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# Clinical Information For Drugs Covered Under the Medical Benefit That Require Medical Necessity Review

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| Actemra® (tocilizumab) | Must submit **all** of the following:<br>• Diagnosis of rheumatoid arthritis<br>• Prescribing physician is a rheumatologist<br>• Previous treatment failure with:<br>o One oral DMARD (must be methotrexate unless contraindicated) for at least 3 months<br>AND<br>o Remicade® OR Simponi Aria®<br>• Any additional pertinent medical information |
| Adagen® (pegademase bovine) | Must submit **all** of the following:<br>• Diagnosis made by or in consultation with an immune specialist<br>• Diagnosis of adenosine deaminase (ADA) deficiency in a member with severe combined immunodeficiency disease (SCID)<br>• Diagnosis confirmed by evidence of combined immunodeficiency AND an absence of thymus and other lymphoid tissues<br>• Evidence that the member tried and failed bone marrow transplantation or was found not to be a suitable candidate for it<br>• No evidence of severe thrombocytopenia<br>• Any additional pertinent medical information |
| Aldurazyme® (laronidase) | Must submit **all** of the following:<br>• Diagnosis of one of the following:<br>o Hurler mucopolysaccharidosis (MPS) I with moderate to severe symptoms<br>o Hurler-Scheie MPS I with moderate to severe symptoms<br>• Diagnosis confirmed by serum assays showing enzyme deficiency of alpha-L-iduronidase AND urinary glycosaminoglycan (GAG), dermatan sulfate or heparin sulfate<br>• Any additional pertinent medical information |
| Aralast NP (alpha-1 proteinase inhibitor) | Must submit **all** of the following:<br>• Evidence that member is 18 years or age or older and is a nonsmoker<br>• Serum levels of alpha-1 antitrypsin<br>• Diagnosis of symptomatic emphysema<br>• Evidence that member has deteriorating pulmonary function as demonstrated by a decline in the FEV1<br>• Any additional pertinent medical information |

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| Aveed® (testosterone undecanoate) | Must submit **all** of the following:<br>• Diagnosis of androgen deficiency syndrome in a male patient<br>o TWO morning testosterone levels in the past year below the testing laboratory's lower limit of normal range (Free testosterone levels may be required.)<br>o Evidence of at least TWO specific signs and/or symptoms of testosterone deficiency (i.e., incomplete/delayed sexual development, breast discomfort, gynecomastia, loss of body hair, etc.)<br>• Names of medications previously used to treat this condition, including dosages, dates of therapy and response<br>• Any additional pertinent medical information |
| Beleodaq™ (belinostat) | Must submit **all** of the following:<br>• Diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL)<br>• Evidence of intolerance to progression of disease on at least one prior therapy<br>• Confirmation that the treating physician is a board-certified oncologist<br>• Names of medications previously used to treat this condition, including dosages, dates of therapy and responses<br>• Any additional pertinent clinical information |
| Benlysta® (belimumab) | Must submit **all** of the following:<br>• Diagnosis of systemic lupus erythematosus (SLE)<br>• Labs confirming member is seropositive<br>• Member's current score on the Safety of Estrogens in the Lupus Erythematosus National Assessment version of the Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI)<br>• Information showing that member does not have severe lupus nephritis, active nephritis or active central nervous system lupus<br>• Names of medications previously used to treat this condition, including dosages, dates of therapy and responses<br>• Dosage of drug and frequency of administration<br>• Any additional pertinent medical information |

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| Berinert® (C1 esterase inhibitor, human) | Must submit **all** of the following:<br>• Diagnosis of type I or type II hereditary angioedema<br>• Diagnosis established by an immunologist, allergist or hematologist<br>• Labs confirming diagnosis<br>• Dosage of drug and frequency of administration<br>• Length of treatment<br>• Names of medications previously used to treat this condition, including dosage, regimens, dates of therapy and response<br>• Any additional pertinent medical information |
| Blincyto® (blinatumomab) | Must submit **all** of the following:<br>• Patient's age and diagnosis<br>• Laboratory results or testing confirming diagnosis<br>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation<br>• Any additional pertinent medical information |
| Boniva® (ibandronate sodium) | Must submit **all** of the following:<br>• Diagnosis. Indicate which diagnosis the drug is being used to treat.<br>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation<br>• Any additional pertinent medical information |
| Botox® (botulinum toxin type A) injections | Must submit **all** of the following:<br>• Diagnosis<br>• Previous treatment<br>• Response to previous treatment<br>• Any additional pertinent medical information |

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| Cerezyme® (imiglucerase) | Must submit **all** of the following:<br>• Diagnosis made by or in consultation with a geneticist or metabolic specialist<br>• Diagnosis of Type 1 Gaucher disease confirmed by one of the following:<br>o Biochemical assay of glucocerebrosidase activity in WBCs or skin fibroblasts is ≤30 percent of normal activity<br>o Genotyping revealing two pathogenic mutations of the glucocerebrosidase gene<br>• Evidence that symptomatic manifestations of the disease are present, such as anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly<br>• Any additional pertinent medical information |
| Cinryze™ (C1 esterase inhibitor, human) | Must submit **all** of the following:<br>• Diagnosis of type I or type II hereditary angioedema<br>• Diagnosis established by an immunologist, allergist or hematologist<br>• Laboratory results confirming diagnosis<br>• Dosage of drug and frequency of administration<br>• Length of treatment<br>• Names of medications previously used to treat this condition, including dosage, regimens, dates of therapy and response<br>• Any additional pertinent medical information |
| Cyramza® (ramucirumab) | Must submit **all** of the following:<br>• Diagnosis<br>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation<br>• Specialty of prescribing physician<br>• Any additional pertinent medical information |
| Delatestryl® (testosterone enanthate) | Must submit **all** of the following:<br>• Diagnosis of androgen deficiency syndrome in a male patient<br>o TWO morning testosterone levels in the past year below the testing laboratory's lower limit of normal range (Free testosterone levels may be required.)<br>o Evidence of at least TWO specific signs and/or symptoms of testosterone deficiency (i.e., incomplete/delayed sexual development, breast discomfort, gynecomastia, loss of body hair, etc.)<br>• Names of medications previously used to treat this condition, including dosages, dates of therapy and response<br>• Any additional pertinent medical information |

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| Depo-Testosterone® (testosterone cypionate) | Must submit **all** of the following:<br>• Diagnosis of androgen deficiency syndrome in a male patient<br>o TWO morning testosterone levels in the past year below the testing laboratory's lower limit of normal range (Free testosterone levels may be required.)<br>o Evidence of at least TWO specific signs and/or symptoms of testosterone deficiency (i.e., incomplete/delayed sexual development, breast discomfort, gynecomastia, loss of body hair, etc.)<br>• Names of medications previously used to treat this condition, including dosages, dates of therapy and response<br>• Any additional pertinent medical information |
| Dysport® (botulinum toxin type A) injections | Must submit **all** of the following:<br>• Diagnosis<br>• Previous treatment<br>• Response to previous treatment<br>• Any additional pertinent medical information |
| Elaprase® (idursulfase) | Must submit **all** of the following:<br>• Diagnosis made by or in consultation with a geneticist or metabolic specialist<br>• Diagnosis of Hunter's syndrome (MPS II)<br>• Diagnosis confirmed by serum levels of assays of enzyme deficiency of iduronate sulfatase AND urinary GAG, dermatan sulfate or heparin sulfate<br>• Any additional pertinent medical information |
| Elelyso™ (taliglucerase alfa) | Must submit **all** of the following:<br>• Diagnosis made by or in consultation with a geneticist or metabolic specialist<br>• Diagnosis of Type 1 Gaucher disease confirmed by one of the following:<br>o Biochemical assay of glucocerebrosidase activity in WBCs or skin fibroblasts is ≤30 percent of normal activity<br>o Genotyping revealing two pathogenic mutations of the glucocerebrosidase gene<br>• Evidence that symptomatic manifestations of the disease are present, such as anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly<br>• Any additional pertinent medical information |

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| Entyvio® (vedolizumab) | Must submit **all** of the following:<br>• Diagnosis of moderate to severe active ulcerative colitis or moderate to severe active Crohn's disease<br>• Evidence that medication is prescribed by, or in consultation with, a gastroenterologist<br>• Evidence that conventional therapy (for example, corticosteroids, immunomodulator,) has been ineffective, contraindicated or not tolerated, based on clinical documentation<br>• Evidence of inadequate response to at least **two** preferred biologic therapies for this indication.<br>• Names of medications previously used to treat this condition, including dosages, dates of therapy and responses<br>• Any additional pertinent medical information |
| Eylea® (aflibercept injection) | Must submit **all** of the following:<br>• Diagnosis the requested drug will be used to treat<br>• Dosage of drug and frequency of administration<br>• Names of medications previously used to treat this condition, including dosage, regimens, dates of therapy and response<br>• Any additional pertinent medical information |
| Fabrazyme® (agalsidase beta) | Must submit **all** of the following:<br>• Diagnosis made by or in consultation with a geneticist or metabolic specialist<br>• Diagnosis of Fabry disease<br>• Evidence that all other conditions, such as cardioembolic stroke or dissection syndromes, have been ruled out<br>• Evidence that diagnosis in males shows deficient activity of the enzyme α-galactosidase in plasma and/or leukocytes AND molecular testing of GLA mutation<br>• Evidence that diagnosis in females includes molecular testing of GLA mutation<br>• Evidence of the clinical manifestations of the disease (kidney dysfunction, severe pain in the extremities, etc.) along with baseline kidney, nervous system and heart function<br>• Any additional pertinent medical information |

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| Firazyr® (icatibant injection) | Must submit **all** of the following:<br>• Diagnosis of type I or type II hereditary angioedema<br>• Diagnosis established by an immunologist, allergist or hematologist<br>• Labs confirming diagnosis<br>• Dosage of drug and frequency of administration<br>• Length of treatment<br>• Names of medications previously used to treat this condition, including dosage, regimens, dates of therapy and response<br>• Any additional pertinent medical information |
| Flolan® (epoprostenol sodium) therapy | Must submit **all** of the following:<br>• Pulmonary hypertension therapy with New York Heart Association Class III or Class IV symptoms<br>• Failure to respond to medical management (for example, oral vasodilator therapy)<br>• Any additional pertinent medical information |
| Fusilev® (levoleucovorin) | Must submit **all** of the following:<br>• Diagnosis. Indicate which diagnosis the drug is being used to treat.<br>• Documentation showing treatment failure of or intolerance or contraindication to leucovorin, including dosage, dates of therapy and response<br>• Dosage of drug, frequency of administration and length of treatment |
| Gazyva® (obinutuzumab) | Must submit **all** of the following:<br>• Patient's age and diagnosis<br>• Any additional pertinent medical information |
| Glassia (alpha 1-proteinase inhibitor) | Must submit **all** of the following:<br>• Evidence that member is 18 years or age or older and is a nonsmoker<br>• Serum levels of alpha-1 antitrypsin<br>• Diagnosis of symptomatic emphysema<br>• Evidence that member has deteriorating pulmonary function as demonstrated by a decline in the FEV1<br>• Any additional pertinent medical information |
| H.P. Acthar® Gel (repository corticotropin injection) | Must submit **all** of the following:<br>• Diagnosis. Indicate which diagnosis the drug is being used to treat.<br>• Names of medications previously used to treat this condition, including dosage, regimens, dates of therapy and response<br>• Any additional pertinent medical information |

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| Ilaris® (canakinumab) | Please submit the following:<br>• Diagnosis of systemic juvenile idiopathic arthritis AND<br>• Evidence of trial and failure of oral nonbiologic DMARDs AND<br>• Evidence of trial and failure of Enbrel®, Remicade® AND Actemra®<br>OR<br>• Laboratory evidence of a genetic mutation, such as in the cold-induced auto-inflammatory syndrome 1 (CIAS1, also referred to as the NLRP-3) AND<br>• Clinical documentation that the member is experiencing the classic symptoms of CAPS, defined as:<br>o Familial cold auto-inflammatory syndrome (FCAS) OR<br>o Muckle-Wells syndrome (MWS)<br>Must **also** submit any additional pertinent medical information |
| Immune globulin replacement therapy (intravenous and subcutaneous) | Must submit **all** of the following:<br>• Diagnosis. Indicate which diagnosis the drug is being used to treat.<br>• Any pertinent laboratory results or testing to confirm diagnosis<br>• Names of medications previously used to treat this condition, including dosage, regimens, dates of therapy and response<br>• Any additional pertinent medical information |
| Jevtana® (cabazitaxel) | Must submit **all** of the following:<br>• Diagnosis of hormone refractory metastatic prostate cancer<br>• Previous treatment with a docetaxel-containing treatment regimen<br>• Evidence that Jevtana is being prescribed in combination with prednisone<br>• Any additional pertinent medical information |
| Kadcyla® (ado-trastuzumab emtansine) | Must submit **all** of the following:<br>• Diagnosis of HER2-positive metastatic breast cancer<br>• Evidence that the member previously received trastuzumab and a taxane, separately or in combination, with disease recurrence during or within six months of completing adjuvant therapy<br>• Any additional pertinent medical information |

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| Kalbitor® (ecallantide) | Must submit **all** of the following:<br>• Diagnosis of type I or type II hereditary angioedema<br>• Diagnosis established by an immunologist, allergist or hematologist<br>• Labs confirming diagnosis<br>• Dosage of drug and frequency of administration<br>• Length of treatment<br>• Names of medications previously used to treat this condition, including dosage, regimens, dates of therapy and response<br>• Any additional pertinent medical information |
| Kanuma™ (sebelipase alfa) | Must submit **all** of the following:<br>• Diagnosis<br>• Lab results or genetic testing confirming diagnosis<br>• Specialty of prescribing physician<br>• Any additional pertinent medical information |
| Keytruda® (pembrolizumab) | Must submit **all** of the following:<br>• Diagnosis the requested drug will be used to treat (FDA indication)<br>• Evidence that member is 18 years or age or older<br>• Evidence that medication is prescribed by an oncologist<br>• Any additional pertinent medical information |
| Krystexxa® (pegloticase) | Must submit **all** of the following:<br>• Evidence of chronic gouty arthritis, with three or more gouty flares in the previous 18 mos<br>• Presence of one or more tophi and evidence that serum uric acid is greater than 8 mg/dL<br>• Treatment with maximally titrated doses of allopurinol (800 mg) and febuxostat (80 mg) is contraindicated or not tolerated or has been ineffective<br>• Dosage of drug and frequency of administration<br>• Any additional pertinent medical information |

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| Kyprolis® (carfilzomib) | Must submit **all** of the following:<br>• Evidence that prescriber is an oncologist or hematologist<br>• Diagnosis of relapsing or refractory multiple myeloma<br>• Evidence of prior treatment and failure with ALL of the following:<br>o Bortezomib-based regimen<br>o Immunomodulatory agent<br>• Any additional pertinent medical information |
| Lemtrada™ (alemtuzumab) | Must submit **all** of the following:<br>• Diagnosis of relapsing form of multiple sclerosis in a member 18 years of age or older<br>• Evidence that prescriber is a neurologist<br>• Evidence of disease activity as demonstrated by either clinical documentation from the last 12 months or a new lesion shown on MRI in the last six months<br>• Evidence of clinical failure resulting from prior treatment with all of the following: one interferon product, two oral agents, Tysabri® and Copaxone®<br>• Evidence that complete blood count with differential, serum creatinine levels, urinalysis, and thyroid function tests was completed prior to treatment course initiation<br>• Evidence that complete blood count with differential, serum creatinine levels and urinalysis will be conducted on a monthly basis AND thyroid function tests will be conducted on a quarterly basis during treatment<br>• Any additional pertinent medical information |
| Lucentis® (ranibizumab injection) | Must submit **all** of the following:<br>• Diagnosis the requested drug will be used to treat<br>• Dosage of drug and frequency of administration<br>• Names of medications previously used to treat this condition, including dosage, regimens, dates of therapy and response<br>• Any additional pertinent medical information |

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| Lumizyme® (alglucosidase alfa) | Must submit **all** of the following:<br>• Diagnosis of infantile-onset or late-onset (non-infantile) Pompe disease with no evidence of cardiac hypertrophy<br>• Diagnosis made by or in consultation with a geneticist or metabolic specialist<br>• Evidence that all other possible conditions have been ruled out<br>• Evidence that the diagnosis has been confirmed by the absence of acid alpha glucosidase (GAA) activity, through GAA mutation testing or GAA activity testing in fibroblasts or muscle<br>• Evidence that the diagnosis is supported by a series of screening tests including a chest X-ray, electrocardiogram (ECG), electromyogram (EMG) AND/OR creatine kinase (CK), among other laboratory tests<br>• Any additional pertinent medical information |
| Makena™ (hydroxy-progesterone caproate injection) | Must submit **all** of the following:<br>• Evidence that member is 16 years of age or older and is at risk of preterm birth with singleton pregnancy<br>• Evidence that gestational age is between 16 weeks, 0 days and 20 weeks, 6 days at treatment initiation and there is no known fetal anomaly<br>• History of spontaneous preterm birth (delivery less than 37 weeks' gestation) with previous singleton pregnancies<br>• Dosage of drug and frequency of administration<br>• Any additional pertinent medical information |
| Myobloc® (botulinum toxin type B) injections | Must submit **all** of the following:<br>• Diagnosis<br>• Previous treatment<br>• Response to previous treatment<br>• Ann additional pertinent medical information |

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| Myozyme® (alglucosidase alfa) | Must submit **all** of the following:<br>• Diagnosis of infantile-onset Pompe disease<br>• Diagnosis made by or in consultation with a geneticist or metabolic specialist<br>• Evidence that all other possible conditions have been ruled out<br>• Evidence that the diagnosis has been confirmed by the absence of acid alpha glucosidase (GAA) activity, through GAA mutation testing or GAA activity testing in fibroblasts or muscle<br>• Evidence that the diagnosis is supported by a series of screening tests including a chest X-ray, electrocardiogram (ECG), electromyogram (EMG) AND/OR creatine kinase (CK), among other laboratory tests<br>• Any additional pertinent medical information |
| Naglazyme® (galsulfase) | Must submit **all** of the following:<br>• Diagnosis of mucopolysaccharidosis (MPS) syndrome VI<br>• Diagnosis made by or in consultation with a geneticist or metabolic specialist<br>• Evidence that diagnosis is confirmed by serum assays of an enzyme deficiency of N-acetylgalactosamine-6-sulfatase AND urinary GAG - dermatan sulfate<br>• Any additional pertinent medical information |
| NPlate® (romiplostim) | Must submit **all** of the following:<br>• Diagnosis of chronic immune thrombocytopenic purpura<br>• Labs confirming diagnosis and supporting use of this therapy<br>• Dosage of drug and frequency of administration<br>• Member's weight<br>• Length of treatment<br>• Names of medications previously used to treat this condition, including dosage, regimens, dates of therapy and response<br>• Any additional pertinent medical information |

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|---|---|
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| Nucala® (mepolizumab) | Must submit **all** of the following:<br>• Diagnosis<br>• Laboratory results or testing confirming diagnosis<br>• Specialty of prescribing physician<br>• Patient's age<br>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation<br>• Any additional pertinent medical information |
| Opdivo® (nivolumab) | Must submit **all** of the following:<br>• Diagnosis<br>• Any pertinent lab results or genetic testing to confirm diagnosis<br>• Specialty of prescribing physician<br>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation<br>• Any additional pertinent medical information |
| Orencia® (abatacept) | Must submit **all** of the following:<br>• Diagnosis of rheumatoid arthritis<br>• Prescribing physician is a rheumatologist<br>• Previous treatment failure with:<br>o One oral DMARD (must be methotrexate unless contraindicated) for at least 3 months<br>AND<br>o Remicade® OR Simponi Aria®<br>• Any additional pertinent medical information |
| Perjeta® (pertuzumab) | Must submit **all** of the following:<br>• Diagnosis<br>• Any pertinent lab results or genetic testing to confirm diagnosis<br>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation<br>• Any additional pertinent medical information |

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| Prolastin®<br>(alpha-1 proteinase inhibitor) | Must submit **all** of the following:<br>• Evidence that member is 18 years or age or older and is a nonsmoker<br>• Serum levels of alpha-1 antitrypsin<br>• Diagnosis of symptomatic emphysema<br>• Evidence that member has deteriorating pulmonary function as demonstrated by a decline in the FEV1<br>• Any additional pertinent medical information |
| Prolia®<br>(denosumab) | Must submit **all** of the following:<br>• Diagnosis. Indicate which diagnosis the drug is being used to treat.<br>• Any pertinent laboratory results or testing to confirm diagnosis<br>• Dosage of drug and frequency of administration<br>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation<br>• Any additional pertinent medical information |
| Provenge®<br>(sipuleucel-T) | Must submit a diagnosis of metastatic prostate cancer and documentation showing that **all** of the following criteria have been met:<br>• Bone scan or CT scan showing evidence of prostate cancer spread to the lymph nodes or bones (but not the lungs, liver or brain) with evidence of progression at either of these sites<br>• Hormone refractory (castrate resistant) evidenced by baseline testosterone levels < 50 ng/mL<br>• Little or no cancer-related pain as evidenced by no need for narcotic pain medications<br>• Any additional pertinent medical information |
| Reclast®<br>(zoledronic acid) | In the e-referral system, the submitter receives a prompt to complete a questionnaire to determine the appropriateness of the requested service. Refer to the **example zoledronic acid questionnaire**.<br>In addition, must submit **all** of the following:<br>• Diagnosis. Indicate which diagnosis the drug is being used to treat.<br>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation<br>• Dosage of drug and frequency of administration<br>• Any additional pertinent medical information |

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|---|---|
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| Remodulin® (treprostinil sodium) | Must submit evidence of **all** of the following:<br>• Pulmonary hypertension therapy with New York Heart Association Class III or Class IV symptoms<br>• Failure to respond to medical management (for example, vasodilator therapy)<br>• Any additional pertinent medical information |
| Ruconest® (C1 esterase inhibitor) | Must submit **all** of the following:<br>• Diagnosis of type I or type II hereditary angioedema<br>• Diagnosis established by an immunologist, allergist or hematologist<br>• Labs confirming diagnosis<br>• Dosage of drug and frequency of administration<br>• Length of treatment<br>• Names of medications previously used to treat this condition, including dosage, regimens, dates of therapy and response<br>• Any additional pertinent medical information |
| Simponi Aria® (golimumab) | Must submit **all** of the following:<br>• Diagnosis of rheumatoid arthritis<br>• Prescribing physician is a rheumatologist<br>• Names of medications previously used to treat this condition, including dosages, dates of therapy and response<br>• Any additional pertinent medical information |
| Soliris® (eculizumab) | Must submit **one** of the following:<br>• Evidence that the member has been vaccinated against meningococcal infection at least two weeks prior to requested treatment<br>• Diagnosis of atypical hemolytic uremic syndrome (aHUS)<br>OR<br>• Documented diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) with the following:<br>o Administration of at least one transfusion in the 24 months preceding eculizumab OR<br>o Documented history of major adverse thrombotic vascular events from thromboembolism<br>o Platelets >30,000 prior to eculizumab therapy<br>Must **also** submit **all** of the following:<br>• Lab results to confirm diagnosis<br>• Any additional pertinent medical information |

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|---|---|
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| Stelara™ (ustekinumab) | Must submit **all** of the following:<br>• Diagnosis: Indicate which diagnosis the drug is being used to treat.<br>• Dosage of drug and frequency of administration<br>• Member's weight<br>• List of treatments previously used for the condition provided, including dosage, regimens, dates of therapy and response<br>• Any additional pertinent medical information |
| Synagis® (palivizumab) | Must submit **all** of the following:<br>• Indication of respiratory syncytial virus (RSV) prophylaxis<br>• Coverage based on recommendations from the American Academy of Pediatrics (AAP) Policy Statement<br>• Any additional pertinent medical information |
| Testopel® (testosterone pellet) | Must submit **all** of the following:<br>• Diagnosis of androgen deficiency syndrome in a male patient<br>o TWO morning testosterone levels in the past year below the testing laboratory's lower limit of normal range (Free testosterone levels may be required.)<br>o Evidence of at least TWO specific signs and/or symptoms of testosterone deficiency (i.e., incomplete/delayed sexual development, breast discomfort, gynecomastia, loss of body hair, etc.)<br>• Names of medications previously used to treat this condition, including dosages, dates of therapy and response<br>• Any additional pertinent medical information |
| Vimizim® (elosulfase alfa) | Must submit **all** of the following:<br>• Diagnosis of mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)<br>• Diagnosis made by or in consultation with a geneticist or metabolic specialist<br>• Evidence that member is 5 years of age or older<br>• Evidence that diagnosis is confirmed by serum assays of enzyme deficiency of Nacetylgalactosamine-6-sulfatase AND urinary GAG keratin ~~dermatan~~ sulfate<br>• Any additional pertinent medical information |

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| Vpriv® (velaglucerase alfa) | Must submit **all** of the following:<br>• Diagnosis of Type 1 Gaucher disease confirmed by one of the following:<br>o Biochemical assay of glucocerebrosidase activity in WBCs or skin fibroblasts is ≤30 percent of normal activity<br>o Genotyping revealing two pathogenic mutations of the glucocerebrosidase gene<br>• Diagnosis made by or in consultation with a geneticist or metabolic specialist<br>• Evidence that symptomatic manifestations of the disease are present, such as anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly<br>• Any additional pertinent medical information |
| Xeomin® (botulinum toxin type A) injections | Must submit **all** of the following:<br>• Diagnosis<br>• Previous treatment<br>• Response to previous treatment<br>• Any additional pertinent medical information |
| Xgeva™ (denosumab) | Must submit **all** of the following:<br>• Diagnosis. Indicate which diagnosis the drug is being used to treat.<br>• Any pertinent laboratory results or testing to confirm diagnosis<br>• Dosage of drug and frequency of administration<br>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation<br>• Any additional pertinent medical information |

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|---|---|
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| Xiaflex® (collagenase clostridium histolyticum) | Must submit **all** of the following:<br>• Diagnosis of Dupuytren's contracture in a member 18 years of age or older AND<br>• Evidence of a finger flexion contracture with a palpable cord involving the metacarpophalangeal (MP) joint or the proximal interphalangeal (PIP) joint AND<br>• Evidence that the administering physician is a surgeon who has experience and training in hand surgeries AND<br>• Evidence that the facility is enrolled to receive Xiaflex through Xiaflex Risk Evaluation and Mitigation Strategy (REMS) Program<br>OR<br>• Diagnosis of Peyronie's disease in a member 18 years of age or older made in consultation with a urologist AND<br>• Palpable plaque and curvature deformity ≥30 degrees at start of therapy AND<br>• Evidence that treatment with AT LEAST two agents (for example, intralesional verapamil AND pentoxifylline or verapamil gel was ineffective, contraindicated or not tolerated AND<br>• Evidence that the facility is enrolled to receive Xiaflex through Xiaflex REMS Program<br>Must **also** submit any additional pertinent medical information |

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|---|---|
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| Xolair® (omalizumab) | Must submit **all** of the following:<br>• Diagnosis of uncontrolled, moderate to severe allergic asthma<br>o Positive skin test or in-vitro reactivity to a perennial aeroallergen<br>o Confirmation of chronic, combination therapy with systematic or high-dose inhaled corticosteroids with long-acting inhaled beta-2 agonists or leukotriene modifiers for at least three months to maintain adequate control<br>o IgE level >30 IU/mL but <700 IU/mL<br>**AND**<br>o Therapy response with a bronchodilator<br>**OR**<br>• Diagnosis of idiopathic urticaria with confirmation that the disease is symptomatic (i.e., daily itching, hives, etc.) for at least 6 weeks<br>• Previous treatment failure with:<br>o Dose-appropriate antihistamine (must be cyproheptadine) AND<br>o Leukotriene receptor antagonist therapy<br>**AND**<br>• Patient is greater than or equal to 12 years of age<br>• Diagnosis is made by or in consultation with an allergist, immunologist or pulmonologist<br>• Any additional pertinent medical information |
| Yervoy® (ipilimumab) | Must submit **all** of the following:<br>• Diagnosis of unresectable or metastatic melanoma<br>• Any additional pertinent medical information |
| Zemaira® (alpha-1 proteinase inhibitor) | Must submit **all** of the following:<br>• Evidence that member is 18 years or age or older and is a nonsmoker<br>• Serum levels of alpha-1 antitrypsin<br>• Diagnosis of symptomatic emphysema<br>• Evidence that member has deteriorating pulmonary function as demonstrated by a decline in the FEV1<br>• Any additional pertinent medical information |

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| Zometa® (zoledronic acid) | In the e-referral system, the submitter receives a prompt to complete a questionnaire to determine the appropriateness of the requested service. Refer to the example zoledronic acid questionnaire.<br>In addition, must submit **all** of the following:<br>• Diagnosis. Indicate which diagnosis the drug is being used to treat.<br>• Any pertinent laboratory results or testing to confirm diagnosis<br>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation, dosage of drug and frequency of administration<br>• Any additional pertinent medical information |

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# Blue Dot Changes to the Clinical Information for Drugs Covered Under the Medical Benefit That Require Medical Necessity Review

— A supplement to the *BCN Referral / Clinical Review Program* —

| Service / Drug | Change Description |
|---|---|
| Various | Medical necessity criteria are added for the following drugs:<br>• Actemra • Delatestryl • Orencia • Testopel<br>• Aveed • Depo-Testosterone • Synagis • Xolair<br>Medical necessity criteria are updated for Simponi Aria. |
| Various | Medical necessity criteria are added for the following drugs:<br>• Blincyto • Kanuma • Nucala • Simponi Aria<br>• Dysport • Myobloc • Opdivo • Xeomin<br>Medical necessity criteria are updated for the following drugs:<br>• Berinert • Elaprase • Gazyva • Myozyme • Remodulin<br>• Botox • Entyvio • Kalbitor • Naglazyme • Ruconest<br>• Cinryze • Firazyr • Keytruda • Perjeta • Vimizim<br>• Cyramza • Flolan • Lemtrada • Provenge |

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