented clinical signs and symptoms of peripheral neuropathy or autonomic neuropathy must be submitted and there must be no ocular or cerebral involvement.

Patients must have all of the following:
• a polyneuropathy disability (PND) score of less than or equal to IIIb
• a baseline familial amyloid polyneuropathy (FAP) of stage 1 or 2
• no history of a liver transplant or plans to undergo a liver transplant
• patient must not have a New York Heart Association heart failure classification greater than 2

Onpattro cannot be used in combination with oligonucleotide agents or transthyretin stabilizers. Medical record notes must be provided to support all requests for Onpattro™.

Orencia®
Coverage is provided for the treatment of rheumatoid arthritis (RA, inflammation in joints), juvenile idiopathic arthritis (JIA, a disease affecting the joints in children), and psoriatic arthritis (PsA, a form of arthritis that affects some people who have psoriasis) in adults when prescribed by a specialist.

For a diagnosis of RA: Treatment with one disease-modifying antirheumatic drug (DMARD; examples of oral DMARDS include: methotrexate, sulfasalazine, hydroxychloroquine) and a trial and failure of Remicade®/Renflexis™/Inflectra™.

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Orencia®.

Prolia®
Coverage is provided for the treatment of osteoporosis when both of the following criteria are met:
• Bone mineral density score at or below -2.5 at the lumbar spine or total hip
• Treatment with at least one drug from a group called bisphosphonates (such as alendronate) for 24 months is not effective (if intolerance to oral administration due to gastrointestinal issues, intravenous administration for 24 months will be required)
• Patient must supplement with 1,000 mg calcium daily and at least 400 IU vitamin D daily

OR

Coverage is provided to increase bone mass in men at high risk for fracture due to receiving androgen deprivation therapy for nonmetastatic prostate cancer or for women at high risk for fracture due to receiving adjuvant aromatase inhibitor therapy for nonmetastatic breast cancer, when all of the following criteria are met:
• The 10–year probability of hip fracture is at least 3 percent or the 10–year probability of a major osteoporosis–related fracture is at least 20 percent.
• Treatment with at least one drug from a group called bisphosphonates (such as alendronate) for 24 months is not effective (if intolerance to oral administration due to gastrointestinal issues, intravenous administration for 24 months will be required).
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- Patient must supplement with 1,000 mg calcium daily and at least 400 IU vitamin D daily.

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Prolia®.

**Radicava™**

Coverage is provided for patients who have a diagnosis of amyotrophic lateral sclerosis (ALS) and are being treated in consultation with a neurologist. Patients will be eligible for start of treatment within 2 years of diagnosis OR after 2 years of diagnosis, with a percent predicted forced vital capacity (FVC) value of greater than or equal to 80%. A pretreatment measurement from the ALSFRS-R (Revised ALS Functional Rating Scale) should be submitted. Patients must also be receiving treatment with riluzole.

Medical record notes must be provided to support all requests for Radicava™.

**Remicade®**

Coverage is provided for the following:

- Active Crohn’s disease diagnosed by a gastroenterologist when treatment with a systemic corticosteroid was ineffective, or the patient was not able to decrease the dose of steroids without experiencing worsening of disease, or the patient is experiencing active flares while stabilized on immunomodulatory medication (such as azathioprine, cyclosporine, or methotrexate).
  - Fistulizing Crohn’s disease diagnosed by a gastroenterologist
  - Pediatric Crohn’s disease diagnosed by a gastroenterologist when the patient has a poor response to conventional therapy
  - Ulcerative colitis diagnosed by a gastroenterologist when treatment with a systemic corticosteroid was ineffective, or the patient was not able to decrease the dose of steroids without experiencing worsening of disease, or the patient is experiencing active flares while stabilized on immunomodulatory medication (such as azathioprine, cyclosporine, or methotrexate)

- Psoriatic arthritis diagnosed by a dermatologist or rheumatologist
  - Plaque psoriasis diagnosed by a dermatologist or rheumatologist with documentation psoriasis is affecting at least 10% of a patient’s body surface area or causing significant functional disability. Treatment with phototherapy or photochemotherapy must have been ineffective. At least one oral systemic agent must have been ineffective. Examples of systemic agents include, but are not limited to, cyclosporine, methotrexate, and acitretin.

- Ankylosing spondylitis diagnosed by a rheumatologist

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Remicade®.

**Renflexis™**

Coverage is provided in patients with the following diagnoses:

- Active Crohn’s disease diagnosed by a gastroenterologist when treatment with a systemic...
corticosteroid was ineffective, or the patient was not able to decrease the dose of steroids without experiencing worsening of disease, or the patient is experiencing active flares while stabilized on immunomodulatory medication (such as azathioprine, cyclosporine, or methotrexate)

• Fistulizing Crohn’s disease diagnosed by a gastroenterologist
• Pediatric Crohn’s disease diagnosed by a gastroenterologist when the patient has a poor response to conventional therapy
• Ulcerative colitis diagnosed by a gastroenterologist when treatment with a systemic corticosteroid was ineffective, or the patient was not able to decrease the dose of steroids without experiencing worsening of disease, or the patient is experiencing active flares while stabilized on immunomodulatory medication (such as azathioprine, cyclosporine, or methotrexate)
• Pediatric ulcerative colitis diagnosed by a gastroenterologist when the patient has a poor response to conventional therapy
• Rheumatoid arthritis diagnosed by a rheumatologist when clinical documentation shows that oral disease-modifying antirheumatic drugs (DMARD, e.g. methotrexate, sulfasalazine, azathioprine, hydroxychloroquine/chloroquine, cyclosporine, gold and penicillamine) were not effective after an adequate trial and Renflexis™ is prescribed with methotrexate
• Psoriatic arthritis diagnosed by a dermatologist or rheumatologist
• Plaque psoriasis diagnosed by a dermatologist or rheumatologist with documentation that psoriasis is affecting at least 10% of the patient’s body surface area or causing significant functional disability. Treatment with phototherapy or photochemotherapy must have been ineffective. At least one oral systemic agent must have been ineffective. Examples of systemic agents include, but are not limited to, cyclosporine, methotrexate, and acitretin
• Ankylosing spondylitis diagnosed by a rheumatologist

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Renflexis™.

**Signifor® LAR**

Coverage is provided for patients diagnosed with acromegaly who have had a poor response to surgery and/or for whom surgery is not an option. Patient must have a higher than normal Insulin-like Growth Factor (IGF-1) level. The prescribing physician must be an endocrinologist.

Patient must have tried and failed at least one of the following: Somatuline Depot®, Sandostatin®, Sandostatin LAR®, or Somavert®

Coverage is provided for a diagnosis of Cushing Disease for patients 18 years of age or older for whom pituitary surgery is not an option or has not been curative. The prescribing physician must be an endocrinologist.

Patient must have tried and failed ketoconazole, mitotane or cabergoline, unless contraindicated or not tolerated; patient must also have tried and failed Signifor. If Signifor did not work, a credible explanation of why Signifor LAR is expected to work must be provided.

Medical record notes must be provided to support all requests for Signifor® LAR.

**Simponi Aria®**

Coverage is provided in patients with the following diagnoses:

• Advanced rheumatoid arthritis when prescribed by, or in conjunction with, a rheumatologist. Patient must have tried and failed at least one oral drug from a class called DMARD (disease-modifying antirheumatic drug; must be methotrexate).
Prior Authorization
Medical Coverage Drug List

- Ankylosing spondylitis when prescribed by, or in conjunction with, a rheumatologist.
- Psoriatic arthritis when prescribed by, or in conjunction with, a dermatologist or rheumatologist.

Treatments will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Simponi Aria®.

**Soliris®**

Coverage is provided for patients who have a diagnosis of atypical hemolytic uremic syndrome (a disease that causes destruction of red blood cells), paroxysmal nocturnal hemoglobinuria (a rare disorder in which red blood cells break apart prematurely), or refractory anti-AChR antibody positive myasthenia gravis (antibody mediated disorder of the nerve), when prescribed by a specialist.

Patient must be immunized with a meningococcal vaccine at least 2 weeks prior to administering the first dose of Soliris.

Patients with paroxysmal nocturnal hemoglobinuria must have had one transfusion in the 24 months prior to receiving Soliris, or documented history of major adverse events from obstruction of a blood vessel.

Patients must also have a platelet count greater than or equal to 30,000 mcL prior to start of Soliris® therapy.

Patients with refractory myasthenia gravis must meet all of the following criteria:

- Positive laboratory test (e.g. positive edrophonium test or a test that records the electrical activity and the electrical pathways in your muscles)
- No history of removal of thymus within past 12 months OR no history of cancer of the thymus
- Extreme muscle weakness throughout the body
- Trial and failure of corticosteroids (for example, prednisone) and at least 2 or more oral immunosuppressive agents (for example, azathioprine, cyclosporine, mycophenolate mofetil or methotrexate)
- Trial and failure of 3 treatments from the following: cyclophosphamide, rituximab, chronic intravenous immunoglobulin (IVIG) and chronic plasma exchange (PLEX)

Treatments will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Soliris®.

**Spinraza®**

Coverage is provided for patients age 14 years and younger with type 1, 2, or 3 spinal muscular atrophy confirmed by genetic testing and who are being treated by a neurologist specializing in pediatric neuromuscular disorders. Patient must not be fully ventilator dependent and submission of baseline (before treatment), age appropriate exam to establish baseline motor function and ability must be included (examples: Hammersmith Infant Neurological Exam (HINE), Hammersmith Functional Motor Scale Expanded (HFMSE), Upper Limb Module (ULM) Test, Six-Minute Walk Test (6MWT) or Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)).

Renewal request for Spinraza® requires record of response to therapy which is defined as a significant improvement in a repeat assessment of motor function and ability.

Medical record notes must be provided to support all requests for Spinraza®.

**Stelara®**

Coverage is provided for patients who have a diagnosis of chronic plaque psoriasis involving at least 10 percent of the body surface area or who experience significant functional disability, when prescribed by a dermatologist. Treatment with phototherapy or photochemotherapy must have been ineffective.
At least one oral systemic agent must have been ineffective. Examples of systemic agents include, but are not limited to, cyclosporine, methotrexate, and acitretin.

Coverage is provided for patients who have a diagnosis of psoriatic arthritis when prescribed by a dermatologist or rheumatologist. At least one disease-modifying antirheumatic drug (DMARD) must have been ineffective. Examples of DMARDs include, but are not limited to, cyclosporine, methotrexate, and sulfasalazine.

Coverage is provided for patients who have a diagnosis of Crohn’s disease when prescribed by a gastroenterologist. Treatment with conventional oral therapies (such as corticosteroids or immunomodulators) must not have been effective or were not tolerated. Treatment with subcutaneous Stelara® will only be approved following documentation of a one-time weight based intravenous dose.

Treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Medical record notes must be provided to support all requests for Stelara®.

**Synagis®**

Coverage is provided for the prevention of respiratory syncytial virus (RSV) infections when one or more of the following criteria are met:

When gestational age is a consideration:

- Patient was born at 28 weeks gestation or less and is less than 12 months of age at the start of RSV season.

- Patient was born at less than 32 weeks gestation and has chronic lung disease (CLD). Patient must have had a requirement of greater than 21% oxygen for at least the first 28 days after birth. Patient must also be less than 1 year of age. **Exceptions may be made for children less than 2 years old who fulfill the definition of CLD of prematurity and continue to require medical support during the 6-month period before the start of the second RSV season.**

When gestational age is not a consideration:

- Patient is younger than 12 months of age with a diagnosis of hemodynamically significant cyanotic or acyanotic coronary heart disease (CHD) (such as congestive heart failure (CHF), moderate to severe pulmonary hypertension, or cyanotic heart disease) which requires treatment.

- Patient is younger than 12 months of age with significant congenital abnormalities of the airway or neuromuscular disease, either of which compromises the handling of respiratory tract secretions.

- Patient is younger than 12 months of age with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise may be considered for prophylaxis.

- Patient is younger than 24 months of age and is immunocompromised with severe combined immunodeficiency or advanced AIDS (acquired immune deficiency syndrome).

Coverage will not be provided for an infant or child who is currently receiving monthly Synagis as prophylaxis treatment and experiences a breakthrough RSV hospitalization/infection.

Medical record notes must be provided to support all requests for Synagis®.

**Testosterone Therapies (Aveed®, Testopel®)**

Coverage is provided for the following:

- Male patients with androgen deficiency syndrome documented by two below-normal morning testosterone levels within the past year. Patient’s signs and symptoms must be suggestive of androgen deficiency (for example, height loss or incomplete or delayed sexual development).

- Patients with breast cancer who are in need of adjunctive palliative treatment.

Medical record notes must be provided to support all requests for Testosterone Therapy.
Trogarzo™
Coverage is provided for the treatment of human immunodeficiency virus type 1 (HIV-1) for patients 18 years of age or older when prescribed by or in consultation with an infectious disease specialist or physician who specializes in the treatment of HIV.
Trogarzo must be used in combination with other anti-retroviral therapy for the treatment of HIV-1. Patient must have been heavily treatment experienced with multidrug resistance demonstrated by documented resistance to at least 1 anti-retroviral medication for each of the 3 drug classes: a nucleoside reverse transcriptase inhibitor (NRTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI), and a protease inhibitor. The patient must also be failing their current anti-retroviral therapy as shown with a RNA viral load greater than 200 copies/mL.
Medical record notes must be provided to support all requests for Trogarzo™.

Xeomin®
See Botox®.

Xgeva®
Coverage is provided for:

- Adults and skeletally mature adolescents with giant cell tumor of the bone documented by computed tomography (CT) scan or magnetic resonance imaging (MRI) when surgery is ruled out as an option.
- The prevention of skeletal related events in patients with multiple myeloma or bone metastases from breast cancer, prostate cancer, or solid tumors with documentation supporting that at least one intravenous (IV) bisphosphonate (examples: pamidronate or zoledronic acid) has been ineffective or is contraindicated
- Treatment of hypercalcemia of malignancy (HCM) with a corrected serum calcium (CSC) level greater than or equal to 12mg/dL with documentation supporting that at least one IV bisphosphonate (examples: pamidronate or zoledronic acid) has been ineffective or is contraindicated

Medical record notes must be provided to support all requests for Xgeva®.

Xiaflex®
Coverage is provided for the treatment of Dupuytren’s contracture in patients 18 or older. Documentation must support a finger flexion contracture with a palpable cord of at least one finger (other than the thumb) involving the metacarpophalangeal joint or the proximal interphalangeal joint. Administering physician must be a surgeon who has experience and training in hand surgeries.
Coverage is provided for the treatment of Peyronie’s disease in patients 18 or older. Documentation must support a palpable plaque and curvature deformity of 30 degrees or more at start of therapy. The patient must also have tried intralesional verapamil and at least one of the following: pentoxifylline or verapamil gel. Administering physician must be a urologist.
The physician must have completed the Xiaflex® training, and the facility must be enrolled to receive Xiaflex® through Xiaflex® REMS.
Medical record notes must be provided to support all requests for Xiaflex®.

Xolair®
Coverage is provided for patients who have a diagnosis of moderate to severe allergic asthma, confirmed with either a positive skin test or reaction to yearly or seasonal allergens.
For a diagnosis of moderate to severe allergic asthma: patient must have tried and failed chronic administration of systemic corticosteroids or a high dose inhaled corticosteroid, in combination with a long acting inhaled beta 2 agonist or leukotriene receptor antagonist for at least 3 months.
Patients 12 years and older must have IgE levels between 30 and 700 IU/ml. Patients between the ages of 6 years and 12 years old must have IgE levels between 30 and 1300 IU/ml.
Prior Authorization
Medical Coverage Drug List

For a diagnosis of moderate to severe allergic asthma, Xolair must be prescribed by an allergist/immunologist or pulmonologist and cannot be used in combination with other biologics such as Nucala® and Cinqair®.

Coverage is provided for patients who have a diagnosis of chronic idiopathic urticaria.

For a diagnosis of chronic idiopathic urticaria, patient must have tried treatment for 2 months and failed the following steps:

- A second generation antihistamine (e.g. Zyrtec, Allegra or Claritin) at the maximum tolerated dose
- Maximal tolerated dose of a first generation antihistamine (e.g. Benadryl) at bedtime, OR an H2 receptor antagonist (e.g. Zantac or Pepcid), OR another second generation antihistamine OR Leukotriene receptor antagonist therapy (e.g. Singulair or Accolate)

AND

For a diagnosis of chronic idiopathic urticaria, Xolair must be prescribed by an allergist/immunologist or dermatologist and cannot be used in combination with other biologics such as Nucala® and Cinqair®.

Medical record notes must be provided to support all requests for Xolair®.

Starting 01/01/2019, treatment coverage will be provided in your home, in a physician’s office, or at an infusion center not associated with a hospital. If you cannot receive your treatment at one of the places mentioned above, documentation supporting medical necessity for outpatient hospital administration must be provided for review.

Yescarta™

Coverage is provided for patients who are greater than 18 years of age who have a diagnosis of large B-cell lymphoma (a type of blood cancer) that is not responding to treatment or has worsened after two or more lines of treatments and when prescribed by an oncologist.

Patients must also meet all of the following criteria:

- Documentation of CD 19 tumor expression (a protein found on the surface of white blood cells)
- Received anti-CD20 monoclonal antibody (a medication used to treat certain autoimmune diseases and types of cancer), unless the specialist determines otherwise
- Received an anthracycline-containing chemotherapy regimen (such as doxorubicin or daunorubicin)

AND

Patients with transformed follicular lymphoma (FL, when the body makes abnormal white blood cells) must have received prior chemotherapy for follicular lymphoma and subsequently have disease that is not responding to chemotherapy after transformation to diffuse large B-cell lymphoma (DLBCL)

Patients will not be eligible for treatment if he/she has any of the following:

- Prior stem cell transplant
- History of cancer of the central nervous system
- ECOG performance status of 2 or greater (a scale used to assess how a patient’s disease is progressing)
- Absolute lymphocyte count (count of one of the subtypes of white blood cell) of less than 100/μL
- Reduced kidney function, reduced liver function, or reduced heart function
- Active serious infection
- Prior treatment with YescartaTM or any other gene therapy

Documentation showing patient’s response to Yescarta™ treatment must be provided within 3 months of treatment.

Medical record notes must be provided to support all requests for Yescarta™.
Zilretta®

Coverage is provided for patients who are greater than 18 years of age with a diagnosis of osteoarthritis of the knee with a Kellgren-Lawrence grade of 2 or greater when prescribed by or in consultation with a rheumatologist or orthopedic surgeon.

The patient must have an inadequate response to two of the following non-pharmacological therapies: resistance exercise, weight reduction, utilization of durable medical equipment, or physical/occupational therapy.

In addition, the patient must try and fail all of the following, unless contraindicated: an oral non-steroidal anti-inflammatory drug (NSAID) at maximum dose, a topical NSAID, and intra-articular triamcinolone acetonide injection. Treatment failure is defined as inadequate pain relief, frequent need for rescue doses of NSAIDs, inability to increase activity levels or the need to decrease activity levels, and adequate pain relief but the patient is experiencing steroid-induced hyperglycemia. A credible explanation as to why Zilretta is expected to work when triamcinolone acetonide did not must be submitted to the plan.

Coverage will not be provided if the patient has had a previous intra-articular corticosteroid injection with the past 3 months.

Medical record notes must be provided to support all requests for Zilretta®.

Zinplava™

Coverage is provided for patients who are greater than 18 years of age and who have a diagnosis of Clostridium difficile infection (CDI) and a positive stool test. Patients also must be at high risk for CDI recurrence (e.g. patients aged 65 years or older, history of CDI in the past 6 months, immunocompromised state, severe CDI at presentation or Clostridium difficile ribotype 027).

Zinplava™ must be prescribed by or in consultation with a gastroenterologist or infectious disease specialist and must be used with standard of care antibacterial agents (i.e. metronidazole or vancomycin).

Medical record notes must be provided to support all requests for Zinplava™.