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| ACTEMRA                   |       | • Active infection including tuberculosis  
|                           |       | • Concurrent therapy with other biologics  
|                           |       | • Inadequate response or intolerance or contraindication to 1 TNF antagonist  
|                           |       | • For reauthorization: Patient’s condition must have improved or stabilized in response to Actemra therapy. |                |                        | Plan year        | • Screening for latent tuberculosis is required. If results are positive, patient must have completed treatment or must currently be receiving treatment for latent tuberculosis.  
|                           |       | | | | | | • Evaluate for HBV risk and initiate treatment if appropriate. |
| ACTIMMUNE                 |       | | | | | | Use for direct replacement for deficient enzyme (no benefit achieved in patients with immunodeficiency due to other causes). |
| ADAGEN                   |       | • Severe thrombocytopenia  
|                           |       | • Use in preparation for or in support of bone marrow transplantation |                |                        | Plan year        |               |
| ADCIRCA                  | Nitrate therapy | PAH confirmed by right heart catheterization | | | | |               |
| ALDURAZYME               |       | | Diagnosis confirmed by measurement of alpha-L-iduronidase activity (enzymatic assay) or DNA testing |               | | Plan year        |               |
| ALPHAI-PROTEINASE        | • Aralast NP  
| INHIBITOR                | • Glassia  
|                           | • Prolastin  
|                           | • Prolastin-C  
|                           | • Zemaira | IgA deficiency with antibody formation |               | | Plan year        |               |
| AMPHETAMINES             | • Adderall XR  
|                           | • Amphetamine/  
|                           | Dextroamphetamine  
|                           | • Dexedrine  
|                           | • Dextroamphetamine Sulfate  
|                           | • Vyvanse | MAOI concurrent use or within the last 14 days unless prescriber is a psychiatrist with experience prescribing both MAOI and amphetamine/dextroamphetamine drugs | | | Plan year        | Consider benefits of use versus potential risks of serious cardiovascular events. |
| AMPYRA                   | • Moderate to severe renal impairment (CrCl less than or equal to 50mL/min)  
|                           | • History of seizures  
|                           | • Dosage exceeding 10mg twice daily | Patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting Ampyra. | 2 months, then plan year upon renewal | Approve for those 3 years of age and older |               | For continuation: Patient must experience an improvement in walking speed or other objective measure of walking ability since starting Ampyra. |
| ANABOLIC STEROIDS        | • Anadrol-50  
|                           | • Oxandrin  
|                           | • Oxandroline | Known or suspected carcinoma of the prostate or breast (in male patients)  
|                           | | Carcinoma of the breast in women with hypercalcemia  
|                           | | Pregnancy  
|                           | | Nephrosis  
<p>|                           | | Hypercalcemia | | | 6 months |               |</p>
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<td><strong>ANAGRELIDE</strong></td>
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<td></td>
<td>ANAGRELIDE</td>
<td>Severe hepatic impairment</td>
<td>• Pretreatment Hgb level less than 10g/dL (or less than or equal to 11g/dL with clinical symptoms of anemia) • After 12 weeks of therapy Hgb must increase at least 1g/dL • Once on therapy, Hgb should be maintained to a level below 12g/dL. If level exceeds 12g/dL, prescriber must reduce the dose.</td>
<td></td>
<td>• Oncologist • Hematologist</td>
<td>6 months</td>
<td>• Patients with chronic kidney disease or those treated with myelosuppressive chemotherapy must have adequate iron stores or be receiving concomitant iron supplementation. • Patient is instructed by the prescriber to report any signs or symptoms of adverse cardiovascular or thrombotic events.</td>
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<tr>
<td><strong>ARANESP</strong></td>
<td>Aranesp Albumin Free</td>
<td>• Uncontrolled hypertension • Hgb at or exceeding 13g/dL</td>
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<td>12 weeks</td>
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<td><strong>ARCALYST</strong></td>
<td></td>
<td>• Active or chronic infection • Concurrent therapy with other biologics</td>
<td>Approve for those 12 years of age and older</td>
<td>Neurologist</td>
<td>Plan year</td>
<td>For reauthorization: Patient’s condition must have improved or stabilized in response to Arcalyst therapy.</td>
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<td><strong>AVONEX</strong></td>
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<td><strong>BETASERON</strong></td>
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<td>• Albumin hypersensitivity • Concurrent use of Interferon-beta therapy (Avonex, Extavia, or Rebif), glatiramer acetate, or mitoxantrone</td>
<td>MRI has been performed and has features suggestive of MS (evidence of lesion)</td>
<td>Neurologist</td>
<td>Plan year</td>
<td>Patients with previous use (12 or more months) must demonstrate one of the following clinical responses: decrease in frequency of relapses, slowing of disease progression, diminished MRI lesions, or patient is stable on therapy.</td>
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<td><strong>BOTOX</strong></td>
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<td>• Cosmetic use • Hypersensitivity to any botulinum toxin preparation or any component of the formulation • Infection at the proposed injection site(s)</td>
<td>• Initial treatment of chronic migraine: inadequate response to at least 8 weeks of oral migraine preventative therapy unless contraindicated or not tolerated • For continuation for chronic migraine: 50% reduction in headache frequency since starting therapy</td>
<td>Neurologist</td>
<td>Plan year for all other indications</td>
<td>Monitor for life-threatening symptoms of spread of toxin effect from injection site (e.g. breathing or swallowing difficulties)</td>
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<td><strong>BUPRENORPHINE</strong></td>
<td>• Buprenorphine HCl • Suboxone • Subutex</td>
<td>Dosage in excess of 4 units daily</td>
<td>Documentation that the member is not receiving other opioids</td>
<td>Prescribers must be certified through Center for Substance Abuse Treatment of Substance Abuse and Mental Health Services Administration to prescribe Suboxone and Subutex.</td>
<td>Approve for those 16 years of age and older</td>
<td>• Buprenorphine - 1 month (12 months if pregnant) • Suboxone - 12 months</td>
<td>• Buprenorphine and Suboxone should be part of an overall treatment program. • Patient should be monitored periodically.</td>
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<td><strong>BYETTA</strong></td>
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<td>History of pancreatitis</td>
<td>• Diagnosis of type-2 diabetes with an HbA1c level greater than 7 • CrCl greater than 30ml/min or normal kidney function • Patient has had an inadequate treatment response, intolerance, or contraindication to metformin or a sulfonylurea medication.</td>
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<td>Patients with previous Byetta therapy must demonstrate a reduction in HbA1c since initiation of therapy.</td>
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| CAMPRAL                  |       | Renal failure     | • Clinical diagnosis for alcohol dependence  
• Clinical evidence indicating patient will be abstinent at least 5 days prior to treatment initiation  
• A trial of naltrexone (oral or injectable) has been attempted at clinically significant dosage and duration or therapy is documented to be clinically inappropriate (hepatic insufficiency, chronic pain medication use). | 6 months |  |  | Medication administration should be part of a comprehensive psychosocial treatment program. |
| CAYSTON                  |       |                   | • Diagnosis of cystic fibrosis confirmed by appropriate diagnostic or genetic testing  
• Confirmation of P. aeruginosa in cultures of the airways | Plan year |  |  |  |
| CELEBREX                 |       | Post-operative pain following CABG surgery |  |  |  |  |  |
| CEREZYME                 |       | Concurrent therapy with Zavesca | • Diagnosis confirmed by bone marrow histology, DNA testing, or measurement of b-glucocerebrosidase enzyme activity less than 30%  
• Patient must have at least one of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly. | Plan year |  |  |  |
| CHANTIX                  |       | Concurrent Zyban use | • Evaluation for neuropsychiatric symptoms  
• If patient is currently receiving Chantix, treatment has resulted in smoking cessation. | Initial therapy – 12 weeks; additional 12 weeks upon renewal |  |  | Patient who has previously received 24 months of Cerezyme therapy must demonstrate a decrease in liver and spleen volume, and/or increase in platelet count, and/or increase in Hgb concentration for reauthorization. |
| CIMZIA                   |       |                   | • RA: inadequate response to either Enbrel or Humira and one of following - 1) inadequate response to MTX 2) inadequate response to another nonbiologic DMARD (e.g., leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX 3) intolerance/contraindication to at least 2 nonbiologic DMARDs  
• Crohn's Disease: inadequate response or contraindication/intolerance to at least one oral corticosteroid and Humira | Approve for those 18 years of age and older |  |  | • Screening for latent tuberculosis is required. If results are positive, patient must have completed treatment or must currently be receiving treatment for latent tuberculosis.  
• Evaluate for HBV risk and initiate treatment if appropriate.  
• For reauthorization: Patient’s condition must have improved or stabilized in response to Cimzia therapy. |
| COPAXONE                 |       | Concurrent use of Interferon-beta therapy (Avonex, Betaseron, Extavia, or Rebif) or mitoxantrone |  | Plan year |  |  | Patients with 12 or more months of previous use must demonstrate one of the following clinical responses: decrease in frequency of relapses, slowing of disease progression, diminished MRI lesions, or patient is stable on therapy. |

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| DRONABINOL | • Dronabinol  
• Marinol | | For diagnosis of nausea and vomiting associated with cancer chemotherapy:  
• Patient is receiving a chemotherapy or radiation regimen.  
• Patient has had a full trial and failure through at least 1 cycle of chemotherapy with IV ondansetron and at least one of the following oral anti-emetic agents: metoclopramide, promethazine, prochlorperazine, meclizine, trimethobenzamide, oral 5-HT3 receptor antagonists.  
• If patient has received previous dronabinol therapy, he/she must show a positive response by showing a reduced incidence of emesis and/or nausea. | 6 months | B vs. D coverage determination per CMS guidelines  
(Required Medical Information continued) For diagnosis of anorexia associated with weight loss in a patient with AIDS:  
• Involuntary weight loss of greater than 10% of pre-illness baseline body weight or a BMI less than 20kg/m2 in the absence of a concurrent illness or medical condition other than HIV that may cause weight loss  
• Failure to respond to a 30-day drug regimen of megestrol  
• If patient has received previous dronabinol therapy, he/she must show a positive response by maintaining or increasing initial weight and/or muscle mass. | |
| EGRIFTA | | • Use for weight loss  
• Pregnancy  
• Active malignancy  
• Disruption of hypothalamic-pituitary axis due to hypophysectomy  
• Hypopituitarism  
• Pituitary tumor/surgery  
• Head irradiation or head trauma | Diagnosis confirmed by DNA testing or enzymatic analysis (deficiency of iduronate 2-sulfatase enzyme activity) | 6 months | For renewal, patient demonstrated clear clinical improvement (e.g., decreased waist circumference, CT scan). |
| ELAPRASE | | | | Plan year | |
| ENBREL | • Active infection including tuberculosis  
• Concurrent use with other biologics | • RA: must have one of the following - 1) inadequate response to MTX 2) inadequate response to another nonbiologic DMARD (e.g. leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX 3) intolerance or contraindication to at least 2 nonbiologic DMARDs 4) use Enbrel as first-line therapy with MTX for severely active RA  
• Psoriatic arthritis with predominantly peripheral symptoms: inadequate response or intolerance or contraindication to at least 1 nonbiologic DMARD  
• AS and psoriatic arthritis with predominantly axial symptoms: inadequate response or intolerance or contraindication to at least 2 NSAIDs  
• Polyarticular JIA: inadequate response to at least 1 nonbiologic DMARD or intolerance or contraindication to at least 2 nonbiologic DMARDs  
Psoriasis – Approve for those 18 years of age or older | Plan year | (Required Medical Information continued)  
• Plaque psoriasis: Affected area is greater than 10% of BSA or affects crucial body areas (e.g. feet, hands, face). Inadequate response or intolerance or contraindication to at least a 60-day trial of to 2 conventional therapies (e.g. phototherapy, calcipotriene, MTX, acitretin)  
• Screening for latent tuberculosis is required. If results are positive, patient must have completed treatment or must currently be receiving treatment for latent tuberculosis.  
• Evaluate for HBV risk and initiate treatment if appropriate.  
• For reauthorization: Patient’s condition must have improved or stabilized in response to Enbrel therapy. |
| EPO | • Epogen  
• Procrit | Uncontrolled hypertension | | 12 weeks | |
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| EXJADE                   |       | • CrCl less than 40mL/min or evidence of overt proteinuria | • Diagnosis of transfusion-dependent anemia with chronic iron overload due to blood transfusions  
• Pretreatment serum ferritin level within the last 60 days of at least 1,000mcg/L.  
• Patient will have baseline and monthly monitoring of serum ferritin, serum creatinine, CrCl, serum transaminases, and bilirubin. | Approve for those 2 years of age and older | Hematologist | 3 months | For patients already receiving Exjade, the prescriber will consider temporary interruption of Exjade when serum ferritin is less than 500mcg/L. |
| EXTAVIA                  |       | Concurrent use of Interferon-beta therapy (Avonex, Betaseron, or Rebif), glatiramer acetate, or mitoxantrone | Diagnosis confirmed with an enzyme assay measuring a deficiency of alphagalactosidase enzyme activity or DNA testing | Plan year |                |                  |               |
| FABRAZYME                |       | • Female   
• For prepubertal cryptorchidism: presence of anatomic obstruction or precocious puberty  
• For hypogonadotropic hypogonadism: presence of prostatic carcinoma or other androgen-dependent neoplasm | New starts: inadequate response or intolerance or contraindication to a trial of a beta interferon agent or Copaxone | Plan year |                |                  |               |
| GILENYA                  |       | • Chorionic Gonadotropin  
• Novarel  
• Pregnyl w/ Dluent Benzyl | (Required Medical Information continued)  
• ISS: Pediatric GHD has been ruled out with one stimulation test.  
• Adult GHD: Patient has been assessed for other causes of GHD-like symptoms. For renewal, patient has seen clinical improvement and IGF-1 will be monitored.  
• Adult GHD with at least 3 pituitary hormone deficiencies (PHD) or panhypopituitarism: low IGF-1  
• Adult GHD with less than 3 PHD: low IGF-1 and failed 1 stimulation test  
• Adult and pediatric GHD without pituitary disease: failed 2 stimulation tests  
• PWS: improved body composition for renewal | Plan year |                |                  |               |
| GONADOTROPIN             |       | • Genotropin  
• Genotropin Mini-quick  
• Humatrope  
• Humatrope Combo Pack  
• Norditropin Flexpro  
• Norditropin Nordiflex Pen  
• Nutropin  
• Nutropin AQ Nuspip 5  
• Nutropin AQ Pen  
• Omnitrope  
• Saizen  
• Saizen Click easy  
• Tev-Tropin | • All pediatric patients: short stature or slow growth velocity and patients have been evaluated for other causes of growth failure. Growth more than 2cm per year for renewal.  
• Pediatric GHD: delayed bone age  
• Pediatric GHD with a pituitary or CNS disorder: clinical evidence of GHD and low IGF-1/IGFBP3  
• Pediatric GHD in neonate with hypoglycemia: randomly assessed GH level less than 20ng/mL. Other causes of hypoglycemia have been ruled out and other treatments have been ineffective.  
• TS and SHOX: diagnosis confirmed by genetic testing  
• CRE: Metabolic, endocrine and nutritional abnormalities have been treated or stabilized and patient has not had a kidney transplant.  
• SGA: low birth weight or length for gestational age  
• TS and SGA – Approve for those 2 years of age and older  
• Noonan syndrome and SHOX – Approve for those 3 years of age and older  
• Endocrinologist  
• Gastroenterologist  
• Infectious Disease Specialist  
• Nutritional Support Specialist  
• Pediatric Nephrologist | Plan year |                |                  |               |
| GROWTH HORMONE           |       | • Active malignancy or history of malignancy in past 12 months  
• Active proliferative or severe non-proliferative diabetic retinopathy  
• Acute critical illness  
• Concurrent use with Increlex  
• Closed epiphyses for pediatric patients  
• For PWS only: upper airway obstruction and severe respiratory impairment | (Required Medical Information continued)  
• ISS: Pediatric GHD has been ruled out with one stimulation test.  
• Adult GHD: Patient has been assessed for other causes of GHD-like symptoms. For renewal, patient has seen clinical improvement and IGF-1 will be monitored.  
• Adult GHD with at least 3 pituitary hormone deficiencies (PHD) or panhypopituitarism: low IGF-1  
• Adult GHD with less than 3 PHD: low IGF-1 and failed 1 stimulation test  
• Adult and pediatric GHD without pituitary disease: failed 2 stimulation tests  
• PWS: improved body composition for renewal | Plan year |                |                  |               |
| HEPSERA                  |       | • Renal impairment without dosing adjustment  
• Patients taking tenofovir or PMPA  
• Use of Hepsera as a first-line therapy in treatment-naive patients with HBV | • Diagnosis of chronic hepatitis B  
• Evidence of a positive HBsAg (+ or -) serological marker for more than 6 months or evidence by a liver biopsy showing chronic hepatitis  
• Hepatitis B viral load greater than 20,000 IU/ml (100,000 copies per ml) except for HBsAg-negative HBV, viral load is greater than 2,000 IU/ml (10,000 copies per ml)  
• Elevations in liver aminotransferases (ALT or AST) that are 2 times greater than normal, or normal levels with evidence of significant disease found on biopsy  
• Documented evidence of diagnosis, serological markers or liver biopsy, viral load, and liver aminotransferases | Approve for those 12 years of age and older | Gastroenterologist  
Infectious Disease Specialist  
Affiliation with an infectious disease or gastroenterology practice  
PCP with experience treating HBV | Plan year | • Patient is not receiving duplicate therapy with Intron A.  
• If patient has received previous Hepsera treatment, documented clinical improvement is shown by a drop in viral load or reduction in liver aminotransferases. |
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<td>HIZENTRA</td>
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<td>• IgA deficiency with antibody formation and a history of hypersensitivity • History of anaphylaxis or severe systemic reaction to the administration of human immune globulin • Hyperprolinaemia</td>
<td>If administered outside a controlled healthcare setting, appropriate treatment (e.g. anaphylaxis kit) should be available for managing an acute hypersensitivity reaction.</td>
<td>Approve for those 2 years of age and older</td>
<td>Plan year</td>
<td>(Required Medical Information continued) • Platelet count: platelet count should be at least 150,000/mL. • White blood cell count: white blood cell count should be less than 10,000/mL. • Hemoglobin: hemoglobin should be less than 10 g/dL. • Blood pressure: blood pressure should be less than 160/100 mm Hg.</td>
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<td>HUMIRA</td>
<td>Humira</td>
<td>• Active infection including tuberculosis • Concurrent use with other biologics</td>
<td>• RA: must have one of the following – 1) inadequate response to MTX 2) inadequate response to another nonbiologic DMARD (e.g. leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX 3) intolerance or contraindication to at least 2 nonbiologic DMARDs 4) use Humira as first-line therapy with MTX for severely active RA • Psoriatic arthritis with predominantly peripheral symptoms: inadequate response or intolerance or contraindication to at least 1 nonbiologic DMARD • AS and psoriatic arthritis with predominantly axial symptoms: inadequate response or intolerance or contraindication to at least 2 NSAIDs • Crohn's disease: Inadequate response or intolerance or contraindication to at least a 60-day trial of to 2 conventional therapies (e.g. sulfasalazine, mesalamine, azathioprine, corticosteroids) or either Remicade or Cimzia</td>
<td>Psoriasis – Approve for those 18 years of age or older</td>
<td>Plan year</td>
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<td>INCIVEK</td>
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<td>• Failed previous therapy with a treatment regimen that includes a protease inhibitor (e.g., Incivek, Victrelis) • Concurrent use with a drug that is highly dependent on CYP3A for clearance or strongly induces CYP3A</td>
<td>• HCV infection confirmed by presence of viral load in serum • HCV Genotype 1 • HCV-RNA less than or equal to 1,000 IU/ml at week 4 of treatment</td>
<td>Initial - 6 weeks • Renewal - up to 12 weeks</td>
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<td>INCRELEX</td>
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<td>• Epiphyseal closure • IV administration of Increlex • Active malignancy • Use in neonates • Concurrent use with GH therapy • Secondary causes of IGF-1 deficiency</td>
<td>• Prior to starting therapy: height greater than 3 SD below the mean for chronological age and sex, and IGF-1 level greater than or equal to 3 SD below the mean for chronological age and gender • One stimulation test showing patient has a normal or elevated GH level</td>
<td>Between 2 and 20 years of age</td>
<td>Endocrinologist</td>
<td>Plan year</td>
<td>For continuation of therapy: Patient grew more than 2.5 cm/year.</td>
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<td>INFERGEN</td>
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<td>• Decompensated liver disease • Autoimmune hepatitis</td>
<td>• Prior to initiating therapy: detectable levels of HCV RNA in the serum • Treatment naïve: Patient must have tried and had intolerance to pegylated interferon-based treatment regimen. Allow Infergen monotherapy if intolerance/contraindication to ribavirin. • Genotype 1 and 4: undetectable HCV RNA after 12 weeks of treatment or at least 2 log decrease in HCV RNA after 12 weeks of therapy and undetectable HCV RNA after 24 weeks of treatment</td>
<td>12 weeks to a total of 72 weeks depending on genotype and initial vs. renewal therapy</td>
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| ITRACONAZOLE             | • Itraconazole  
• Sporanox  
• Sporanox Pulsepak | • Concurrent use with drugs metabolized by CYP3A4 (e.g. cisapride, dofetilide, pimozide, quinidine)  
• Ventricular dysfunction (congestive heart failure or history of CHF) – do not use for onychomycosis. | Diagnosis of one of the following:  
• Blastomycosis, pulmonary or extrapulmonary  
• Histoplasmosis, including chronic cavitary pulmonary disease or disseminated, non-meningeal histoplasmosis  
• Aspergillosis, pulmonary or extrapulmonary  
• Onychomycosis of the toenail or fingernail due to dermatophytes (tinea unguium) – confirmed with fungal diagnostic test (e.g. KOH preparation, fungal culture, or nail biopsy) | 12 weeks | - | Gamunex/Gamunex-C: If administered SC outside a controlled healthcare setting, appropriate treatment (anaphylaxis kit) should be available for managing an acute hypersensitivity reaction. |  |
| IVIG                     | • Carimune Nanofiltered  
• Gammagard liquid  
• Gammaplex  
• Gamunex | • IgA deficiency with antibody formation and a history of hypersensitivity  
• History of anaphylaxis or severe systemic reaction to human immune globulin  
• Presence of risk factor(s) for acute renal failure unless patient will receive IGIV products at the minimum concentration available and at the minimum rate of infusion practicable or Gamunex/Gamunex-C is administered SC for PID | CIDP: presence of objective findings consistent with diagnosis  
• CLL: serum IgG level less than 500mg/dL and recurrent bacterial infections  
• Kawasaki syndrome: use of IGIV in conjunction with high-dose aspirin | Plan year | CIDP diagnosis by a neurologist | Gamunex/Gamunex-C: If administered SC outside a controlled healthcare setting, appropriate treatment (anaphylaxis kit) should be available for managing an acute hypersensitivity reaction. |  |
| JAKAFI                   | | | Intermediate or high-risk myelofibrosis | Plan year | | Prior authorization applies to new starts only. Refills will be approved unless use is not coverable under Part D per Medicare drug coverage policies. |  |
| KINERET                  | • Active infection  
• Concurrent use with other biologics | Must have one of following: 1) inadequate response to MTX 2) inadequate response to another nonbiologic DMARD (e.g., leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX 3) intolerance or contraindication to at least 2 nonbiologic DMARDs 4) use Kineret as first-line therapy with MTX for severely active RA | Plan year | | | For reauthorization: Patient’s condition must have improved or stabilized in response to Kineret therapy. |  |
| KUVAN                    | | • Blood phenylalanine (Phe) levels  
• Pretreatment Phe levels greater than 10mg/dL if patient is older than 12 years of age, or greater than 6mg/dL if less than or equal to 12 years of age.  
• Response to a therapeutic trial (greater than or equal to a 30% reduction in blood Phe levels) is required for long-term authorization. | • Initial – 1 month  
• Renewal – Plan year | Blood Phe levels should be checked after 1 week of therapy and periodically up to 1 month during a therapeutic trial. |  |  |
| LETAIRIS                 | Pregnancy | • NYHA class II or III symptoms  
• PAH confirmed by right heart catheterization | Plan year | | | For women of childbearing potential: IUD or 2 appropriate contraceptive methods must be used. |  |
| LEUKINE                  | | • Administration within 24 hours preceding or following chemotherapy or radiotherapy  
• Hypersensitivity to yeast-derived products  
• For prophylaxis of febrile neutropenia: use to increase chemotherapy dose intensity or dose schedule above established regimens  
• For treatment of febrile neutropenia: when patient receives Neulasta during the current chemotherapy cycle  
• For AML: excessive (greater than or equal to 10%) leukemic myeloid blasts in the bone marrow or peripheral blood | Patients with nonmyeloid malignancies receiving myelosuppressive chemotherapy: Leukine may be used for prevention of chemotherapy-induced febrile neutropenia if the patient experienced febrile neutropenia with a previous chemotherapy cycle or the patient is at high risk (greater than 20%) or intermediate risk (10-20%) for developing febrile neutropenia.  
• Patients at low risk (less than 10%) for developing for febrile neutropenia may also receive Leukine for prophylaxis if there is a significant risk for serious medical consequences due to febrile neutropenia and the intent of chemotherapy is to prolong survival or cure the disease. | 6 months | (Required Medical Information continued)  
• Leukine is allowable for treatment of febrile neutropenia in patients who have received prophylaxis with Leukine or Neupogen or in patients at risk for infection-related complications.  
• All patients must receive baseline and regular monitoring of complete blood counts and platelet counts. |  |
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| LIDODERM                 |                                                                       | • Sensitivity to local anesthetics of the amide type (procaine, tetracaine, benzocaine)  
• Dosage in excess of 3 patches per day  
• Broken or inflamed skin where patch is to be applied | • Diagnosis documented as post-herpetic neuralgia  
• Patient has completed a one-month documented trial/failure or has a demonstrated adverse event or contraindication to gabapentin or Lyrica |                                                                  | 3 months                  |                   |                   | Appropriate medical support is readily available when Lumizyme is administered in the event of anaphylaxis, severe allergic reaction, or acute cardiorespiratory failure. |
| LUMIZYME                 |                                                                       | • Diagnosis of Pompe disease confirmed by an enzyme assay demonstrating a deficiency of GAA enzyme activity, or by DNA testing that identifies mutations in the GAA gene  
• Patient has late (non-infantile) onset Pompe disease with no evidence of cardiac hypertrophy. |                                                             | Approve for those 8 years of age and older                  | Plan year                |                   |                                                                                                   |
| LUPRON                   | • Leuprolide acetate  
• Lupron Depot  
• Lupron Depot-Ped | • Pregnancy and breastfeeding in female patients of childbearing potential  
• For prostate cancer: use as neoadjuvant androgen deprivation therapy (ADT) for radical prostatectomy  
• For endometriosis and fibroids: undiagnosed abnormal vaginal bleeding | Prostate cancer: Allow for one of the following - 1) locally advanced, recurrent or metastatic disease 2) initial long-term neoadjuvant/concurrent/adjuvant ADT in combination with radiation therapy for clinically localized disease with high risk of recurrence 3) initial short-term neoadjuvant/concurrent/adjuvant ADT in combination with radiation therapy for clinically localized disease with intermediate risk of recurrence, or with brachytherapy for clinically localized disease with high risk of recurrence 4) neoadjuvant therapy in conjunction with brachytherapy in patients with a large prostate to shrink the prostate to an acceptable size for brachytherapy | CPP - must be less than 12 years old if female and less than 13 years old if male | 1 year  
6 months for short term use  
• Fibroids - 3 months  
• Endometriosis - 6 months  
• CPP - 1 year | Plan year                | Endometriosis: Patient must have completed a trial/failure of at least 2 of the following therapies: oral contraceptives, medroxyprogesterone, danazol. |
| METHYLPHENIDATES         | • Concerta  
• Daytrana  
• Metadate CD  
• Metadate ER  
• Methylid  
• Methylphenidate  
• Methylphenidate SR  
• Ritalin  
• Ritalin LA  
• Ritalin SR | MAOI concurrent use or within the last 14 days | Sleep studies for narcolepsy diagnosis | Approve for those 6 years of age or older | Plan year                |                   | Consider benefits of use versus the potential risks of serious cardiovascular events. |
| MOZOBIL                  |                                                                       | MAOI concurrent use or within the last 14 days |                                                                 |                                                                  | 6 months                  | Mozobil is given in combination with granulocyte-colony stimulating factor. |
| MYOZYME                  |                                                                       | Diagnosis confirmed by DNA testing or an enzymatic assay showing a deficiency in acid alpha glucosidase |                                                                 |                                                                  | Plan year                |                   |                                                                                                   |
| NAGLAZYME                |                                                                       | Diagnosis confirmed by DNA testing or an enzymatic assay showing a deficiency in N-acetylgalactosamine activity |                                                                 |                                                                  | Plan year                |                   |                                                                                                   |
| NEULASTA                 |                                                                       | • Treatment for febrile neutropenia  
• Known hypersensitivity to filgrastim  
• Use in the period 14 days before and 24 hours after administration of chemotherapy  
• Myeloid malignancy  
• Use to increase the chemotherapy dose intensity or dose schedule above established regimens | • Patients with nonmyeloid malignancies receiving myelosuppressive chemotherapy; Neulasta may be used for prevention of chemotherapy-induced febrile neutropenia if the patient experienced febrile neutropenia with a previous chemotherapy cycle or the patient is at high risk (greater than 20%) or intermediate risk (10-20%) for developing febrile neutropenia.  
• Patients at low risk (less than 10%) for developing for febrile neutropenia may also receive Neulasta for prophylaxis if there is a significant risk for serious medical consequences due to febrile neutropenia and the intent of chemotherapy is to prolong survival or cure the disease. |                                                                  | 6 months                  | All patients must receive baseline and regular monitoring of complete blood counts and platelet counts. |
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| **NEUPOGEN**             |       | • Administration within 24 hours preceding or following chemotherapy or radiotherapy  
• E. coli hypersensitivity  
• For prophylaxis of febrile neutropenia: use to increase chemotherapy dose intensity or dose schedule above established regimens  
• For treatment of febrile neutropenia: when patient receives Neulasta during the current chemotherapy cycle | • Patients with nonmyeloid malignancies receiving myelosuppressive chemotherapy: Neupogen may be used for prevention of chemotherapy-induced febrile neutropenia if the patient experienced febrile neutropenia with a previous chemotherapy cycle or the patient is at high risk (greater than 20%) or intermediate risk (10-20%) for developing febrile neutropenia.  
• Patients at low risk (less than 10%) for developing febrile neutropenia may also receive Neupogen for prophylaxis if there is a significant risk for serious medical consequences due to febrile neutropenia and the intent of chemotherapy is to prolong survival or cure the disease.  
(Required Medical Information continued)  
• Neupogen is allowable for treatment of febrile neutropenia in patients who have received prophylaxis with Leukine or Neupogen or in patients at risk for infection-related complications.  
• All patients must receive baseline and regular monitoring of complete blood counts and platelet counts. | | | 6 months | |
| **NICOTINE**             |       | • Nicotrol Inhaler  
• Nicotrol NS | Documentation that patient is enrolled in a smoking cessation program | | | 6 months | |
| **NUEDEXTA**             |       | • Concurrent use with other drugs containing quinidine, quinine, mefloquine, MAOIs, or drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g. thioridazine and pimozide)  
• Prolonged QT interval  
• Congenital long QT syndrome or a history suggestive of torsades de pointes  
• Heart failure  
• Patients with or at high risk for complete atrioventricular block without implanted pacemaker  
• Dosage in excess of 2 capsules per day | | | Plan year | |
| **NUVIGIL**              |       | | | | | Plan year | |
| **OCTREOTIDE**           |       | • Octreotide Acetate  
• Sandostatin | | | | Plan year | |
| **ORAL FENTANYL**        |       | • Abstral  
• Actiq  
• Fentanyl Citrate TRA  
• Fentora  
• Onsolis | Patients taking strong or moderate cytochrome P450 3A4 inhibitor(s) (e.g. aprepitant, clarithromycin, diltiazem, erythromycin, fosamprenavir, fluconazole, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, verapamil) who will not be monitored or have dosing adjustments made if necessary.  
• Narcolepsy: sleep lab evaluation required  
• OSAHS: polysomnography required and whether patient is using CPAP (or CPAP is contraindicated or ineffective)  
• Shift Work Sleep Disorder: Patient works night shift (at least 6 hours between 10pm and 8am) permanently or frequently (5 times or more per month) and experiences excessive sleepiness while working.  
• Mild obstructive sleep apnea/hypopnea syndrome: whether patient is using and being compliant with an oral appliance | • Actiq - 16 years of age and older  
• All others - 18 years of age and older | | 6 months | |
| **ORAL TESTOSTERONES**   | Androxy | Male patients with confirmed or suspected carcinoma of the prostate or breast | | | | Plan year | |

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<tr>
<td>ORENCIA</td>
<td>Forteo</td>
<td>• Active infection including tuberculosis &lt;br&gt;• Concurrent use with other biologics</td>
<td>• RA: must have one of the following – 1) inadequate response to MTX 2) inadequate response to another nonbiologic DMARD (e.g. leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX 3) intolerance or contraindication to at least 2 nonbiologic DMARDs 4) use Orenica as first-line therapy with MTX for severely active RA &lt;br&gt;• Polyarticular JIA: inadequate response to at least 1 nonbiologic DMARD or intolerance or contraindication to at least 2 nonbiologic DMARDs</td>
<td>Plan year</td>
<td></td>
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<tr>
<td>OSTEOPOROSIS</td>
<td>Forteo</td>
<td>• Paget's disease of bone &lt;br&gt;• Unexplained elevations in alkaline phosphatase &lt;br&gt;• Open epiphyses &lt;br&gt;• Prior radiation of the skeleton &lt;br&gt;• History of skeletal malignancy or bone metastases &lt;br&gt;• Pre-existing hypercalcemia &lt;br&gt;• Metabolic bone disease other than osteoporosis &lt;br&gt;• Concurrent bisphosphonate use &lt;br&gt;• Cumulative use of Forteo for more than 24 months lifetime</td>
<td>Patient must meet one of the following criteria: &lt;br&gt;• Prior fragility fracture &lt;br&gt;• Inadequate response or intolerance or contraindication to an adequate (1-year) trial of a bisphosphonate &lt;br&gt;• Patient has 2 of the following risk factors for fracture - advanced age, parental history of fracture, low BMI, current smoker, chronic alcohol use, RA, chronic steroid use, or other secondary cause of osteoporosis.</td>
<td>Plan year</td>
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<tr>
<td>OXSORALEN</td>
<td>Oxsoralen Ultra</td>
<td>• Aphakia &lt;br&gt;• Melanoma &lt;br&gt;• Invasive squamous cell carcinoma</td>
<td>Patient must be diagnosed with CTCL or psoriasis &lt;br&gt;• If diagnosis is psoriasis, patient must have previous inadequate response or intolerance or contraindication to at least 1 topical steroid.</td>
<td>Plan year</td>
<td>Dermatologist &lt;br&gt;Oncologist &lt;br&gt;Affiliation with a dermatology/oncology practice</td>
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<td>PEGASYS</td>
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<td>• Decompensated liver disease &lt;br&gt;• Autoimmune hepatitis &lt;br&gt;• Concurrent administration of didanosine with ribavirin in patients co-infected with HIV</td>
<td>• HCV: detectable levels of HCV RNA in the serum prior to initiating therapy &lt;br&gt;• HCV treatment naïve: allow as monotherapy if patient has an intolerance/contraindication to ribavirin &lt;br&gt;• HCV retreatment: Use in combination with ribavirin and must have nonresponse or relapse with prior therapy. Allow only one time for retreatment with pegylated interferon and ribavirin. &lt;br&gt;• Genotype 1 and 4: undetectable HCV RNA after 12 weeks of treatment or at least 2 log decrease in HCV RNA after 12 weeks of therapy and undetectable HCV RNA after 24 weeks</td>
<td>HCV - 12 to 72 weeks total depending on genotype and initial vs. renewal therapy &lt;br&gt;HBV - 48 weeks</td>
<td>ID specialist &lt;br&gt;Gastroenterologist &lt;br&gt;Oncologist</td>
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<tr>
<td>PEGINTRON</td>
<td>Peginteron &lt;br&gt;Peginteron Redipen</td>
<td>• Decompensated liver disease &lt;br&gt;• Autoimmune hepatitis &lt;br&gt;• Concurrent administration of didanosine with ribavirin in patients co-infected with HIV</td>
<td>• HCV: detectable levels of HCV RNA in the serum prior to initiating therapy &lt;br&gt;• HCV treatment naïve: allow as monotherapy if patient has an intolerance/contraindication to ribavirin &lt;br&gt;• Genotype 1 and 4: undetectable HCV RNA after 12 weeks of treatment or at least 2 log decrease in HCV RNA after 12 weeks of therapy and undetectable HCV RNA after 24 weeks</td>
<td>12 to 72 weeks total depending on genotype and initial vs. renewal therapy</td>
<td>ID specialist &lt;br&gt;Gastroenterologist &lt;br&gt;Oncologist</td>
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| PRIVIGEN                 |       | • IgA deficiency with antibody formation and a history of hypersensitivity  
|                          |       | • History of anaphylaxis or severe systemic reaction to human immune globulin  
|                          |       | • Hyperprolinemia  
|                          |       | • Presence of risk factor(s) for acute renal failure (pre-existing renal insufficiency, diabetes, age greater than 65 years, volume depletion, sepsis, paraproteinemia, or receiving known nephrotoxic drugs) unless patient will receive Privigen at the minimum concentration available and at the minimum rate of infusion practicable | • Kawasaki syndrome: use Privigen in conjunction with high-dose aspirin  
• CLL: serum IgG level less than 500mg/dL and recurrent bacterial infections  
• CIDP: presence of objective findings consistent with diagnosis (e.g. electromyography, elevated cerebrospinal fluid protein, or nerve biopsy) | CIDP diagnosis by a neurologist | Plan year |  |
| PROLIA                   |       | Hypocalcemia      | • New starters: Patients must be evaluated for other causes of thrombocytopenia and have had an insufficient response or intolerance to corticosteroids, immunoglobulins, or splenectomy. At the time of diagnosis of ITP one of the following is required: 1) pretreatment platelet count less than 30,000/microL  
2) platelet count less than or equal to 50,000/microL with significant mucous membrane bleeding or risk factors for bleeding.  
• For all patients receiving Promacta therapy: If platelets increase above 200,000/microL, therapy will be adjusted to maintain the minimal platelet count needed to reduce the risk for bleeding. Liver function must be assessed pretreatment and regularly throughout therapy. | Initial – 6 months  
• Renewal – 12 months with platelet response, 3 months without platelet response |  |  | For continuation of therapy: Alanine aminotransferase levels must not be greater than or equal to 3 times ULN with any of the following characteristics: progressive, persistent, or accompanied by increased bilirubin, symptoms of liver injury, or evidence of hepatic decompensation. One of the following is required: 1) increase in platelet count to greater than or equal to 50,000/microL  
2) increase in platelet level that is sufficient to avoid clinically important bleeding after at least 4 weeks of Promacta at the maximum dose. |
| PROMACTA                 |       |                   | • Narcolepsy: sleep lab evaluation required  
• OSAHS: polysomnography required and whether patient is using CPAP (or CPAP is contraindicated or ineffective)  
• Shift Work Sleep Disorder: Patient works night shift (at least 6 hours between 10pm and 8am) permanently or frequently (5 times or more per month) and experiences excessive sleepiness while working.  
• Mild obstructive sleep apnea/hypopnea syndrome: whether patient is using and being compliant with an oral appliance |  |  |  |  |
| PROVIGIL                 |       |                   | • Relistor is being prescribed for treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care.  
• Patient must have previous trial/failure of polyethylene glycol. |  |  |  |  |
| REBIF                    | • Rebif  
• Rebif titration pack | Known or suspected mechanical gastrointestinal obstruction |  |  |  |  |
<p>| RELISTOR                 |       |                   |  |  |  |  |</p>
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| REMICADE                  |       | • Active infection including tuberculosis  
• Concurrent use with other biologics  
• Unstable moderate to severe HF (NYHA Functional Class III/IV) | • RA: inadequate response or intolerance to Enbrel or Humira. Patient must also have one of the following – 1) inadequate response to MTX 2) inadequate response to another nonbiologic DMARD (e.g. leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX 3) intolerance/contraindication to at least 2 nonbiologic DMARDs  
• Psoriatic arthritis with predominantly peripheral symptoms: inadequate response or intolerance to or contraindication to either Enbrel or Humira and at least an 8-week maximum tolerated dose trial of at least 1 nonbiologic DMARD  
• AS and psoriatic arthritis with predominantly axial symptoms: inadequate response or intolerance/contraindication to at least 2 NSAIDs  
• Plaque psoriasis: Affected area is greater than 10% of BSA or affects crucial body areas (e.g. feet, hands, face). Inadequate response or intolerance/contraindication to at least a 60-day trial of 2 conventional therapies (e.g. phototherapy, calcipotriene, MTX, acitretin) | Plaque psoriasis - approve for those 18 years of age and older |                      | Plan year | (Required Medical Information continued)  
• Crohn's disease: inadequate response or intolerance or contraindication to at least a 60-day trial of 1 conventional therapy (e.g. sulfasalazine, mesalamine, azathioprine, corticosteroids) and either Humira or Cimzia  
• Ulcerative colitis: inadequate response or intolerance or contraindication to at least a 60-day trial of 2 conventional therapies (e.g. corticosteroids, mesalamine)  
• Screening for latent tuberculosis is required. If results are positive, patient must have completed treatment or must currently be receiving treatment for latent tuberculosis.  
• Evaluate for HBV risk and initiate treatment if appropriate.  
• For reauthorization: Patient’s condition must have improved or stabilized in response to Remicade therapy. |
| REVATIO                   | Nitrates therapy | • Diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1)  
• PAH confirmed by right heart catheterization  
• If patient is an infant, PAH diagnosed by Doppler echocardiogram  
• Patient has had an inadequate response or intolerance to Adcirca. |                      |                      | Plan year |                      | |
| REVlimid                  | Pregnancy | • Active myeloma: Revlimid is used in one of the following ways - 1) after at least one prior therapy or as salvage therapy 2) with dexamethasone as primary induction therapy or in combination with melphalan and prednisone in nontransplant candidates 3) as maintenance monotherapy following response to either stem cell transplant or primary induction therapy.  
• Low or Intermediate-1 Risk MDS: For those with 5q deletion, patients should have transfusion-dependent anemia or symptomatic anemia with clinically significant cytopenias. For those with non-5q deletion and symptomatic anemia, patients should have failed to respond to epoetin alfa or darbepoetin or have a pretreatment serum erythropoietin level greater than 500mU/ml and a low probability of response to immunosuppressive therapy. |                      |                      | Plan year |                      | |
| RIBAVIRIN                 | • Copegus  
• Rebetol  
• Ribapak  
• Ribaphere  
• Ribavirin | • Hgb less than 8.5g/dL  
• Hemoglobinopathy  
• History of unstable heart disease  
• CrCl less than 50ml/min and unwilling to use modified dose  
• Pregnancy (self or partner)  
• Unwilling to use effective contraception  
• Coadministration with didanosine in HIV coinfected patients  
• Detectable levels of HCV RNA in the serum prior to initiating therapy  
• Must use in combination with interferon  
• HCV retreatment: Patient must have nontresponse or relapse with prior therapy. Allow only one time for retreatment with pegylated interferon and ribavirin or Infergen and ribavirin.  
• Genotype 1 and 4: undetectable HCV RNA after 12 weeks of treatment or at least 2 log decrease in HCV RNA after 12 weeks of therapy and undetectable HCV RNA after 24 weeks | • ID specialist  
• Gastroenterologist  
• Oncologist | 12 weeks to a total of 72 weeks depending on genotype and initial vs. renewal therapy |                      |                      | Patient has been instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy. |

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### Prior Authorization Group

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| **RITUXAN**          | • History of severe skin or infusion reaction with Rituxan than cannot be appropriately managed  
                      • Use in combination with another biologic agent                                    | • RA: inadequate response to MTX or another nonbiologic DMARD if intolerance or contraindication to MTX (except when RA is severely active and frontline Rituxan therapy is warranted) and inadequate response or intolerance/contraindication to a TNF antagonist. For continuation of RA therapy, improvement in clinical symptoms (e.g. tender and swollen joint count, mobility, stiffness, or delay in progression of disease) is required from the last treatment course which was at least 16 weeks earlier.  
                      • Rituxan must be used in combination with chemotherapy for mantle cell lymphoma (or other agents), Burkitt's lymphoma, lymphoblastic lymphoma, and AIDS-related B-cell lymphoma. |                  |                         |                   | • Hematologic malignancies must be positive for CD20.  
                      • Induction therapy for Burkitt's lymphoma  
                      • Prior to initiating therapy, prescriber must have assessed the risk for hepatitis B and, if appropriate, ruled out or initiated treatment for hepatitis B.  
                      • Patient must be monitored for pulmonary toxicity |
| **SAMSCA**           | • Anuria  
                      • Patients requiring an urgent increase in serum sodium  
                      • Patients unable to sense and respond to thirst  
                      • Concurrent use of a strong CYP 3A inhibitor (e.g. clarithromycin, ketoconazole) | Patient received initial treatment with Sandostatin injection (not Depot form) for at least 2 weeks and treatment was effective and tolerable. |                  |                         |                   | Samsca must be initiated or re-initiated in a hospital setting. |
| **SANDOSTATIN LAR**  | Sandostatin LAR Depot **Patient received initial treatment with Sandostatin injection (not Depot form) for at least 2 weeks and treatment was effective and tolerable.** | **Patient received initial treatment with Sandostatin injection (not Depot form) for at least 2 weeks and treatment was effective and tolerable.** |                  |                         |                   | **Patient received initial treatment with Sandostatin injection (not Depot form) for at least 2 weeks and treatment was effective and tolerable.** |
| **SEROSTIM**         | • Acute critical illness  
                      • Active malignancy or history of malignancy in past 12 months | • Patient is on concurrent antiretroviral therapy.  
                      • Alternative causes of wasting have been ruled out or treated appropriately. | 12 weeks        |                         |                   | For continuation of therapy: Patients treated with Serostim for 12 or more weeks must show a response to therapy (BMI has improved or stabilized), |
| **SIMPONI**          | • Active infection including tuberculosis  
                      • Concurrent use with other biologics | • RA: must have one of the following: 1) inadequate response to MTX  
                      2) inadequate response to another nonbiologic DMARD (e.g., leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX  
                      3) intolerance/contraindication to at least 2 nonbiologic DMARDs  
                      4) use Simponi as first-line therapy with MTX for severely active RA  
                      • AS: inadequate response or intolerance or contraindication to at least 2 NSAIDs |                  |                         |                   | • Screening for latent tuberculosis is required. If results are positive, patient must have completed treatment or must currently be receiving treatment for latent tuberculosis.  
                      • Evaluate for HBV risk and initiate treatment if appropriate.  
                      • For reauthorization: Patient’s condition must have improved or stabilized in response to Simponi therapy. |
| **SOMATULINE DEPOT** |                                                                                     |                                                                                              |                  |                         |                   |                                                                                              |
| **SOMAVERT**         | • IV administration of Somavert  
                      • Concurrent use of Sandostatin or Somatuline | • Diagnosis of acromegaly confirmed by elevated IGF-1 level or elevated GH level with a glucose tolerance test  
                      • Patient has failed at least a 3-month trial of Sandostatin or Somatuline. |                  | Endocrinologist        |                   | For renewal: reduction in IGF-1 level from baseline |

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<td><strong>SORIATANE</strong></td>
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<td>• Severely impaired liver function</td>
<td>If patient is female and able to bear children:  • Unresponsive to other therapies for this diagnosis or the other therapies are contraindicated due to clinical condition of the patient  • Pregnancy has been excluded by 2 negative urine or serum pregnancy tests with a sensitivity of at least 25 mIU/mL  • Patient has chosen to use any of the following methods of contraception: one primary form (e.g. tubal ligation, partner's vasectomy, intrauterine devices, birth control pills, injectable/implantable/insertable/topical hormonal birth control products) plus one secondary form (e.g. diaphragms, latex condoms, cervical caps) used in combination with a spermicide; or absolute abstinence</td>
<td>Plan year</td>
<td></td>
<td></td>
<td>• Negative pregnancy test on a monthly basis  • Female patient or guardian signed a Patient Agreement/Informed Consent.  • Patient has agreed to use chosen form of contraception at least 1 month before initiation of Soriatane therapy, during therapy, and for at least 3 years after discontinuation of therapy.  • Patient has been advised that ethanol must not be ingested by female patients during and for 2 months following therapy.</td>
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<td><strong>STELARA</strong></td>
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<td>• Active infection including tuberculosis • Concurrent use with other biologics</td>
<td>Affected area is greater than 10% of BSA or affects crucial body areas (e.g. feet, hands, face). Inadequate response or intolerance or contraindication to at least a 60-day trial of 2 conventional therapies (e.g. phototherapy, calcipotriene, MTX, acitretin)</td>
<td>Approve for those 18 years of age and older</td>
<td></td>
<td></td>
<td>• Screening for latent tuberculosis is required. If results are positive, patient must have completed treatment or must currently be receiving treatment for latent tuberculosis.  • For reauthorization: Patient’s condition must have improved or stabilized in response to Stelara therapy.</td>
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<td><strong>STRATTERA</strong></td>
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<td>MAOI concurrent use or within the last 14 days</td>
<td>Approve for those 6 years of age or older</td>
<td>Plan year</td>
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<td>Monitor for suicidality, clinical worsening, changes in behavior, blood pressure changes, heart rate changes, and liver injury.</td>
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<td><strong>SYLATRON</strong></td>
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<td>• Autoimmune hepatitis • Decompensated hepatic disease • Uncontrolled major depression or severe mental illness</td>
<td>Melanoma: Melanoma has microscopic or gross nodal involvement. Sylatron is used following surgical resection of the tumor and complete lymphadenectomy, and is being requested for use within 12 weeks of the surgery.  • CML: unable to tolerate TKIs (e.g. imatinib, dasatinib, or nilotinib) or patient is post-transplant without remission or with relapse of CML</td>
<td>Plan year</td>
<td></td>
<td></td>
<td>Patient must be monitored and evaluated for signs and symptoms of depression and other psychiatric symptoms throughout treatment with Sylatron.</td>
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<tr>
<td><strong>SYMLIN</strong></td>
<td>• Symlin  • Symlinpen 60  • Symlinpen 120</td>
<td>• Severe hypoglycemia that required assistance during the past 6 months  • Gastroparesis  • Patient requires drug therapy to stimulate gastrointestinal motility  • Presence of hypoglycemia unawareness (inability to detect and act upon signs or symptoms of hypoglycemia)</td>
<td>Inadequate glycemic control (HbA1c greater than 7% but less than 9%) at initiation of therapy  • Patient is currently receiving optimal mealtime insulin therapy.</td>
<td>Plan year</td>
<td></td>
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<td>If patient has taken Symlin in previous 6 months, patient demonstrated a reduction in HbA1c since initiating therapy.</td>
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<tr>
<td><strong>TESTOSTERONES</strong></td>
<td>• Androderm  • Androgel  • Androgel pump  • Axiron  • Fortesta  • Striant  • Testim</td>
<td>• Female  • Prostate cancer  • Breast cancer</td>
<td>Before start of testosterone therapy patient has a confirmed low testosterone level (i.e. total testosterone less than 300 ng/dL, free or bioavailable, testosterone less than 5 ng/dL) or absence of endogenous testosterone.</td>
<td>Plan year</td>
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<tr>
<th>Prior Authorization Group</th>
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<th>Exclusion Criteria</th>
<th>Required Medical Information</th>
<th>Age Restrictions</th>
<th>Prescriber Restrictions</th>
<th>Coverage Duration</th>
<th>Other Criteria</th>
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<tbody>
<tr>
<td>THALOMID</td>
<td></td>
<td>Pregnancy</td>
<td>Active myeloma: Thalomid is used for one of the following - 1) salvage or palliative therapy 2) newly diagnosed disease or primary induction therapy in combination with dexamethasone or in combination with melphalan and prednisone in nontransplant candidates 3) maintenance monotherapy following response to either stem cell transplant or primary induction therapy.</td>
<td>Plan year</td>
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<td>THORIDAZINE</td>
<td></td>
<td>Not covered for those who are 65 years of age and older.</td>
<td></td>
<td>Plan year</td>
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<tr>
<td>TOPICAL IMMUNO-SUPPRESSANT</td>
<td>Elidel</td>
<td>Protopic</td>
<td>Diagnosis documented as atopic dermatitis or eczema. Patient has completed a documented trial/failure or intolerance or unresponsiveness to at least 2 medium or higher potency topical steroids.</td>
<td>Approve for those 2 years of age and older</td>
<td>Plan year</td>
<td>Patient has been advised that Elidel and Protopic should only be used to treat the immediate problem and should be stopped when condition improves.</td>
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<tr>
<td>TOPICAL - ULCERS</td>
<td>Reganex</td>
<td>Neoplasm(s) at site(s) of application</td>
<td>Must be used for treatment of lower-extremity diabetic ulcers. Ulcer must extend into subcutaneous tissue or beyond and be less than 10cm² in size. Tissue must have adequate blood supply. Patient must have concurrent good ulcer treatment practices including debridement, pressure relief, and infection relief.</td>
<td>10 weeks</td>
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<td>TRACLEER</td>
<td></td>
<td>AST/ALT level greater than 3 times ULN</td>
<td>PAH confirmed by right heart catheterization NYHA Class II-IV symptoms</td>
<td>Plan year</td>
<td></td>
<td></td>
<td>Female patient of child-bearing potential must use more than 1 method of contraception concurrently.</td>
</tr>
<tr>
<td>TYSABRI</td>
<td></td>
<td>Tysabri will be used as monotherapy.</td>
<td>Tysabri will be used as monotherapy. MS: inadequate response or intolerance to other MS therapies</td>
<td>MS – 12 months</td>
<td>CD – initial 3 months, renewal 12 months</td>
<td>Crohn's disease renewal: Patient's condition must have improved or stabilized in response to Tysabri therapy.</td>
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<tr>
<td>TYZEKA</td>
<td>Use of Tyzeka as first-line therapy in treatment-naïve patients with HBV</td>
<td>Diagnosis of chronic hepatitis B Evidence of a positive HBsAg (+ or -) serological marker for more than 6 months or evidence by a liver biopsy showing chronic hepatitis Hepatitis B viral load greater than 20,000 IU/ml (100,000 copies/ml) except if for HBsAg-negative HBV, the viral load is greater than 2,000 IU/ml (10,000 copies/ml) Elevations in liver aminotransferases (ALT or AST) that are 2 times greater than normal or normal liver aminotransferase levels with evidence of significant disease found on biopsy Patient has been tested for HIV and is negative.</td>
<td>Approve for those 16 years of age and older</td>
<td>Plan year</td>
<td>(Required Medical Information continued)</td>
<td>If patient has received previous Tyzeka treatment, documented clinical improvement is shown by a drop in viral load or reduction in the patient's liver aminotransferases. Patient is not receiving duplicate therapy that includes Baraclude, Epivir and/or Intron A. Evidence of diagnosis, serological markers or liver biopsy, viral load, and liver aminotransferases is documented in patient's chart.</td>
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<td>VICTRELIS</td>
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<td>Failed previous therapy with a treatment regimen that includes a protease inhibitor (e.g., Incivek, Vitekis) Concurrent administration with a drug that is highly dependent on CYP3A4/5 for clearance or potent CYP3A4/5 inducer</td>
<td>HCV infection confirmed by presence of viral load in serum HCV Genotype 1 HCV-RNA less than 100 IU/ml after 12 weeks of therapy and undetectable HCV RNA after 24 weeks of treatment</td>
<td>Initial - 8 weeks</td>
<td>Renewal - up to 44 weeks</td>
<td>Vicrelis must be given in combination with pegylated interferon (i.e. Pegasys or PegIntron) and ribavirin. Patient must receive 4 weeks of pegylated interferon and ribavirin prior to starting Vicrelis.</td>
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| **VIVAGLOBIN**            | • IgA deficiency with antibody formation and a history of hypersensitivity  
                          | • History of anaphylaxis or severe systemic reaction to the administration of human immune globulin  
                          | If administered outside a controlled health care setting, appropriate treatment (e.g. anaphylaxis kit) should be available for managing an acute hypersensitivity reaction.  
                          | Approve for those 2 years of age or older                                                                                   | Plan year |
| **VPRIV**                 | Concurrent use of miglustat (Zavesca)  
                          | • Diagnosis confirmed by bone marrow histology, DNA testing, or measurement of beta-glucocerebrosidase enzyme activity less than 30%  
                          | • Patient must have at least one of the following conditions as a result of Type 1 Gaucher disease: anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly  
                          | Plan year                                                                                                                  | Plan year |
|                           | Patients who have previously received 24 months of VPRIV therapy must have a decrease in liver and spleen volume and/or increase in platelet count and/or increase in Hgb concentration for reauthorization. | Plan year                                                                                                                  | Plan year |
| **XALKORI**               | Diagnosis of locally advanced or metastatic non-small cell lung cancer that is ALK-positive as detected by an FDA-approved test  
                          | Plan year                                                                                                                  | Plan year |
|                           | Prior authorization applies to new starts only. Refills will be approved unless use is not coverable under Part D per Medicare drug coverage policies. | Plan year                                                                                                                  | Plan year |
| **XENAZINE**             | • Actively suicidal  
                          | • Untreated or inadequately treated depression  
                          | • Use in combination with MAOIs or reserpine (or it has been less than 20 days since reserpine was discontinued)  
                          | Plan year                                                                                                                                 | Plan year |
| **XEOMIN**               | • Cosmetic use   
                          | • Hypersensitivity to any botulinum toxin preparation or any component of the formulation  
                          | • Infection at the proposed injection site(s)  
                          | • Blepharospasm: Patient has previously been treated with Botox.  
                          | • Initial treatment of chronic migraine: Patient experiences 15 or more headache days per month with headaches lasting 4 hours or longer. Patient completed an adequate trial (8 weeks or more) of oral migraine preventative therapy unless intolerant or contraindicated.  
                          | • Severe primary axillary hyperhidrosis: Patient has tried conventional treatments, such as topical aluminum chloride solution or iontophoresis, without relief.  
                          | • Urinary incontinence associated with a neurologic condition: inadequate response or intolerance to an anticholinergic medication.  
                          | • Chronic migraine initial - 12 weeks  
                          | • Plan year for all other indications and chronic migraine renewal  
                          | • Renewal for chronic migraine: Patient achieved or maintained a 50% reduction in monthly headache frequency since starting botulinum toxin A therapy.  
                          | • Monitor for life-threatening symptoms of spread of toxin effect from injection site (e.g. breathing or swallowing difficulties) | Plan year |
| **XGEVA**                | Uncorrected hypocalcemia  
                          | Patient has bone metastases from a solid tumor  
                          | Approve for those 18 years of age and older  
                          | Plan year                                                                                                                  | Plan year |
|                           | Patient will receive concurrent calcium and vitamin D supplementation as needed to prevent hypocalcemia. | Plan year                                                                                                                  | Plan year |
| **XIFAXAN**             | • Hypersensitivity reaction to rifamycin antimicrobial agents  
                          | • For hepatic encephalopathy: dosage exceeding the recommended two 550mg tablets daily  
                          | Approve for those 12 years of age and older  
                          | Hepatic encephalopathy – 6 months                                                                                           | Plan year |
|                           | • Evidence of reversible disease (demonstrates at least 20% improvement in PEF with a short-acting bronchodilator challenge)  
                          | • Patient has experienced 2 or more asthma exacerbations per month within the last 3 months.  
                          | • Positive skin test to at least 1 perennial allergen  
                          | • Baseline IgE level at or above 30 IU/ml  
                          | • Asthma is inadequately controlled despite adherent use of inhaled corticosteroids.  
                          | • Inadequate response to a trial of a leukotriene modifier or long-acting beta2-agonist (unless patient demonstrates intolerance to the therapeutic trial)  
                          | • Pulmonologist  
                          | • Allergist  
                          | • Immunologist                                                                                                               | Plan year |
|                           | • For continuation: must demonstrate an improvement in asthma control with use of Xolair | Plan year                                                                                                                  | Plan year |

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<td>XYREM</td>
<td>Patients taking any of the following: anxiolytics, sedatives, hypnotics, barbiturates, benzodiazepines or ethanol.</td>
<td>• Diagnosis documented as excessive daytime sleepiness with symptoms that limit ability to perform normal daily activities&lt;br&gt;• Diagnosis documented as cataplexy in patients with narcolepsy</td>
<td>3 months</td>
<td>Patients with prior Xyrem treatment must experience a decrease in daytime sleepiness and/or cataplexy in a narcoleptic patient.</td>
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<tr>
<td>ZAVESCA</td>
<td>• Severe renal impairment&lt;br&gt;• Pregnancy</td>
<td>• Diagnosis confirmed by bone marrow histology, DNA testing, or measurement of β-glucocerebrosidase enzyme activity less than 30%&lt;br&gt;• Trial of enzyme replacement therapy or it is not a therapeutic option (e.g. allergy, poor venous access)&lt;br&gt;• Female patients of childbearing age must use an effective method of contraception and be educated about the potential hazards associated with Zavesca use in pregnancy.</td>
<td>Plan year</td>
<td>Patients who have previously received 24 months of Zavesca therapy must demonstrate a decrease in liver and spleen volume and/or increase in platelet count and/or increase in Hgb concentration.</td>
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<td>ZELBORAF</td>
<td>• Diagnosis of unresectable or metastatic melanoma&lt;br&gt;• Tumor is positive for the BRAF V600E mutation as detected by an FDA-approved test.</td>
<td></td>
<td>Plan year</td>
<td>Prior authorization applies to new starts only. Refills will be approved unless use is not coverable under Part D per Medicare drug coverage policies.</td>
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<td>ZORBTIVE</td>
<td>• Active malignancy (newly diagnosed or recurrent)&lt;br&gt;• Acute critical illness due to complications following open heart or abdominal surgery&lt;br&gt;• Accidental trauma or acute respiratory failure</td>
<td>• Initial - 4 weeks&lt;br&gt;• Renewal - 4 weeks (up to a lifetime maximum of 8 weeks)&lt;br&gt;For continuation: Patient must show a response to Zurbtive therapy (e.g. requirements for nutritional support have decreased or patient's weight has stabilized or increased).</td>
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<td>ZYTIGA</td>
<td>Use in combination with prednisone</td>
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<td>Plan year</td>
<td>Patient received prior chemotherapy containing docetaxel.</td>
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<td><strong>HIGH RISK MEDICATIONS (HRM)</strong></td>
<td>Not covered for those who are 65 years of age and older</td>
<td>Amrix, Bentyl, Carisoprodol, Carisoprodol/Aspirin, Carisoprodol/Aspirin/Codine, Cenestin, Chlorzoxazone, Cyclobenzaprine, Cyproheptadine, Dicyclomine, Diphenoxylate/Atropine, Dipyrinamoime, Enjuvia, Estropipate, Fexmid, Flexeril, Hydroxyzine Pamoate, Lomotil, Menest, Metaxalone, Methocarbamol, Motifen, Orphenadrine Citrate ER, Orphenadrine Compound DS, Orphenadrine/ASA/Caffeine, OrthoEst, Parafon Forte DSC, Persantine, Phenadox, Premarin, Premphase, Prempiro, Promethazine HCl, Promethazine VC, Promethegan, Robaxin, Skelaxin, Soma, Tigan, Transderm-Scop, Trimethobenzamide, Vistaril</td>
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