PRIOR AUTHORIZATION PROTOCOLS

How do I request an exception to the Ultimate Health Plans' Formulary?

You can ask Ultimate Health Plans to make an exception to our coverage rules. There are several types of exceptions that you can ask us to make.

- You can ask us to cover your drug even if it is not on our formulary.
- You can ask us to waive coverage restrictions or limits on your drug. For example, for certain drugs, Ultimate Health Plans limits the amount of the drug that we will cover. If your drug has a quantity limit, you can ask us to waive the limit and cover more.
- You can ask us to provide a higher level of coverage for your drug. If your drug is contained in our non-preferred tier, you can ask us to cover it at the cost-sharing amount that applies to drugs in the preferred tier instead. This would lower the amount you must pay for your drug. Please note, if we grant your request to cover a drug that is not on our formulary, you may not ask us to provide a higher level of coverage for the drug. "Also, you may not ask us to provide a higher level of coverage for drugs that are in the specialty tier."

Generally, Ultimate Health Plans will only approve your request for an exception if the alternative drugs included on the plan's formulary, the lower-tiered drug or additional utilization restrictions would not be as effective in treating your condition and/or would cause you to have adverse medical effects.

You should contact us to ask us for an initial coverage decision for a formulary, tiering or utilization restriction exception. **When you are requesting a formulary, tiering or utilization restriction exception you should submit a statement from your physician supporting your request.** Generally, we must make our decision within 72 hours of getting your prescribing physician's supporting statement. You can request an expedited (fast) exception if you or your doctor believe that your health could be seriously harmed by waiting up to 72 hours for a decision. If your request to expedite is granted, we must give you a decision no later than 24 hours after we get your prescribing physician's supporting statement.

Your physician must submit a statement supporting your coverage determination or exception request. In order to help us make a decision more quickly, you should include supporting medical information from your doctor when you submit your exception request.

What if I have additional questions?
You can call us at: 1-800-546-5677 (seven days a week, 24 hours a day) if you have any additional questions. If you have a hearing or speech impairment, please call us at TTY 1-866-706-4757.

ABSTRAL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 Â¿g/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day). Trial and failure or intolerance to generic fentanyl lozenge.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.

COVERAGE DURATION: 12 months

OTHER CRITERIA:

ACTEMRA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Actemra therapy. Systemic Juvenile Idiopathic arthritis (SJIA) (Initial): Diagnosis of active SJIA. Failure, contraindication, or intolerance to one NSAID or systemic glucocorticoid. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Actemra therapy. All indications (Initial, reauth): Patient is not receiving Actemra in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Actemra in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: All uses (Initial): Prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION: All uses (Initial, reauth): 12 months

OTHER CRITERIA: All uses (Reauth): Documentation of positive clinical response to Actemra therapy.

ADAGEN

COVERED USES:	All medically accepted indications not otherwise excluded from Part D.
EXCLUSION CRITERIA:	Excluded if patient has severe thrombocytopenia
REQUIRED INFO:	Adenosine deaminase (ADA) deficiency: Diagnosis of ADA deficiency in a patient with severe combined immunodeficiency disease (SCID) AND patient is not a suitable candidate for, or who has failed, bone marrow transplantation, hematopoietic stem cell transplant, or gene therapy.
AGE RESTRICTIONS:	
MD RESTRICTIONS:	
COVERAGE DURATION:	12 months
OTHER CRITERIA:	Approve for continuation of prior therapy.

ADAPALENE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Diagnosis of acne.

AGE RESTRICTIONS: PA applies to members 26 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

ADCIRCA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTIONS:

MD RESTRICTIONS: PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION: PAH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA: PAH (Reauth): Documentation of positive clinical response to therapy.

ADEMPAS

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. Chronic thomboembolic pulmonary hypertension (CTEPH) (Initial): One of the following: A) Both of the following: 1) Diagnosis of inoperable or persistent/recurrent CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any therapy for the diagnosis of CTEPH.

AGE RESTRICTIONS:

MD RESTRICTIONS: PAH, CTEPH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION: PAH, CTEPH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA: PAH, CTEPH (Reauth): Documentation of positive clinical response to therapy.

ALDURAZYME

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Mucopolysaccharidosis I: confirmed diagnosis of Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I), OR confirmed diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I) who have moderate to severe symptoms.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

ALOSETRON HYDROCHLORIDE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women (initial): All of the following: 1) diagnosis of severe diarrhea-predominant IBS, 2) symptoms for at least 6 months, 3) female patient, AND 4) trial and failure, contraindication, or intolerance to an antidiarrheal agent [eg, loperamide].

AGE RESTRICTIONS: Initial: 18 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: IBS (initial): 12 weeks. IBS (reauth): 6 mo.

OTHER CRITERIA: IBS (reauthorization): Symptoms of IBS continue to persist, AND documentation of positive clinical response to Lotronex therapy.

AMPHETAMINE/DEXTROAMPHETA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

AMPYRA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS) (initial): Diagnosis of MS. Physician confirmation that patient has difficulty walking (eg, timed 25 foot walk test). One of the following: expanded disability status scale (EDSS) score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).

AGE RESTRICTIONS:

MD RESTRICTIONS: MS (Initial): Prescribed by or in consultation with a neurologist.

COVERAGE DURATION: MS (Initial): 6 months. (Reauth): 12 months.

OTHER CRITERIA: MS (Reauth): Physician confirmation that the patient's walking improved with Ampyra therapy. One of the following: EDSS score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).

ANADROL-50

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Anemia (initial): Diagnosis of anemia caused by deficient red cell production AND trial and failure or intolerance to standard therapies for anemia (i.e., erythropoiesis-stimulating agents, immunosuppressants) AND Treatment will not replace other supportive measures (e.g., transfusion, correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, antibacterial therapy, corticosteroids).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Initial and reauth: 12 months

OTHER CRITERIA: Anemia (reauth): patient has experienced an objective improvement in anemia (e.g., increased hemoglobin, increased reticulocyte count, reduction/elimination for need of blood transfusions)

ANDRODERM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reaut

OTHER CRITERIA: HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

ANDROGEL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reaut

OTHER CRITERIA: HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

ANDROGEL PUMP

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reaut

OTHER CRITERIA: HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

APOKYN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: PD (Initial, reauth): Patient is using Apokyn with any 5-HT3 antagonist (eg, ondansetron, granisetron, dolasetron, palonosetron, alosetron)

REQUIRED INFO: Parkinson's disease (PD) (Initial): Diagnosis of advanced PD. Patient is experiencing acute intermittent hypomobility (defined as Â¿offÂ¿ episodes characterized by muscle stiffness, slow movements, or difficulty starting movements). Patient is receiving Apokyn in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, benztropine, etc.).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: PD (Initial, reauth): 12 months

OTHER CRITERIA: PD (Reauth): Patient is benefiting from therapy (eg, patient had an improvement in motor function).

ARALAST NP

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency: All of the following: A) Patient has an alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency AND B) Diagnosis of emphysema AND C) One of the following: 1) Patient has a high risk phenotype: PiZZ, PiZ(null), or Pi(null)(null) OR 2) Patient has serum alpha-1 antitrypsin concentrations of less than 11 Â¿M/L (80 mg/dL), AND D) One of the following: FEV1 level is between 30% and 65% of predicted OR the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment, AND E) Trial and failure, or intolerance to Prolastin-C.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

ARANESP ALBUMIN FREE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with chemo (Initial): Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS. CKD (init, reauth), Chemo (init), MDS (init): Verify iron evaluation for adequate iron stores.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: CKD (Init): 6 mo. CKD (reauth): 12 mo. Chemo(init, reauth): 3 mo. M

OTHER CRITERIA: Subject to ESRD review. CKD (Reauth): Dx of CKD. Most recent or average (avg) Hct over 3 mo is 33% or less OR most recent or avg Hgb over 3 months is 11 g/dL or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Off-label uses (except MDS):

Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.

ARCALYST

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Cryopyrin-Associated Periodic Syndromes (CAPS) (Initial): Diagnosis of CAPS, including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS). The medication will not be used in combination with another biologic.

AGE RESTRICTIONS: CAPS (Initial): 12 years of age or older

MD RESTRICTIONS: CAPS (Initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist.

COVERAGE DURATION: CAPS (initial, reauth): 12 months

OTHER CRITERIA: CAPS (Reauth): Patient has experienced disease stability or improvement in clinical symptoms while on therapy as evidence by one of the following: A) improvement in rash, fever, joint pain, headache, conjunctivitis, B) decreased number of disease flare days, C) normalization of inflammatory markers (CRP, ESR, SAA), D) corticosteroid dose reduction, OR E) improvement in MD global score or active joint count.

ARMODAFINIL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Obstructive sleep apnea/hypopnea syndrome (OSAHS) (Initial): Diagnosis (dx) of OSAHS defined by one of the following: a) 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or b) both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), AND 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work sleep disorder (SWSD) (Initial):Dx of SWSD confirmed by symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, or sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). No other medical condition or medication accounts for the symptoms. Narcolepsy (initial): Dx of narcolepsy as confirmed by sleep study (unless prescriber provides justification confirming that a sleep study is not feasible).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: OSAHS (Initial): 3 months (Reauth): 12 months. SWSD (Initial, Reau

OTHER CRITERIA: OSAHS (Reauth): Documentation of positive clinical response to prior therapy. SWSD (Reauth): Documentation of positive clinical response to prior therapy. Patient still requires treatment for SWSD. Narcolepsy (reauth): Documentation of positive clinical response to prior therapy.

AUBAGIO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

AVITA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: Acne: Diagnosis of acne.

AGE RESTRICTIONS: PA applies to members 26 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

AVONEX

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

AVONEX PEN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

BENLYSTA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Systemic lupus erythematosus (SLE) (init): Diagnosis of active SLE. Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL). Currently receiving at least one standard of care treatment for active SLE (eg, antimalarials [eg, Plaquenil (hydroxychloroquine)], corticosteroids [eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran (azathioprine), CellCept (mycophenolate mofetil)]).

AGE RESTRICTIONS:

MD RESTRICTIONS: SLE (init): Prescribed by or in consultation with a rheumatologist

COVERAGE DURATION: SLE (init, reauth): 6 months

OTHER CRITERIA: SLE (reauth): Documentation of positive clinical response to Benlysta therapy

BERINERT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Firazyr, Kalbitor, or Ruconest).

AGE RESTRICTIONS:

MD RESTRICTIONS: HAE: Prescribed by an immunologist, allergist, or rheumatologist

COVERAGE DURATION: 12 months

OTHER CRITERIA:

BETASERON

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

BIVIGAM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. G

REQUIRED INFO: Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG Â¿ Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.

AGE RESTRICTIONS: HIV (initial): patient is less than or equal to 12 years of age.

MD RESTRICTIONS: All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

COVERAGE DURATION: 4 months: Solid organ transplant. 12 months: all other diagnoses.

OTHER CRITERIA: [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-BarrÂ¿ syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

BOTOX

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Neuromuscular Disorders (init): Strabismus, blepharospasm associated with dystonia (eg, benign essential blepharospasm), treatment of upper or lower limb spasticity, VII cranial nerve disorders (hemifacial spasms), cervical dystonia Hyperhidrosis(HH): (Init) Dx of primary axillary HH. Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) or skin maceration with secondary infection. Migraine:(Init) Dx of chronic migraines (greater than or equal to 15 migraine headache days per month with headache lasting 4 hours a day or longer). TF/C/I to prophylactic therapy with at least two of the following agents, each given for a trial of at least two months: antidepressants [ie, Effexor (venlafaxine)], antiepileptics [ie, Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [eg, atenolol, Inderal (propranolol), nadolol, timolol, Toprol XL (metoprolol)] Achalasia:(Init) High risk of complication from or failure to pneumatic dilation or myotomy, or prior dilation caused esophageal perforation, or patient has an epiphrenic diverticulum or hiatal hernia. Anal Fissure (AF)(Init): Dx of chronic AF. At least 2 months of either nocturnal pain and bleeding or postdefecation pain. Chronic Back Pain (CBP):(Init) Dx of low back pain lasting greater than or equal to six months. Urinary incont (UI):(init) Neurogenic detrusor overactivity associated with a neurologic condition (eg, spinal cord injury [SCI], multiple sclerosis) or detrusor sphincter dyssynergia with SCI. Overactive bladder (OAB): (init) Dx of OAB. One of the following symptoms: urge urinary incontinence, urgency, frequency.

AGE RESTRICTIONS:

MD RESTRICTIONS: Migraine (Initial): Prescribed by a neurologist or pain specialist. CBP (Initial): Prescribed by a neurologist, neurosurgeon, orthopedist, or pain specialist. UI, OAB (initial): Prescribed by a neurologist, neurosurgeon, or urologist.

COVERAGE DURATION: Achalasia: 6moCBP:1 tx(series of inj̨xs)UI:3mo(1 dose,200units)Oth

OTHER CRITERIA: UI, OAB, CBP, Neuromuscular Disorders:(Reauth) Confirmed improvement in symptoms with initial Botox treatment. At least 3 months have or will have elapsed since the last treatment with Botox HH:(Reauth) At least a 2-point improvement in HDSS. Migraine:(Reauth) Reduction in headache frequency or intensity.

Confirmation of decreased utilization of pain medications (eg, narcotic analgesics, NSAIDs) or triptans, or a reduction in the number of ER visits. Achalasia:(Reauth) Documentation of improvement or reduction in symptoms of achalasia (ie, dysphagia, regurgitation, chest pain). At least 6 months have or will have elapsed since last series of injections AF: (Reauth) Incomplete healing of fissure or recurrence of fissure. Improved symptoms with prior treatment with Botox.

CARIMUNE NANOFILTERED

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. G

REQUIRED INFO: Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG Â¿ Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.

AGE RESTRICTIONS: HIV (initial): patient is less than or equal to 12 years of age.

MD RESTRICTIONS: All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

COVERAGE DURATION: 4 months: Solid organ transplant. 12 months: all other diagnoses.

CARIMUNE NANOFILTERED

OTHER CRITERIA: [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-BarrÂ¿ syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

CARISOPRODOL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: The drug is being prescribed for an FDA-approved indication. If the patient is 65 years of age or older, the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

CAYSTON

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Cystic fibrosis (CF) (Initial, Reauth): Diagnosis of CF AND Patient has evidence of Pseudomonas aeruginosa in the lungs

AGE RESTRICTIONS: CF (Initial): 7 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: CF (Initial, reauth): 12 months

OTHER CRITERIA: CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations)

CERDELGA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Gaucher disease (Initial): Diagnosis of Gaucher disease type 1. Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test.

AGE RESTRICTIONS: Gaucher disease (initial): 18 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: Gaucher disease (initial, reauth): 12 months

OTHER CRITERIA: Gaucher disease (Reauth): PatientÂ¿s condition has not progressed, as defined by ALL of the following: A) Hemoglobin level decreased greater than 1.5 g/dL from baseline, AND B) Platelet count decreased greater than 25% from baseline, AND C) Spleen volume increased greater than 25% from baseline, AND D) Liver volume increased greater than 20% from baseline.

CEREZYME

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Gaucher disease: Diagnosis of type 1 Gaucher disease. Patient has evidence of symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Gaucher disease: 12 months

OTHER CRITERIA:

CHOLBAM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) Cholbam will be used as an adjunctive treatment.

AGE RESTRICTIONS:

MD RESTRICTIONS: All uses (initial): Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.

COVERAGE DURATION: All uses (initial, reauth): 12 months

OTHER CRITERIA: All uses (reauth): documentation of positive clinical response to Cholbam therapy

CHORIONIC GONADOTROPIN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Prepubertal Cryptorchidism: Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction. Male Hypogonadotropic Hypogonadism (MHH) (initial): Diagnosis of male hypogonadism secondary to pituitary deficiency, and low testosterone (below normal reference value provided by the physician's laboratory) and one of the following: a) low LH (below normal reference value provided by the physician's laboratory) or b) low FSH (below normal reference value provided by the physician's laboratory).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Prepubertal Cryptorchidism: 6 wks. MHH (initial, reauth): 12 months.

OTHER CRITERIA: Excluded if used to promote fertility. MHH (Reauth): Documentation of positive clinical response to therapy.

CIALIS

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Concurrent use of nitrates.

REQUIRED INFO: Diagnosis of benign prostatic hyperplasia (BPH). Trial and failure, contraindication, or intolerance to an alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) or a 5-alpha reductase inhibitor (e.g., dutasteride, finasteride).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

CICLOPIROX NAIL LACQUER

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: All of the following: 1) Patient does not have dermatophytomas or lunula (matrix) involvement, 2) one of the following: a) Diagnosis of onychomycosis of the toenails, OR b) Diagnosis of onychomycosis of the fingernails, 3) Diagnosis of onychomycosis has been confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, 4) If toenail onychomycosis, patient has mild to moderate disease involving at least 1 great toenail, AND 5) Trial and inadequate response, intolerance or hypersensitivity to oral terbinafine.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 48 weeks.

OTHER CRITERIA:

CIMZIA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA, initial): Diagnosis (dx) of moderately to severely active RA. TF/C/I to Enbrel and Humira OR for continuation of prior Cimzia therapy. Crohn's Disease (CD, initial): Dx of moderately to severely active CD. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), Azathioprine (Imuran), Corticosteroid (eg, prednisone, methylprednisolone), Methotrexate (Rheumatrex, Trexall). TF/C/I to Humira OR for continuation of prior Cimzia therapy. Psoriatic Arthritis (PsA, initial): Dx of active PsA. TF/C/I to Cosentyx and either Humira or Enbrel OR for continuation of prior Cimzia therapy. Ankylosing Spondylitis (AS, initial): Dx of active AS. TF/C/I to Enbrel and Humira OR for continuation of prior Cimzia therapy.

AGE RESTRICTIONS:

MD RESTRICTIONS: CD (init): Prescribed by or in consultation with a gastroenterologist. RA, AS (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist.

COVERAGE DURATION: RA, PsA, AS (init,reauth): 12 mos. CD (init): 16 wks. (reath): 12 mos.

OTHER CRITERIA: Reauthorization (all indications): Documentation of positive clinical response to Cimzia therapy. All indications (initial and reauth): Patient is not receiving Cimzia in combination with either of the following: Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab), Orencia (abatacept)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

CINRYZE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For prophylaxis against HAE attacks. For continuation of prior therapy or Trial and failure, contraindication, or intolerance of one of the following: 17-alpha alkylated androgen (eg, danazol, oxandrolone) or antifibrinolytics (eg, aminocaproic acid, tranexamic acid).

AGE RESTRICTIONS:

MD RESTRICTIONS: HAE (prophylaxis, treatment): Prescribed by an immunologist, allergist, or rheumatologist

COVERAGE DURATION: 12 months

OTHER CRITERIA:

CLARAVIS

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Acne (initial): Diagnosis of acne. Trial and failure, contraindication or intolerance to an adequate trial (at least 6 weeks) on both of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin)] AND b) combination therapy with benzoyl peroxide and one of the following: 1) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)] OR 2) topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)].

AGE RESTRICTIONS:

MD RESTRICTIONS: Acne (Initial): Prescribed by a dermatologist

COVERAGE DURATION: Acne (initial, reauth): 5 months

OTHER CRITERIA: Acne (reauth): One of the following: A) After more than 2 months off therapy, persistent or recurring severe recalcitrant nodular acne is still present, OR B) the total cumulative dose is less than 150 mg/kg (will be approved up to a total of 150 mg/kg).

CLINDAMYCIN PHOSPHATE/TRE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Acne: Diagnosis of acne.

AGE RESTRICTIONS: PA applies to members 26 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

COPAXONE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

CORLANOR

COVERED USES:	All medically accepted indications not otherwise excluded from Part D.
EXCLUSION CRITERIA:	CHF (initial, reauth): BP less than 90/50, severe hepatic impairment, a. fib.
REQUIRED INFO:	Chronic heart failure (CHF) (initial): Diagnosis of CHF with NYHA Class II, III, or IV symptoms. Left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm with a resting heart rate of greater than or equal to 70 BPM and has been hospitalized for worsening HF in the previous 12 months. Trial and failure, intolerance, or contraindication to maximally tolerated doses of at least one beta-blocker with proven mortality benefit (i.e., carvedilol, bisoprolol, sustained-release metoprolol) AND trial and failure, intolerance, or contraindication to maximally tolerated doses of an ACE inhibitor or ARB.
AGE RESTRICTIONS:	
MD RESTRICTIONS:	CHF (initial): Prescribed by or in consultation with a cardiologist
COVERAGE DURATION:	CHF (initial, reauth): 12 months
OTHER CRITERIA:	CHF (reauth): patient does not have contraindications/exclusions to therapy.

COSENTYX

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) OR Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Cosentyx therapy. All indications (Initial, reauth): Patient is not receiving Cosentyx in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

AGE RESTRICTIONS:

MD RESTRICTIONS: Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS (Initial): Prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION: All indications (Initial, reauth): 12 months

OTHER CRITERIA: All indications (Reauth): Documentation of positive clinical response to Cosentyx therapy.

COSENTYX SENSOREADY PEN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) OR Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Cosentyx therapy. All indications (Initial, reauth): Patient is not receiving Cosentyx in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

AGE RESTRICTIONS:

MD RESTRICTIONS: Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS (Initial): Prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION: All indications (Initial, reauth): 12 months

OTHER CRITERIA: All indications (Reauth): Documentation of positive clinical response to Cosentyx therapy.

CRINONE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All indications: Excluded if for fertility uses.

REQUIRED INFO: Secondary amenorrhea: Diagnosis of secondary amenorrhea (the absence of menses in women who have already started menstruation who are not pregnant, breastfeeding, or in menopause).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

CYSTARAN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Cystinosis: Diagnosis of cystinosis, confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation AND Patient is concomitantly receiving treatment with oral cysteamine

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

DALIRESP

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Chronic Obstructive Pulmonary Disease (COPD): (Initial) Diagnosis of severe COPD. Patient has chronic bronchitis. Trial and failure, intolerance, or contraindication to two prior therapies for COPD.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: COPD (init, reauth): 12 months

OTHER CRITERIA: COPD (reauth): Documentation of positive clinical response to Daliresp therapy.

DARAPRIM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Toxoplasmosis: 1) Patient is using Daraprim for the treatment of toxoplasmic encephalitis, secondary prophylaxis of toxoplasmic encephalitis, or treatment of congenital toxoplasmosis OR 2) Patient is using Daraprim for the primary prophylaxis of toxoplasmic encephalitis, patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX), and one of the following: patient has been re-challenged with TMP-SMX using a desensitization protocol and is still unable to tolerate, or evidence of life-threatening reaction to TMP-SMX in the past (eg, toxic epidermal necrolysis, Stevens-Johnson syndrome). Malaria: Patient is using Daraprim for the treatment of acute malaria or chemoprophylaxis of malaria. Patient does not have megaloblastic anemia due to folate deficiency. The provider acknowledges that Daraprim is not recommended by the Centers for Disease Control and Prevention (CDC) for the treatment and/or prophylaxis of malaria.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with an infectious disease specialist

COVERAGE DURATION: 12 months

OTHER CRITERIA: Toxoplasmosis only: Approve for continuation of prior therapy.

DEPO-TESTOSTERONE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reaut

OTHER CRITERIA: HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

DEXMETHYLPHENIDATE HCL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

DEXMETHYLPHENIDATE HCL ER

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

DEXTROAMPHETAMINE SULFATE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

DICLOFENAC SODIUM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Initial, reauth: History of severe allergic-type reactions after taking aspirin or other non-steroidal anti-inflammatory (NSAIDs), including urticaria and asthma (aspirin-sensitive asthma).

REQUIRED INFO: Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees and diclofenac will not be used in the treatment of peri-operative pain in the setting of coronary artery bypass graft surgery. Patient meets one of the following: 1) Treatment failure with at least two prescription strength oral non-steroidal anti-inflammatory drugs (NSAIDs) OR 2) Documented swallowing disorder OR 3) History of peptic ulcer disease/gastrointestinal bleed OR 4) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Initial, reauth: 12 months

OTHER CRITERIA: Osteoarthritis of the knees (reauth): Patient has experienced a response to therapy (e.g., improvement in pain symptoms of osteoarthritis).

DRONABINOL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Trial and failure, contraindication, or intolerance to one 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). Trial and failure, contraindication, or intolerance to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS. Patient is on antiretroviral therapy.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: CINV: 6 months. AIDS anorexia: 3 months.

OTHER CRITERIA: Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving cancer chemotherapy.

EGRIFTA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: HIV-associated lipodystrophy (initial): All of the following: 1) diagnosis of HIV-associated lipodystrophy, 2) one of the following: a) waist-circumference of greater than or equal to 95 cm (37.4 inches) in men, OR b) waist-circumference of greater than or equal to 94 cm (37 inches) for women, 3) one of the following: a) Waist-to-hip ratio of greater than or equal to 0.94 for men, OR b) waist-to-hip ratio of greater than or equal to 0.88 for women, 4) body mass index (BMI) greater than 20 kg/m^2, AND 5) fasting blood glucose (FBG) levels less than or equal to 150 mg/dL (8.33 mmol/L), AND 6) patient has been on a stable regimen of antiretrovirals (eg, NRTIs, NNRTI, Protease Inhibitors, Integrase Inhibitors) for at least 8 weeks.

AGE RESTRICTIONS: (Initial): 18 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: (initial, reauth): 6 months

OTHER CRITERIA: (reauth): documentation of clinical improvement (eg, improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance, etc) while on Egrifta therapy.

ELAPRASE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Diagnosis of Hunter Syndrome (Mucopolysaccharidosis II (MPS II))

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

ENBREL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Failure, contraindication, or intolerance to one disease-modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Trial and failure, contraindication, or intolerance to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Trial and failure, contraindication, or intolerance to two NSAIDs. All indications (Initial, reauth): Patient is not receiving Enbrel in combination with a biologic DMARD [eg, Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]. Patient is not receiving Enbrel in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA (Initial), PJIA (Initial), AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (Initial): Prescribed by or in consultation with

COVERAGE DURATION: All indications (Initial, reauth): 12 months

OTHER CRITERIA: All indications (Reauth): Documentation of positive clinical response to Enbrel therapy.

ENBREL SURECLICK

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Failure, contraindication, or intolerance to one disease-modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Trial and failure, contraindication, or intolerance to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Trial and failure, contraindication, or intolerance to two NSAIDs. All indications (Initial, reauth): Patient is not receiving Enbrel in combination with a biologic DMARD [eg, Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]. Patient is not receiving Enbrel in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA (Initial), PJIA (Initial), AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (Initial): Prescribed by or in consultation with

COVERAGE DURATION: All indications (Initial, reauth): 12 months

OTHER CRITERIA: All indications (Reauth): Documentation of positive clinical response to Enbrel therapy.

ENTRESTO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Initial, reauth: Excluded if patient has a history of angioedema associated with use of the following: Angiotensin converting enzyme (ACE) Inhibitor therapy, Angiotensin receptor blocker (ARB) therapy.

REQUIRED INFO: Heart failure (HF) (initial): Diagnosis of heart failure (with or without hypertension). Ejection fraction is less than or equal to 40 percent. Heart failure is classified as NYHA Class II, III or IV. Patient is receiving concomitant therapy with one of the following beta-blockers at a maximally tolerated dose or has a contraindication or intolerance to beta-blocker therapy: bisoprolol, carvedilol or metoprolol succinate. Patient is not concomitantly on aliskiren therapy. Patient is not pregnant. Patient will discontinue use of any concomitant ACE Inhibitor or ARB. ACE inhibitors must be discontinued at least 36 hours prior to initiation of Entresto.

AGE RESTRICTIONS:

MD RESTRICTIONS: HF (initial): Prescribed by or in consultation with a cardiologist

COVERAGE DURATION: HF (initial reath): 12 months

OTHER CRITERIA: HF (reauth): documentation of positive clinical response to therapy.

EPCLUSA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Criteria will be applied consistent with current AASLD/IDSA guideline. Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus. Patient is not receiving Epclusa in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir), Olysio (simeprevir)]. One of the following: a) genotypes 2, 3, 5, or 6, or b) genotypes 1 or 4: trial and failure, contraindication, or intolerance to Harvoni and Zepatier or, for patients with decompensated cirrhosis, trial and failure, contraindication, or intolerance to Harvoni, or c) for continuation of prior Epclusa therapy.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine

COVERAGE DURATION: 12 to 24 weeks. Criteria will be applied consistent with current AASL

OTHER CRITERIA:

EPIDUO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Diagnosis of acne.

AGE RESTRICTIONS: PA applies to members 26 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

EPIDUO FORTE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Diagnosis of acne.

AGE RESTRICTIONS: PA applies to members 26 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

ESBRIET

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Idiopathic pulmonary fibrosis (IPF) (initial): Both of the following: 1) diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity), AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF, AND 2) not used in combination with Ofev (nintedanib).

AGE RESTRICTIONS:

MD RESTRICTIONS: IPF (initial): Prescribed by a pulmonologist

COVERAGE DURATION: initial, reauth: 12 months

OTHER CRITERIA: IPF (reauth): Documentation of positive clinical response to Esbriet therapy

EXJADE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of MDS. Patient has Low or Intermediate-1 disease or is a potential transplant patient. Patient has received more than 20 red blood cell transfusions. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than 300 mcg/L.

AGE RESTRICTIONS: Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 m

OTHER CRITERIA: Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin level or LIC.

EXONDYS 51

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Initial: Diagnosis of Duchenne muscular dystrophy (DMD). Documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping. Patient is ambulatory. Initial/Reauth: Exondys 51 dosing for DMD is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 30 mg/kg infused once weekly.

AGE RESTRICTIONS:

MD RESTRICTIONS: (initial, reauth): Prescribed by or in consultation with a neurologist who has experience treating children

COVERAGE DURATION: Initial: 6 months, Reauth: 12 months

OTHER CRITERIA: Reauth: One of the following: 1) All of the following: Patient has been on therapy for less than 12 months, patient is maintaining ambulatory status, and patient is tolerating therapy, OR 2) All of the following: Patient has been on therapy for 12 months or more, Patient is maintaining ambulatory status, patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients), and patient is tolerating therapy.

EXTAVIA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

FABRAZYME

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Fabry Disease: Diagnosis of Fabry disease.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Fabry Disease: 12 months

OTHER CRITERIA:

FENTANYL CITRATE ORAL TRA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 Â¿g/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day).

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.

COVERAGE DURATION: 12 months

OTHER CRITERIA:

FERRIPROX

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Transfusional iron overload due to thalassemia syndromes (Initial): Patient has a diagnosis of transfusional iron overload due to thalassemia syndromes. Absolute neutrophil count (ANC) greater than 1.5 x 109/L. One of the following: A) Patient has failed prior chelation therapy (e.g., Exjade) [failure defined as serum ferritin greater than 2,500 mcg/L] OR B) Patient has a contraindication or intolerance to Desferal (deferoxamine) or Exjade (deferasirox).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: All uses (initial, reauth): 12 months

OTHER CRITERIA: All uses (reauth): Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline. ANC greater than 0.5 x 109/L.

FIRAZYR

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Kalbitor, or Ruconest).

AGE RESTRICTIONS:

MD RESTRICTIONS: HAE: Prescribed by an immunologist, allergist, or rheumatologist

COVERAGE DURATION: 12 months

OTHER CRITERIA:

FLEBOGAMMA DIF

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. G

REQUIRED INFO: Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG Â¿ Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.

AGE RESTRICTIONS: HIV (initial): patient is less than or equal to 12 years of age.

MD RESTRICTIONS: All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

COVERAGE DURATION: 4 months: Solid organ transplant. 12 months: all other diagnoses.

FLEBOGAMMA DIF

OTHER CRITERIA: [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-BarrÂ¿ syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

FOCALIN XR

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

FORTEO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Postmenopausal Osteoporosis or men with primary or hypogonadal osteoporosis (initial): Set I) Both of the following: A) Diagnosis of osteoporosis defined as bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) either 1) patient has a history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) patient has a trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia (denosumab)). Set II) Both of the following: A) Diagnosis of osteopenia defined by bone mineral density (BMD) T-score of between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site), AND B) One of the following: 1) patient has a history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) Trial and failure, contraindication, or intolerance to at least one prior osteoporosis therapy (e.g., alendronate, risedronate, zoledronic acid, Prolia (denosumab) and ii) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture is 3% or more in the U.S., or the country-specific threshold in other countries or regions. Postmenopausal Osteoporosis or men with primary or hypogonadal osteoporosis (reauth): Documentation of a positive clinical response to Forteo (teriparatide) therapy and total duration has not exceeded a total of 24 months during the patient's lifetime. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: All indications: 12 months, max 2 years of therapy.

OTHER CRITERIA: Glucocorticoid-Induced Osteoporosis: Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose of greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: A) BMD T score of -2.0 or less based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) or B) Both of the following: 1) BMD T score between -1.0 and -2.0 (BMD T-score greater than -2.0 and less than or equal to -

1.0) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) and 2) either history of one of the following fx resulting from minimal trauma (vertebral compression fx, fx of the hip, or fx of the distal radius) or trial and failure, contraindication, or intolerance (TF/C/I) to one bisphosphonate [e.g., Fosamax (alendronate)] or C) Both of the following: 1) history of one of the following fractures resulting from minimal trauma (vertebral compression fx, fx of the hip, or fx of the distal radius) and 2) TF/C/I to one bisphosphonate [e.g., Fosamax (alendronate)]. Treatment duration has not exceeded a total of 24 months during the patient's lifetime.

GAMASTAN S/D

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).

REQUIRED INFO: Immune globulin is being used intramuscularly. The immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Patient requires immunization for hepatitis A, measles, rubella, or varicella.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 3 months (Approve one dose only)

OTHER CRITERIA: Subject to Part B vs D review.

GAMMAGARD LIQUID

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. G

REQUIRED INFO: Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG Â¿ Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.

AGE RESTRICTIONS: HIV (initial): patient is less than or equal to 12 years of age.

MD RESTRICTIONS: All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

COVERAGE DURATION: 4 months: Solid organ transplant. 12 months: all other diagnoses.

GAMMAGARD LIQUID

OTHER CRITERIA: [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-BarrÂ¿ syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

GAMMAGARD S/D IGA LESS TH

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. G

REQUIRED INFO: Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG Â¿ Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.

AGE RESTRICTIONS: HIV (initial): patient is less than or equal to 12 years of age.

MD RESTRICTIONS: All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

COVERAGE DURATION: 4 months: Solid organ transplant. 12 months: all other diagnoses.

GAMMAGARD S/D IGA LESS TH

OTHER CRITERIA: [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-BarrÂ¿ syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

GAMMAKED

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. G

REQUIRED INFO: Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG Â¿ Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.

AGE RESTRICTIONS: HIV (initial): patient is less than or equal to 12 years of age.

MD RESTRICTIONS: All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

COVERAGE DURATION: 4 months: Solid organ transplant. 12 months: all other diagnoses.

OTHER CRITERIA: [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-BarrÂ¿ syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

GAMMAPLEX

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. G

REQUIRED INFO: Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG Â¿ Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.

AGE RESTRICTIONS: HIV (initial): patient is less than or equal to 12 years of age.

MD RESTRICTIONS: All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

COVERAGE DURATION: 4 months: Solid organ transplant. 12 months: all other diagnoses.

OTHER CRITERIA: [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-BarrÂ¿ syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

GAMUNEX-C

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. G

REQUIRED INFO: Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG Â¿ Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.

AGE RESTRICTIONS: HIV (initial): patient is less than or equal to 12 years of age.

MD RESTRICTIONS: All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

COVERAGE DURATION: 4 months: Solid organ transplant. 12 months: all other diagnoses.

OTHER CRITERIA: [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-BarrÂ¿ syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

GATTEX

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Short Bowel Syndrome (SBS) (Initial) Diagnosis of SBS. Patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 consecutive months.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: SBS (Init): 6 months. SBS (Reauth): 12 months.

OTHER CRITERIA: SBS (Reauth): Documentation of positive clinical response to Gattex therapy.

GENOTROPIN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTIONS:

MD RESTRICTIONS: PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrazole,letrazole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

GENOTROPIN MINIQUICK

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTIONS:

MD RESTRICTIONS: PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrazole,letrazole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

GILENYA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

GLASSIA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency: All of the following: A) Patient has an alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency AND B) Diagnosis of emphysema AND C) One of the following: 1) Patient has a high risk phenotype: PiZZ, PiZ(null), or Pi(null)(null) OR 2) Patient has serum alpha-1 antitrypsin concentrations of less than 11 Â¿M/L (80 mg/dL), AND D) One of the following: FEV1 level is between 30% and 65% of predicted OR the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment, AND E) Trial and failure, or intolerance to Prolastin-C.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

GLATIRAMER ACETATE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

GLATOPA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

GRANIX

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) patient receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with a history of FN during a previous course of chemotherapy. All indications: History of failure or intolerance to Zarxio (filgrastim-sndz).

AGE RESTRICTIONS:

MD RESTRICTIONS: All uses: Prescribed by or in consultation with a hematologist/oncologist or infectious disease specialist

COVERAGE DURATION: CFN, secondary prophylaxis of FN:3mo or duration of tx

OTHER CRITERIA:

H.P. ACTHAR

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Infantile Spasm (West Syndrome): Diagnosis of infantile spasms (West Syndrome). Multiple Sclerosis (MS): Acute exacerbations of MS. Rheumatic disorders: As adjunctive therapy for short-term administration in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis. Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematous, systemic dermatomyositis (polymyositis). Dermatologic diseases: Severe erythema multiforme, Stevens-Johnson syndrome. Allergic states: Serum sickness. Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as: keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation. Respiratory diseases: Symptomatic sarcoidosis. Edematous state: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. All indications except for infantile spasms: Trial and failure, contraindication, or intolerance to treatment with two corticosteroids.

AGE RESTRICTIONS: Infantile spasms: less than 2 years old

MD RESTRICTIONS: Infantile Spasm, MS: neurologist. Rheumatic disorder, collagen disease: rheumatologist. Dermatologic: dermatologist. Allergic state: allergist, immunologist. Ophthalmic disease: optometrist, ophthalmologist. Respiratory diseases: pulmonologist. Edematous

COVERAGE DURATION: Infantile Spasms: 4 weeks. MS: 3 weeks. All other FDA-approved us

OTHER CRITERIA:

HARVONI

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Criteria will be applied consistent with current AASLD/IDSA guideline. ALL (including patients with genotype 5 or 6 infection AND decompensated cirrhosis): A) Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C (CHC) virus AND B) Patient is not receiving Harvoni in combination with another HCV direct acting antiviral agent [eg, Sovaldi (sofosbuvir), Olysio (simeprevir)]. For the following: 1) genotype 1, with cirrhosis, ribavirin ineligible, and with prior failure to HCV protease inhibitor triple therapy OR with prior failure to peginterferon plus ribavirin (except in 1) patients 12 to 17 years of age or 2) both of the following: a) patients weighing at least 35 kg and b) less than 18 years of age) OR 2) genotype 4, treatment-experienced, with cirrhosis, and ribavirin ineligible: trial and failure, intolerance or contraindication to Epclusa OR for continuation of prior Harvoni therapy.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine

COVERAGE DURATION: 12 to 24 wks. Criteria will be applied consistent with current AASLD/I

OTHER CRITERIA:

HETLIOZ

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Non-24-Hour Sleep-Wake Disorder (Non-24) (initial): Both of the following: 1) Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome), AND 2) patient is totally blind (has no light perception).

AGE RESTRICTIONS:

MD RESTRICTIONS: Non-24 (initial): Prescribed by or in consultation with a specialist in sleep disorders or neurologist

COVERAGE DURATION: Non-24 (initial): 6 mo. (reauth): 12 mo

OTHER CRITERIA: Non-24 (reauth): Documentation of positive clinical response to Hetlioz therapy.

HUMATROPE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTIONS:

MD RESTRICTIONS: PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrazole,letrazole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

HUMATROPE COMBO PACK

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTIONS:

MD RESTRICTIONS: PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrazole,letrazole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

HUMIRA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to two NSAIDs. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. TF/C/I to one of the following conventional therapies:Â¿ 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall), or failure (ie, lost response) or intolerance to infliximab. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. All indications (initial, reauth): Patient is not receiving Humira in combination with a biologic DMARD [eg, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]. Patient is not receiving Humira in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA, AS, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (Initial): Prescribed by or in consultation with a dermatologist. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.

HUMIRA

COVERAGE DURATION: UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial, r

OTHER CRITERIA: RA, JIA, PsA, Plaque psoriasis, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to Humira therapy. UC (Reauth): For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy.

HUMIRA PEDIATRIC CROHNS D

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to two NSAIDs. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. TF/C/I to one of the following conventional therapies:Â¿ 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall), or failure (ie, lost response) or intolerance to infliximab. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. All indications (initial, reauth): Patient is not receiving Humira in combination with a biologic DMARD [eg, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]. Patient is not receiving Humira in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA, AS, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (Initial): Prescribed by or in consultation with a dermatologist. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.

HUMIRA PEDIATRIC CROHNS D

COVERAGE DURATION: UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial, r

OTHER CRITERIA: RA, JIA, PsA, Plaque psoriasis, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to Humira therapy. UC (Reauth): For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy.

HUMIRA PEN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to two NSAIDs. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. TF/C/I to one of the following conventional therapies:Â¿ 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall), or failure (ie, lost response) or intolerance to infliximab. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. All indications (initial, reauth): Patient is not receiving Humira in combination with a biologic DMARD [eg, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]. Patient is not receiving Humira in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA, AS, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (Initial): Prescribed by or in consultation with a dermatologist. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.

HUMIRA PEN

COVERAGE DURATION: UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial, r

OTHER CRITERIA: RA, JIA, PsA, Plaque psoriasis, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to Humira therapy. UC (Reauth): For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy.

HUMIRA PEN-CROHNS DISEASE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to two NSAIDs. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. TF/C/I to one of the following conventional therapies:Â¿ 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall), or failure (ie, lost response) or intolerance to infliximab. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. All indications (initial, reauth): Patient is not receiving Humira in combination with a biologic DMARD [eg, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]. Patient is not receiving Humira in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA, AS, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (Initial): Prescribed by or in consultation with a dermatologist. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.

HUMIRA PEN-CROHNS DISEASE

COVERAGE DURATION: UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial, r

OTHER CRITERIA: RA, JIA, PsA, Plaque psoriasis, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to Humira therapy. UC (Reauth): For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy.

HUMIRA PEN-PSORIASIS STAR

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to two NSAIDs. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. TF/C/I to one of the following conventional therapies:Â¿ 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall), or failure (ie, lost response) or intolerance to infliximab. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. All indications (initial, reauth): Patient is not receiving Humira in combination with a biologic DMARD [eg, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]. Patient is not receiving Humira in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA, AS, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (Initial): Prescribed by or in consultation with a dermatologist. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.

HUMIRA PEN-PSORIASIS STAR

COVERAGE DURATION: UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial, r

OTHER CRITERIA: RA, JIA, PsA, Plaque psoriasis, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to Humira therapy. UC (Reauth): For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy.

HYDROXYPROGESTERONE CAPRO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All uses (initial): Pregnant patients.

REQUIRED INFO: Amenorrhea: Diagnosis of primary or secondary amenorrhea. Amenorrhea is due to hormonal imbalance in the absence of organic pathology (e.g., submucous fibroids or uterine cancer) Secretory endometrium and desquamation: Used for production of secretory endometrium and desquamation in patients with endometrial disorder. Adenocarcinoma: Diagnosis of Stage III or IV adenocarcinoma of the uterine corpus. Estrogen production test: Used for the testing of endogenous estrogen production.

AGE RESTRICTIONS:

MD RESTRICTIONS: Adenocarcinoma (initial): Prescribed by or in consultation with an oncologist

COVERAGE DURATION: 12 months

OTHER CRITERIA: Approve for continuation of prior therapy.

ILARIS

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Periodic Fever Syndromes (Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF)). (Initial) Diagnosis of one of the autoinflammatory Periodic Fever Syndromes: CAPS (including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS)), TRAPS, HIDS/MKD, or FMF, AND The medication will not be used in combination with another biologic agent. Systemic juvenile idiopathic arthritis (sJIA) (Initial): Diagnosis of active sJIA AND The medication will not be used in combination with another biologic

AGE RESTRICTIONS: SJIA (initial): 2 years of age or older

MD RESTRICTIONS: Periodic Fever Syndromes (CAPS, TRAPS, HIDS/MKD, FMF) (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: Periodic Fever Syndrome (CAPS, TRAPS, HIDS/MKD, FMF) ((Reauth) and SJIA (Reauth): Documentation of positive clinical response to therapy.

INFLECTRA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Dx of moderately to severely active CD or FCD. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. Rheumatoid arthritis (RA) (initial): Diagnosis (Dx) of moderately to severely active RA. Ankylosing spondylitis (AS) (initial): Dx of active AS. Psoriatic arthritis (PsA) (initial): Dx of active PsA. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. CD, FCD (initial): Trial and failure, contraindication or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). UC (initial): TF/C/I to one of the following conventional therapies: corticosteroids, aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine/Sulfazine)], azathioprine (Imuran), 6-mercaptopurine (Purinethol). RA (initial): Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), or TF/C/I to methotrexate. AS (initial): TF/C/I to two or more NSAIDs. All indications (initial): One of the following: 1) Trial and failure or intolerance to Remicade or 2) For continuation of prior Inflectra therapy. All indications (Initial): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA, AS: Prescribed or recommended by a rheumatologist. PsA: Prescribed or recommended by rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed or recommended by a gastroenterologist. Plaque Psoriasis: Prescribed or

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy. All indications (re-auth): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept),

Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

ITRACONAZOLE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: 1) patient has a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), OR 2) patient is resistant to topical antifungal treatment and has one of the following diagnoses: a) tinea corporis (ringworm), OR b) tinea cruris (jock itch), OR c) tinea pedis (athleteÂ¿s foot), OR d) tinea capitis (scalp ringworm), OR e) pityriasis versicolor, OR 3) all of the following: a) patient has a diagnosis of onychomycosis confirmed by one of the following (CAPSULE ONLY): i) positive potassium hydroxide (KOH) preparation, OR ii) culture, OR iii) histology, AND b) patient has had a trial and inadequate response, intolerance or hypersensitivity to oral terbinafine, OR 4) patient has a diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole (ORAL SOLUTION ONLY).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: systemic fungal infxn:6mo.(candidiasis,fingernail onycho.):1 mo.(toe

OTHER CRITERIA:

JADENU

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of MDS. Patient has Low or Intermediate-1 disease or is a potential transplant patient. Patient has received more than 20 red blood cell transfusions. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than 300 mcg/L.

AGE RESTRICTIONS: Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 m

OTHER CRITERIA: Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin level or LIC.

JADENU SPRINKLE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of MDS. Patient has Low or Intermediate-1 disease or is a potential transplant patient. Patient has received more than 20 red blood cell transfusions. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than 300 mcg/L.

AGE RESTRICTIONS: Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 m

OTHER CRITERIA: Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin level or LIC.

JUXTAPID

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Homozygous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient has been receiving at least 12 consecutive weeks of ONE LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. Trial and failure after 12 consecutive weeks or intolerance to Repatha therapy. One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: LDL-C greater than or equal to 100 mg/dL with ASCVD OR LDL-C greater than or equal to 130 mg/dL without ASCVD. Not used in combination with Kynamro (mipomersen). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient is not pregnant. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests. Patient is not concomitantly on moderate or strong CYP 3A4 inhibitors (eg, clarithromycin).

AGE RESTRICTIONS:

MD RESTRICTIONS: HoFH (initial, reauth): Prescribed by a cardiologist, endocrinologist, or lipid specialist.

COVERAGE DURATION: HoFH (initial): 6 months. (reauth): 12 months

OTHER CRITERIA: HoFH (reauthorization): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior Juxtapid therapy) while on Juxtapid therapy. Not used in combination with Kynamro (mipomersen). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient is not pregnant. Patient does not have moderate or severe hepatic

impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests. Patient is not concomitantly on moderate or strong CYP 3A4 inhibitors (eg, clarithromycin).

KALYDECO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Cystic Fibrosis (CF) (Initial): Diagnosis of cystic fibrosis. Patient has one of the following mutations on at least one allele in the cystic fibrosis transmembrane conductance regulator gene: A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, F1052V, F1074L, G178R, G551D, G551S, G1069R, G1244E, G1349D, K1060T, L206W, P67L, R74W, R117C, R117H, R347H, R352Q, R1070Q, R1070W, S549N, S549R, S945L, S977F, S1251N, or S1255P. The presence of a mutation was documented by an FDA-cleared cystic fibrosis mutation test and followed by verification with bi-directional sequencing when recommended by the mutation test instructions.

AGE RESTRICTIONS: CF (Initial): 2 years of age or older

MD RESTRICTIONS: CF (Initial): Prescribed by or in consultation with a pulmonologist

COVERAGE DURATION: CF (initial, reauth): 12 months

OTHER CRITERIA: CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).

KANUMA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Lysosomal acid lipase deficiency: Diagnosis of lysosomal acid lipase deficiency (LAL-D). Diagnosis was confirmed by an enzymatic blood (e.g., dried blood spot test) or genetic test.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, gastroenterologist, or lipidologist

COVERAGE DURATION: 12 months

OTHER CRITERIA:

KEVEYIS

COVERED USES:	All medically accepted indications not otherwise excluded from Part D.
EXCLUSION CRITERIA:	All Uses (Initial and Reauth): Hepatic insufficiency (e.g., Child-Pugh class A). Severe pulmonary disease [e.g., severe chronic obstructive pulmonary disease]. Concomitant use with high dose aspirin (i.e., greater than 100 mg per day).
REQUIRED INFO:	Periodic paralysis (Initial): Diagnosis of one of the following: Primary hyperkalemic periodic paralysis, Primary hypokalemic periodic paralysis, or Paramyotonia Congenita with periodic paralysis
AGE RESTRICTIONS:	
MD RESTRICTIONS:	All uses (Initial): Prescribed by or in consultation with a neurologist
COVERAGE DURATION:	All uses (Initial): 3 months. (Reauth): 12 months
OTHER CRITERIA:	All uses (Reauth): Documentation of positive clinical response to Keveyis therapy.

KINERET

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Kineret therapy. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID AND dx of NOMID has been confirmed by one of the following: NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation OR evidence of active inflammation including both of the following: clinical symptoms (eg, rash, fever, arthralgia) and elevated acute phase reactants (eg, ESR, CRP). All Uses (initial, reauth): Patient is not receiving Kineret in combination with a biologic disease modifying antirheumatic drug (DMARD) [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving Kineret in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA (initial): Prescribed by or in consultation with a rheumatologist. NOMID (initial): Prescribed by or in consultation with allergist/immunologist or rheumatologist or pediatrician.

COVERAGE DURATION: All Uses (initial, reauth): 12 months

OTHER CRITERIA: All Uses (Reauth): Documentation of positive clinical response to Kineret therapy.

KORLYM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Cushing's syndrome (Initial): Diagnosis of endogenous CushingÂ¿s syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Diagnosis of either type 2 diabetes mellitus or diagnosis of glucose intolerance. Patient has either failed surgery or patient is not a candidate for surgery. Patient is not pregnant.

AGE RESTRICTIONS:

MD RESTRICTIONS: Initial: Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION: Initial, reauth: 6 months

OTHER CRITERIA: Reauthorization: Documentation of one of the following: patient has improved glucose tolerance while on Korlym therapy or patient has stable glucose tolerance while on Korlym therapy.

KUVAN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient is a new start to Kuvan (sapropterin dihydrochloride). Patient will have blood Phe levels measured after 1 week of therapy and periodically for up to 2 months of therapy to determine response.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: PKU (Init): 2 months (Reauth): 12 months

OTHER CRITERIA: PKU (reauth): Patient is currently on therapy with Kuvan (sapropterin dihydrochloride). Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline. Patient will continue to have blood Phe levels measured periodically during therapy.

KYNAMRO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Homozygous familial hypercholesterolemia (HoFH) (initial):Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH) , or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient has been receiving at least 12 consecutive weeks of ONE LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. Trial and failure after 12 consecutive weeks or intolerance to Repatha therapy. One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: LDL-C greater than or equal to 100 mg/dL with ASCVD OR LDL-C greater than or equal to 130 mg/dL without ASCVD. Not used in combination with Juxtapid (lomitapide). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests.

AGE RESTRICTIONS:

MD RESTRICTIONS: HoFH (initial, reauth): Prescribed by a cardiologist, endocrinologist, or lipid specialist.

COVERAGE DURATION: HoFH (initial): 6 months. (reauth): 12 months

OTHER CRITERIA: HoFH (reauthorization): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior Juxtapid therapy) while on Kynamro therapy. Not used in combination with Juxtapid (lomitapide). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests.

LETAIRIS

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTIONS:

MD RESTRICTIONS: PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION: PAH (Initial): 6 months. PAH (Reauth): 12 months

OTHER CRITERIA: PAH (Reauth): Documentation of positive clinical response to therapy.

LEUKINE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Bone marrow/stem cell transplant (BMSCT): One of the following: 1) patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, OR 2) for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, OR 3) for peripheral stem cell transplant (PSCT) patients who have received myeloablative chemotherapy. Acute myeloid leukemia (AML): patients with AML following induction or consolidation chemotherapy, AND age greater than or equal to 55 years. Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) patient receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with a history of FN during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) Patient is receiving National Cancer InstituteÂ¿s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with FN at high risk for infection-associated complications.

AGE RESTRICTIONS:

MD RESTRICTIONS: (Initial): Prescribed by hematologist/oncologist except HIVN: Prescribed by hematologist/oncologist or infectious disease specialist

COVERAGE DURATION: BMSCT, AML, CFN, FN (prophylaxis), NDDC:3mo or duration of tx.

OTHER CRITERIA: HIV-related neutropenia (HIVN)(off-label): Patients infected with HIV, and ANC less than or equal to 1000 (cells/mm^3).

LIDOCAINE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO:

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 Months

OTHER CRITERIA:

LUMIZYME

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Pompe disease: Diagnosis of Pompe disease [acid alpha-glucosidase (GAA) deficiency].

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

LUPANETA PACK

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Endometriosis (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID or one oral contraceptive. Trial and failure, contraindication, or intolerance to Lupron Depot (7.5 mg, 22.5 mg, 30 mg, and 45 mg).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Endomet (init, reauth): 6 months

OTHER CRITERIA: Endometriosis (reauthorization): Patient is experiencing recurrence of symptoms after an initial course of therapy.

LUPRON DEPOT-PED (1-MONTH

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range.

AGE RESTRICTIONS:

MD RESTRICTIONS: CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.

COVERAGE DURATION: CPP (init, reauth): 12 months

OTHER CRITERIA: CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.

MAKENA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Preterm birth prophylaxis: Patient had a previous singleton (single offspring) spontaneous preterm birth. Patient is having a singleton pregnancy. Therapy will be started between 16 weeks, 0 days and 20 weeks, 6 days of gestation. Therapy will be continued until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.

AGE RESTRICTIONS:

MD RESTRICTIONS: Preterm birth prophylaxis: Prescribed by a specialist in obstetrics and gynecology

COVERAGE DURATION: Preterm birth prophylaxis: 21 weeks

OTHER CRITERIA:

MENEST

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.

AGE RESTRICTIONS: PA applies to patients 65 years or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA: Approve for continuation of therapy.

METADATE ER

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

METHITEST

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC,

OTHER CRITERIA: HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

METHYLPHENIDATE HCL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

METHYLPHENIDATE HCL CD

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

METHYLPHENIDATE HCL ER

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

METHYLPHENIDATE HCL ER (L

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

METHYLPHENIDATE HYDROCHLO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

METHYLTESTOSTERONE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC,

OTHER CRITERIA: HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

MIGLUSTAT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease. Patient is unable to receive enzyme replacement therapy due to one of the following conditions: allergy or hypersensitivity to enzyme replacement therapy, poor venous access, unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Gaucher disease: 12 months

OTHER CRITERIA:

MIRVASO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rosacea (init): Diagnosis of rosacea. Patient has moderate to severe persistent (nontransient) facial erythema.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Rosacea (init, reauth): 12 months

OTHER CRITERIA: Rosacea (reauth) Documentation of positive clinical response to Mirvaso therapy.

MODAFINIL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Obstructive sleep apnea/hypopnea syndrome (OSAHS) (Initial): Diagnosis (dx) of OSAHS defined by one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work sleep disorder (SWSD) (Initial):Dx of SWSD confirmed by symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, or sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). No other medical condition or medication accounts for the symptoms. Narcolepsy (initial): Dx of narcolepsy as confirmed by sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). MS Fatigue (initial): Dx of multiple sclerosis (MS). Patient is experiencing fatigue. Depression (initial): Treatment-resistant depression defined as diagnosis of major depressive disorder (MDD) or bipolar depression, AND trial and failure, contraindication, or intolerance to at least two antidepressants from different classes (eg, SSRIs, SNRIs, bupropion). Used as adjunctive therapy.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: OSAHS/MS/dep(init), SWSD (init,reauth): 3 mo.OSAHS/dep(reauth):

OTHER CRITERIA: OSAHS (Reauth): Documentation of positive clinical response to prior therapy. SWSD (Reauth): Documentation of positive clinical response to prior therapy. Patient still requires treatment for SWSD. Narcolepsy (reauth): Documentation of positive clinical response to prior therapy. MS Fatigue (reauth): Patient is experiencing relief of fatigue with modafinil therapy. Idiopathic Hypersomnia (reauth): Documentation of positive clinical response to modafinil therapy. Depression (reauth): Documentation of positive clinical response to

modafinil therapy. Used as adjunctive therapy.

MOZOBIL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hematopoietic Stem Cell (HSC) Mobilization: Patient with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM) who will be undergoing autologous HSC transplantation. Used in combination with granulocyte-colony stimulating factor (G-CSF).

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with a hematologist/oncologist

COVERAGE DURATION: One course of therapy up to 4 days

OTHER CRITERIA:

MYALEPT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Lipodystrophy (initial): Diagnosis of congenital or acquired generalized lipodystrophy AND Patient is refractory to current standards of care for lipid and diabetic management AND One or more of the following metabolic abnormalities are present: A) Insulin resistance (defined as requiring more than 200 units per day), B) Hypertriglyceridemia, or C) Diabetes

AGE RESTRICTIONS:

MD RESTRICTIONS: Initial: Prescribed by or in consultation with an endocrinologist

COVERAGE DURATION: Initial and reauth: 12 months

OTHER CRITERIA: Lipodystrophy (reauth): Patient has experienced an objective response to therapy, such as A) Sustained reduction in hemoglobin A1c (HbA1c) level from baseline OR B) Sustained reduction in triglyceride (TG) levels from baseline

MYORISAN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Acne (initial): Diagnosis of acne. Trial and failure, contraindication or intolerance to an adequate trial (at least 6 weeks) on both of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin)] AND b) combination therapy with benzoyl peroxide and one of the following: 1) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)] OR 2) topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)].

AGE RESTRICTIONS:

MD RESTRICTIONS: Acne (Initial): Prescribed by a dermatologist

COVERAGE DURATION: Acne (initial, reauth): 5 months

OTHER CRITERIA: Acne (reauth): One of the following: A) After more than 2 months off therapy, persistent or recurring severe recalcitrant nodular acne is still present, OR B) the total cumulative dose is less than 150 mg/kg (will be approved up to a total of 150 mg/kg).

NAGLAZYME

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Mucopolysaccharidosis (MPS VI): Diagnosis of MPS VI (Maroteaux-Lamy Syndrome)

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: MPS VI: 12 months

OTHER CRITERIA:

NATPARA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypocalcemia (Initial): Diagnosis of hypocalcemia due to chronic hypoparathyroidism. NATPARA is not being used in the setting of acute post-surgical hypoparathyroidism. Patient does not have a known calcium-sensing receptor mutation. Patient has a documented parathyroid hormone concentration that is inappropriately low for the level of calcium, recorded on at least two occasions within the previous 12 months. Patient has been optimized on adequate doses of oral calcium (more than 2,000 mg daily) and vitamin D (calcitriol at least 1 microgram/day) supplementation. Patient has normal thyroid-stimulating hormone concentrations if not on thyroid hormone replacement therapy (or if on therapy, the dose had to have been stable for greater than or equal to 3 months). Patient has normal magnesium and serum 25-hydroxyvitamin D concentrations. Creatinine clearance is at least 30 mL/min on two separate measurements, or greater than 60 mL/min (one measurement) with an accompanying serum creatinine concentration of less than 1.5 mg/dL. NATPARA will be used as an adjunct to calcium and vitamin D.

AGE RESTRICTIONS:

MD RESTRICTIONS: Hypocalcemia (Initial): Prescribed by or in consultation with an endocrinologist.

COVERAGE DURATION: Initial: 4 months. Reauth: 12 months

OTHER CRITERIA:

NEULASTA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) patient receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with a history of FN during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) patient is receiving National Cancer InstituteÂ¿s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with FN at high risk for infection-associated complications. Acute radiation syndrome (ARS): Patient was acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).

AGE RESTRICTIONS:

MD RESTRICTIONS: All uses (initial): Prescribed by a hematologist/oncologist

COVERAGE DURATION: FN (treatment), ARS: 1 mo. CFN, NDDC, FN (prophylaxis): 3 mo or

OTHER CRITERIA:

NEUPOGEN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Bone marrow/stem cell transplant (BMSCT): One of the following: 1) pts with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, OR 2) for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, OR 3) for peripheral stem cell transplant (PSCT) pts who have received myeloablative chemotherapy. Acute myeloid leukemia (AML): patients with AML following induction or consolidation chemotherapy. Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) Pt is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) Pt receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) Pts receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) Pts with a history of FN during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) Pt is receiving National Cancer InstituteÂ¿s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) Pt is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Severe chronic neutropenia (SCN): Pts with SCN (ie, congenital, cyclic, and idiopathic neutropenias with chronic ANC less than or equal to 500 cells/mm^3). Treatment of FN (off-label): Both of the following: 1) Pts receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) Pts with FN at high risk for infection-associated complications. Acute radiation syndrome (ARS): Pt is/was acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrom

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by hematologist/oncologist except HIVN: Prescribed by hematologist/oncologist or infectious disease specialist

COVERAGE DURATION: BMSCT,AML,CFN,secondary ppx of FN,NDDC:3mo or tx duration. S

OTHER CRITERIA: HIV-related neutropenia (HIVN)(off-label): Patients infected with

HIV, and ANC less than or equal to 1000 (cells/mm^3). Hepatitis C treatment-related neutropenia (HCN)(off-label): One of the following: 1) patients infected with Hepatitis C virus undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a) who experience neutropenia (ANC less than or equal to 500 cells/mm3) after dose reduction of Peg-Intron or Pegasys, OR 2) patients who experience interferon-induced neutropenia (ANC less than or equal to 500 cells/mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a), AND one of the following: a) patient with HIV co-infection, OR b) status post liver transplant, OR c) patient with established cirrhosis. All indications: History of failure or intolerance to Zarxio (filgrastim-sndz).

NORDITROPIN FLEXPRO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTIONS:

MD RESTRICTIONS: PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrazole,letrazole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

NORTHERA

COVERED USES:	All medically accepted indications not otherwise excluded from Part D.
EXCLUSION CRITERIA:	
REQUIRED INFO:	Neurogenic orthostatic hypotension (NOH) (init): Diagnosis of symptomatic NOH. NOH is caused by one of the following conditions: primary autonomic failure (eg, Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, non-diabetic autonomic neuropathy. Trial and failure, contraindication, or intolerance to one of the following agents: fludrocortisone acetate, midodrine.
AGE RESTRICTIONS:	
MD RESTRICTIONS:	NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist
COVERAGE DURATION:	NOH (init): 1 month (reauth): 12 months
OTHER CRITERIA:	NOH (reauth): Documentation of positive clinical response to therapy

NOVAREL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Prepubertal Cryptorchidism: Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction. Male Hypogonadotropic Hypogonadism (MHH) (initial): Diagnosis of male hypogonadism secondary to pituitary deficiency, and low testosterone (below normal reference value provided by the physician's laboratory) and one of the following: a) low LH (below normal reference value provided by the physician's laboratory) or b) low FSH (below normal reference value provided by the physician's laboratory).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Prepubertal Cryptorchidism: 6 wks. MHH (initial, reauth): 12 months.

OTHER CRITERIA: Excluded if used to promote fertility. MHH (Reauth): Documentation of positive clinical response to therapy.

NUTROPIN AQ NUSPIN 10

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTIONS:

MD RESTRICTIONS: PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrazole,letrazole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

NUTROPIN AQ NUSPIN 20

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTIONS:

MD RESTRICTIONS: PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrazole,letrazole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

NUTROPIN AQ NUSPIN 5

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTIONS:

MD RESTRICTIONS: PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrazole,letrazole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

OCALIVA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Primary Biliary Cholangitis (PBC) (initial): Diagnosis of PBC (aka primary biliary cirrhosis). One of the following: a) patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after at least 12 consecutive months of treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) AND used in combination with UDCA, OR b) contraindication or intolerance to UDCA.

AGE RESTRICTIONS:

MD RESTRICTIONS: PBC (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist.

COVERAGE DURATION: PBC (initial): 6 months, (reauth): 12 months

OTHER CRITERIA: PBC (reauthorization): Submission of medical records (eg, laboratory values) documenting a reduction in ALP level from pre-treatment baseline (ie, prior Ocaliva therapy) while on Ocaliva therapy.

OCTAGAM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. G

REQUIRED INFO: Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG Â¿ Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.

AGE RESTRICTIONS: HIV (initial): patient is less than or equal to 12 years of age.

MD RESTRICTIONS: All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

COVERAGE DURATION: 4 months: Solid organ transplant. 12 months: all other diagnoses.

OTHER CRITERIA: [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-BarrÂ¿ syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

OCTREOTIDE ACETATE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) History of failure to surgical resection and/or pituitary irradiation OR B) patient is not a candidate for surgical resection or pituitary irradiation AND Trial and failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea and flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: All Uses (Initial and reauth): 12 months

OTHER CRITERIA: Acromegaly (reauth): Patient has had a clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): patient has improvement in number of diarrhea and flushing episodes. Vasoactive intestinal peptide tumor (reauth): patient has improvement in number of diarrhea episodes.

OFEV

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Idiopathic pulmonary fibrosis (IPF) (initial): Both of the following: 1) diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF, AND 2) not used in combination with Esbriet (pirfenidone).

AGE RESTRICTIONS:

MD RESTRICTIONS: IPF (initial): Prescribed by a pulmonologist

COVERAGE DURATION: Initial, reauth: 12 months

OTHER CRITERIA: IPF (reauth): Documentation of positive clinical response to Ofev therapy.

OMNITROPE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTIONS:

MD RESTRICTIONS: PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrazole,letrazole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

OPSUMIT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTIONS:

MD RESTRICTIONS: PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION: PAH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA: PAH (Reauth): Documentation of positive clinical response to therapy.

ORENCIA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. All indications (Initial): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Orencia therapy. Patient is not receiving Orencia in combination with a biologic disease modifying antirheumatic drug (DMARD) [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist.

COVERAGE DURATION: All indications (Initial, reauth): 12 months

OTHER CRITERIA: All indications (Reauth): Documentation of positive clinical response to Orencia therapy. Patient is not receiving Orencia in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

ORENCIA CLICKJECT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. All indications (Initial): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Orencia therapy. Patient is not receiving Orencia in combination with a biologic disease modifying antirheumatic drug (DMARD) [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist.

COVERAGE DURATION: All indications (Initial, reauth): 12 months

OTHER CRITERIA: All indications (Reauth): Documentation of positive clinical response to Orencia therapy. Patient is not receiving Orencia in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

ORENITRAM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTIONS:

MD RESTRICTIONS: PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION: PAH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA: PAH (Reauth): Documentation of positive clinical response to therapy.

ORKAMBI

COVERED USES:	All medically accepted indications not otherwise excluded from Part D.
EXCLUSION CRITERIA:	
REQUIRED INFO:	Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene. The presence of the mutation was documented by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments-approved facility.
AGE RESTRICTIONS:	CF (Initial): Patient is 6 years of age or older
MD RESTRICTIONS:	CF (Initial): Prescribed by or in consultation with a pulmonologist
COVERAGE DURATION:	CF (initial, reauth): 12 months
OTHER CRITERIA:	CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations)

OTEZLA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Psoriatic arthritis (PsA, initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. PsA, plaque psoriasis (initial): Trial and failure, contraindication, or intolerance to both Humira and Enbrel, OR for continuation of prior Otezla therapy.

AGE RESTRICTIONS:

MD RESTRICTIONS: PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION: Initial, Reauth: 12 months

OTHER CRITERIA: Reauthorization (all indications): Documentation of positive clinical response to Otezla therapy.

OXANDROLONE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Promote weight gain (initial): Medication will be used as an adjunct therapy to promote weight gain AND One of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons. Counterbalance protein catabolism (initial): Oxandrin will be used to counterbalance protein catabolism associated with chronic corticosteroid administration. Bone pain (initial): Diagnosis of bone pain associated with osteoporosis.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: bone pain (initial, reauth): 1 month. Others (initial, reauth): 3 months

OTHER CRITERIA: All diagnoses (reauth): patient has experienced an objective improvement (i.e. weight gain, increase in lead body mass, or reduction in muscle pain/weakness)

PEGASYS

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks.

OTHER CRITERIA:

PEGASYS PROCLICK

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks.

OTHER CRITERIA:

PLEGRIDY

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

PLEGRIDY STARTER PACK

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

PRALUENT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Initial: Submission of medical records (eg, chart notes, laboratory values) documenting one of the following diagnoses: Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Documented assessment of patient using Dutch Lipid Clinic Network diagnostic criteria with a cumulative score greater than or equal to 9 points (ie, definite FH), (2) Presence of tendinous xanthomas in patient, first degree relative, or second degree relative, AND Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult, (3) Genetic confirmation of a mutation in the LDL receptor, ApoB, or PCSK9. OR Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin. One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: (1) LDL-C greater than or equal to 100 mg/dL with ASCVD. (2) LDL-C greater than or equal to 130 mg/dL without ASCVD.

AGE RESTRICTIONS:

MD RESTRICTIONS: Initial, reauth: Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist

COVERAGE DURATION: Initial: 6 months. Reauth: 12 months

OTHER CRITERIA: HeFH/ASCVD: Initial: One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one high-intensity statin therapy and will continue to receive a HIGH-INTENSITY statin [ie, atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg] at maximally tolerated dose, OR (2) Both of the following: A) Patient is unable to tolerate high-intensity statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), AND B) One of the following: a) Patient has been receiving at least 12 consecutive weeks of one moderate-intensity or low-intensity statin therapy and will continue to receive a MODERATE-INTENSITY or LOW-INTENSITY statin [ie, atorvastatin 10-20 mg, Crestor (rosuvastatin) 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80

mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at maximally tolerated dose, OR b) Patient is unable to tolerate moderate-intensity or low-intensity statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), OR (3) Submission of medical records documenting patient has a labeled contraindication to all statins, OR (4) Patient has experienced rhabdomyolysis on one statin therapy. Reauth: Patient continues to receive statin at the maximally tolerated dose (unless patient has documented inability to take statins). Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior to Praluent therapy) while on Praluent therapy. Initial, reauth: Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.

PREGNYL W/DILUENT BENZYL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Prepubertal Cryptorchidism: Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction. Male Hypogonadotropic Hypogonadism (MHH) (initial): Diagnosis of male hypogonadism secondary to pituitary deficiency, and low testosterone (below normal reference value provided by the physician's laboratory) and one of the following: a) low LH (below normal reference value provided by the physician's laboratory) or b) low FSH (below normal reference value provided by the physician's laboratory).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Prepubertal Cryptorchidism: 6 wks. MHH (initial, reauth): 12 months.

OTHER CRITERIA: Excluded if used to promote fertility. MHH (Reauth): Documentation of positive clinical response to therapy.

PRIVIGEN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. G

REQUIRED INFO: Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG Â¿ Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.

AGE RESTRICTIONS: HIV (initial): patient is less than or equal to 12 years of age.

MD RESTRICTIONS: All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

COVERAGE DURATION: 4 months: Solid organ transplant. 12 months: all other diagnoses.

OTHER CRITERIA: [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-BarrÂ¿ syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patientÂ¿s age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

PROCRIT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia with chemo (Initial):Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 mos, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon or peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo.

OTHER CRITERIA: Subject to ESRD review. CKD (Reauth): Dx of CKD. Most recent or average (avg) Hct over 3 months is 33% or less OR most recent or avg Hgb over 3 months is 11 g/dL or less. Decrease in the need for

blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Off-label uses (except MDS): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.

PROCYSBI

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Nephropathic cystinosis: Diagnosis of nephropathic cystinosis, confirmed by elevated leukocyte cystine levels (LCL) or genetic analysis of the CTNS gene AND Trial and failure or intolerance to therapy with Cystagon (immediate-release cysteamine bitartrate).

AGE RESTRICTIONS: 2 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

PROLASTIN-C

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency: All of the following: A) Patient has an alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency AND B) Diagnosis of emphysema AND C) One of the following: 1) Patient has a high risk phenotype: PiZZ, PiZ(null), or Pi(null)(null) OR 2) Patient has serum alpha-1 antitrypsin concentrations of less than 11 Â¿M/L (80 mg/dL) AND D) One of the following: FEV1 level is between 30% and 65% of predicted OR the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

PROLIA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Postmenopausal osteoporosis (PMO) (initial): Diagnosis (dx) of PMO. History (hx) of vertebral compression fractures (fx), or fx of the hip, or distal radius resulting from minimal trauma, or bone mineral density score (BMD) indicative of osteoporosis (OP): T-score less than or equal to -2.5 (2.5 standard deviations [SD] or greater below the mean for young adults). PMO, prophylaxis (initial): For prevention of PMO. BMD scan indicative of osteopenia: T-score -1.0 to -2.5. Nonmetastatic prostate cancer (NMPC) bone loss (initial): Dx of NMPC. Pt is 70 years or older, or less than 70 years old with BMD T-score below -1.0 (1.0 SD or greater below the mean for young adults) or hx of vertebral compression fx or fx of the hip or distal radius resulting from minimal trauma. NMPC (reauth): No evidence of metastases. Breast cancer (BC) bone loss (initial): Dx of BC. BMD T-score below -1.0 (1.0 SD or greater below the mean for young adults) or hx of vertebral compression fx or fx of the hip or distal radius resulting from minimal trauma. OP in men (initial): Pt is a male with OP. Hx of vertebral compression fx or fx of the hip or distal radius resulting from minimal trauma, or BMD indicative of OP: T-score less than or equal to -2.0 (2.0 SD or greater below the mean for young adults).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: All uses (initial, reauth): 12 months

OTHER CRITERIA: NMPC bone loss (initial and reauth): Receiving androgen deprivation therapy (ADT) from luteinizing hormone/gonadotropin releasing hormone (LHRH/GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), Zoladex (goserelin)] or bilateral orchiectomy (i.e., surgical castration). BC bone loss (initial and reauth): Pt is receiving aromatase inhibitor (AI) therapy [e.g., Arimidex (anastrozole), Aromasin (exemestane), Femara (letrozole)]. All indications except NMPC (initial): One of the following A) Patient has a documented trial and therapeutic failure with a bisphosphonate, where therapeutic failure is defined as new fractures in compliant patients on therapy for at least 6 months, failure to produce a clinically significant change in a biochemical marker(s) of bone turnover, or significant loss of bone mineral density on follow-up scans after 12 to 24 months of therapy or B)

	Patient has a documented contraindication or intolerance to bisphosphonate therapy, or is unable to comply with appropriate administration recommendations for oral or injectable bisphosphonate therapy. All indications (renewal):The patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, or improved biochemical markers, etc.)

PROMACTA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Chronic immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of relapsed/refractory chronic ITP for greater than 6 months. Baseline platelet count is less than 50,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. One of the following: A) Trial and failure, intolerance, contraindication to corticosteroids or immune globulin OR B) Trial and failure or contraindication to splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C. Patient has thrombocytopenia defined as platelets less than 90,000/mcL for initiation (pre-treatment) of interferon therapy. Severe aplastic anemia (initial): Diagnosis of severe aplastic anemia. Patient has a platelet count less than 30,000/mcL. Trial and failure, intolerance, or contraindication to immunosuppressive therapy with antithymocyte globulin and cyclosporine.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: ITP (init, reauth): 12mo. HepC: 9wks (init), 24wks (reauth). Aplas an

OTHER CRITERIA: ITP (reauth): After at least 4 weeks of therapy at the maximum weekly dose (10 mcg/kg), the platelet count increased to a sufficient level to avoid clinically important bleeding. Hepatitis C (reauth): Platelets less than 75,000/mcL for maintenance of optimal interferon-based therapy. Aplastic anemia (reauth): Patient has experienced an increase in platelet count.

PULMOZYME

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Cystic Fibrosis (CF) (Initial, Reauth): Diagnosis of CF

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: CF (initial, reauth): 12 months

OTHER CRITERIA: Part B vs D determination applies. CF (reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).

QUININE SULFATE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Malaria: Diagnosis of uncomplicated malaria. One of the following: 1) Treatment in areas of chloroquine-sensitive malaria, and trial and failure, contraindication, or intolerance to chloroquine or hydroxychloroquine, OR 2) Treatment in areas of chloroquine-resistant malaria. Not used for the treatment or prevention of nocturnal leg cramps.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 7 days

OTHER CRITERIA:

RAVICTI

COVERED USES:	All medically accepted indications not otherwise excluded from Part D.
EXCLUSION CRITERIA:	
REQUIRED INFO:	Urea cycle disorders (UCDs) (Initial): Diagnosis of UCDs.
AGE RESTRICTIONS:	UCDs (Initial): Age greater than or equal to 2 months
MD RESTRICTIONS:	
COVERAGE DURATION:	UCDs (Initial, reauth): 12 months
OTHER CRITERIA:	UCDs (reauth): Documentation of positive clinical response to Ravicti therapy.

REBIF

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

REBIF REBIDOSE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

REBIF REBIDOSE TITRATION

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

REBIF TITRATION PACK

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

REGRANEX

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Diabetic neuropathic ulcers: Patient has a lower extremity diabetic neuropathic ulcer. Treatment will be given in combination with ulcer wound care (eg, debridement, infection control, and/or pressure relief)

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 5 months

OTHER CRITERIA:

RELISTOR

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Opioid-induced constipation (OIC) (non-cancer pain, initial): Diagnosis of OIC. Patient is an adult with a diagnosis of chronic non-cancer pain. Patient has used an opioid medication for a minimum of 4 weeks. Patient is experiencing fewer than 3 bowel movements in a week or no bowel movement for longer than 2 days. Trial and failure, contraindication, or intolerance to Amitiza (lubiprostone).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 6 months

OTHER CRITERIA: OIC (Reauth): Diagnosis of OIC. Patient is an adult with a diagnosis of chronic non-cancer pain. Documentation of a positive clinical response to Relistor therapy (e.g., increase in bowel movements).

REMICADE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (Initial): Diagnosis (Dx) of moderately to severely active CD or FCD. Failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall). Ulcerative colitis (UC) (Initial): Dx of moderately to severely active UC. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Rheumatoid arthritis (RA) (Initial): Dx of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), OR TF/C/I to methotrexate (Rheumatrex/Trexall). Ankylosing spondylitis (AS) (Initial): Dx of active AS. TF/C/I to two NSAIDs. Psoriatic arthritis (PsA) (Initial): Dx of active PsA. Plaque psoriasis (Initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. Sarcoidosis (initial): TF/C/I to one immunosuppressant [eg, methotrexate (Rheumatrex/Trexall), cyclophosphamide, or azathioprine (Imuran)] AND TF/C/I to one corticosteroid (eg, prednisone). All indications (Initial): Patient is not receiving Remicade in combination with a biologic DMARD [eg, Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept), Kineret (anakinra)]. Patient is not receiving Remicade in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: CD, FCD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. RA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with rheumatologist or dermatologist. Plaque Psori

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy. All indications (re-auth): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept),

Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

REMODULIN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTIONS:

MD RESTRICTIONS: PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION: PAH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA: Subject to Part B vs. D Review. PAH (Reauth): Documentation of positive clinical response to therapy.

RENFLEXIS

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (Initial): Diagnosis (Dx) of moderately to severely active CD or FCD. Failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall). Ulcerative colitis (UC) (Initial): Dx of moderately to severely active UC. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Rheumatoid arthritis (RA) (Initial): Dx of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), OR TF/C/I to methotrexate (Rheumatrex/Trexall). Ankylosing spondylitis (AS) (Initial): Dx of active AS. TF/C/I to two NSAIDs. Psoriatic arthritis (PsA) (Initial): Dx of active PsA. Plaque psoriasis (Initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. Sarcoidosis (initial): TF/C/I to one immunosuppressant [eg, methotrexate (Rheumatrex/Trexall), cyclophosphamide, or azathioprine (Imuran)] AND TF/C/I to one corticosteroid (eg, prednisone). All indications (Initial): Patient is not receiving Remicade in combination with a biologic DMARD [eg, Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept), Kineret (anakinra)]. Patient is not receiving Remicade in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: CD, FCD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. RA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with rheumatologist or dermatologist. Plaque Psori

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy. All indications (re-auth): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept),

Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)] or Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

REPATHA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: HeFH/ASCVD (initial): Submission of medical records (eg, chart notes, laboratory values) documenting one of the following diagnoses: Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Documented assessment of patient using Dutch Lipid Clinic Network diagnostic criteria with a cumulative score greater than or equal to 9 points (ie, definite FH), or (2) Presence of tendinous xanthomas in patient, first degree relative, or second degree relative, AND Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult, or (3) Genetic confirmation of a mutation in the LDL receptor, ApoB, or PCSK9. OR Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin. HoFH (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: (1) Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or (2) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL, AND either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia in both parents. HeFH/ASCVD/HoFH (initial): One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: (1) LDL-C greater than or equal to 100 mg/dL with ASCVD, or (2) LDL-C greater than or equal to 130 mg/dL without ASCVD.

AGE RESTRICTIONS:

MD RESTRICTIONS: HeFH/ASCVD/HoFH (init, reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist

COVERAGE DURATION: HeFH/ASCVD (init): 6 mon. HoFH (init): 3 mon. HeFH/ASCVD/HoFH

OTHER CRITERIA: One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one maximally-tolerated statin therapy and will continue to receive a statin at maximally tolerated dose, or (2) Patient is unable to tolerate statin as evidenced by intolerable and

persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), or (3) Submission of medical records documenting patient has a labeled contraindication to all statins, or (4) Patient has experienced rhabdomyolysis on one statin therapy. HoFH (initial): One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one maximally-tolerated statin therapy and will continue to receive a statin at maximally tolerated dose, or (2) both of the following: a) One of the following: 1. Patient is unable to tolerate statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), or 2. Submission of medical records documenting patient has a labeled contraindication to all statins, or 3. Patient has experienced rhabdomyolysis on one statin therapy, AND b) patient has been receiving at least 12 consecutive weeks of other LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. HeFH/ASCVD (reauth): Patient continues to receive statin at the maximally tolerated dose (unless patient has documented inability to take statins). HoFH (reauth): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). HeFH/ASCVD/HoFH (reauth): Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior to Repatha therapy) while on Repatha therapy. HeFH/ASCVD/HoFH (Initial, reauth): Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. HoFH (Initial, reauth): Not used in combination with Juxtapid (lomitapide) or Kynamro (mipomersen).

REPATHA PUSHTRONEX SYSTEM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: HeFH/ASCVD (initial): Submission of medical records (eg, chart notes, laboratory values) documenting one of the following diagnoses: Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Documented assessment of patient using Dutch Lipid Clinic Network diagnostic criteria with a cumulative score greater than or equal to 9 points (ie, definite FH), or (2) Presence of tendinous xanthomas in patient, first degree relative, or second degree relative, AND Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult, or (3) Genetic confirmation of a mutation in the LDL receptor, ApoB, or PCSK9. OR Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin. HoFH (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: (1) Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or (2) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL, AND either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia in both parents. HeFH/ASCVD/HoFH (initial): One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: (1) LDL-C greater than or equal to 100 mg/dL with ASCVD, or (2) LDL-C greater than or equal to 130 mg/dL without ASCVD.

AGE RESTRICTIONS:

MD RESTRICTIONS: HeFH/ASCVD/HoFH (init, reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist

COVERAGE DURATION: HeFH/ASCVD (init): 6 mon. HoFH (init): 3 mon. HeFH/ASCVD/HoFH

OTHER CRITERIA: One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one maximally-tolerated statin therapy and will continue to receive a statin at maximally tolerated dose, or (2) Patient is unable to tolerate statin as evidenced by intolerable and

persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), or (3) Submission of medical records documenting patient has a labeled contraindication to all statins, or (4) Patient has experienced rhabdomyolysis on one statin therapy. HoFH (initial): One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one maximally-tolerated statin therapy and will continue to receive a statin at maximally tolerated dose, or (2) both of the following: a) One of the following: 1. Patient is unable to tolerate statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), or 2. Submission of medical records documenting patient has a labeled contraindication to all statins, or 3. Patient has experienced rhabdomyolysis on one statin therapy, AND b) patient has been receiving at least 12 consecutive weeks of other LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. HeFH/ASCVD (reauth): Patient continues to receive statin at the maximally tolerated dose (unless patient has documented inability to take statins). HoFH (reauth): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). HeFH/ASCVD/HoFH (reauth): Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior to Repatha therapy) while on Repatha therapy. HeFH/ASCVD/HoFH (Initial, reauth): Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. HoFH (Initial, reauth): Not used in combination with Juxtapid (lomitapide) or Kynamro (mipomersen).

REPATHA SURECLICK

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: HeFH/ASCVD (initial): Submission of medical records (eg, chart notes, laboratory values) documenting one of the following diagnoses: Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Documented assessment of patient using Dutch Lipid Clinic Network diagnostic criteria with a cumulative score greater than or equal to 9 points (ie, definite FH), or (2) Presence of tendinous xanthomas in patient, first degree relative, or second degree relative, AND Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult, or (3) Genetic confirmation of a mutation in the LDL receptor, ApoB, or PCSK9. OR Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin. HoFH (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: (1) Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or (2) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL, AND either xanthoma before 10 years of age or evidence of heterozygous familial hypercholesterolemia in both parents. HeFH/ASCVD/HoFH (initial): One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: (1) LDL-C greater than or equal to 100 mg/dL with ASCVD, or (2) LDL-C greater than or equal to 130 mg/dL without ASCVD.

AGE RESTRICTIONS:

MD RESTRICTIONS: HeFH/ASCVD/HoFH (init, reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist

COVERAGE DURATION: HeFH/ASCVD (init): 6 mon. HoFH (init): 3 mon. HeFH/ASCVD/HoFH

OTHER CRITERIA: One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one maximally-tolerated statin therapy and will continue to receive a statin at maximally tolerated dose, or (2) Patient is unable to tolerate statin as evidenced by intolerable and

persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), or (3) Submission of medical records documenting patient has a labeled contraindication to all statins, or (4) Patient has experienced rhabdomyolysis on one statin therapy. HoFH (initial): One of the following: (1) Patient has been receiving at least 12 consecutive weeks of one maximally-tolerated statin therapy and will continue to receive a statin at maximally tolerated dose, or (2) both of the following: a) One of the following: 1. Patient is unable to tolerate statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), or 2. Submission of medical records documenting patient has a labeled contraindication to all statins, or 3. Patient has experienced rhabdomyolysis on one statin therapy, AND b) patient has been receiving at least 12 consecutive weeks of other LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. HeFH/ASCVD (reauth): Patient continues to receive statin at the maximally tolerated dose (unless patient has documented inability to take statins). HoFH (reauth): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). HeFH/ASCVD/HoFH (reauth): Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pre-treatment baseline (ie, prior to Repatha therapy) while on Repatha therapy. HeFH/ASCVD/HoFH (Initial, reauth): Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. HoFH (Initial, reauth): Not used in combination with Juxtapid (lomitapide) or Kynamro (mipomersen).

REVATIO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. For Revatio injection only (Initial): Patient is temporarily unable to take oral medications. For Revatio oral suspension only (initial, reauth): One of the following: A) Intolerance to generic Revatio tablets, OR B) Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following: age, oral-motor difficulties, or dysphagia.

AGE RESTRICTIONS:

MD RESTRICTIONS: PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION: PAH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA: PAH (Reauth): Documentation of positive clinical response to therapy

RILUZOLE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Amyotrophic lateral sclerosis (ALS): Diagnosis of amyotrophic lateral sclerosis (ALS)

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: ALS: 12 months

OTHER CRITERIA:

RITALIN LA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

RUCONEST

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Firazyr, or Kalbitor).

AGE RESTRICTIONS:

MD RESTRICTIONS: HAE: Prescribed by an immunologist, allergist, or rheumatologist

COVERAGE DURATION: 12 months

OTHER CRITERIA:

SAIZEN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTIONS:

MD RESTRICTIONS: PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrazole,letrazole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

SAIZEN CLICK.EASY

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)], and ped GH dosing used as defined by PI. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.

AGE RESTRICTIONS:

MD RESTRICTIONS: PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist

COVERAGE DURATION: All indications (initial, reauth): 12 months

OTHER CRITERIA: All(init): No prerequisites needed for Genotropin and Nutropin. All others: trial and failure or intolerance to Genotropin and Nutropin.

AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH,glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD(init,reauth):panhypopituitarism OR other dx and not used in combo w/aromatase inhibitors(eg,anastrazole,letrazole) or androgens(eg,testosterone cypionate), and adult dosing used as def by PI. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial):adult GH dosing used as def by PI/AACE 2009 tx GL, attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones:ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3), and cont adult GH dosing used as def by PI/AACE 2009 tx GL. IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

SANDOSTATIN LAR DEPOT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) Failure to surgical resection and/or pituitary irradiation OR B) patient is not a candidate for surgical resection or pituitary irradiation AND Trial and failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea and flushing episodes AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy. Vasoactive peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: All Uses (Initial and reauth): 12 months

OTHER CRITERIA: Acromegaly (reauth): Patient has had a clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): patient has improvement in number of diarrhea and flushing episodes. Vasoactive intestinal peptide tumor (reauth): patient has improvement in number of diarrhea episodes.

SEROSTIM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: HIV wasting (Initial): Diagnosis of HIV-associated wasting syndrome or cachexia, and one of the following: unintentional weight loss greater than 10% over the last 12 months, or unintentional weight loss greater than 7.5% over the last 6 months, or loss of 5% body cell mass (BCM) within 6 months, or body mass index (BMI) less than 20 kg/m2, or patient is male and has BCM less than 35% of total body weight (TBW) and BMI less than 27 kg/m2, or patient is female and has BCM less than 23% of TBW and BMI less than 27 kg/m2. Nutritional evaluation since onset of wasting first occurred. Anti-retroviral tx has been optimized to decrease the viral load. Patient has not had weight loss as a result of other underlying treatable conditions (eg, depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes). Patient has tried and had an inadequate response or intolerance to dronabinol or megestrol acetate.

AGE RESTRICTIONS:

MD RESTRICTIONS: Initial, Reauth: Prescribed by or in consultation with an infectious disease specialist.

COVERAGE DURATION: Initial: 3 months, Reauth: 6 months

OTHER CRITERIA: HIV wasting (reauth): Evidence of positive response to therapy. One of the following targets or goals has not been achieved: weight, BCM, BMI. Patient is currently receiving treatment with antiretrovirals.

SIGNIFOR

COVERED USES:	All medically accepted indications not otherwise excluded from Part D.
EXCLUSION CRITERIA:	
REQUIRED INFO:	Cushing's disease (initial): Diagnosis of CushingÂ¿s disease AND failure to or patient is not a candidate for pituitary surgery.
AGE RESTRICTIONS:	Initial: 18 years of age or older
MD RESTRICTIONS:	
COVERAGE DURATION:	Initial: 3 months. Reauth: 12 months.
OTHER CRITERIA:	Cushing's disease (reauth): a clinically meaningful reduction in 24-hour urinary free cortisol levels or improvement in signs or symptoms of the disease

SIGNIFOR LAR

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Acromegaly (initial): Diagnosis of acromegaly AND failure to surgery or patient is not a candidate for surgery

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA: Acromegaly (reauth): patientÂ¿s growth hormone (GH) level or insulin-like growth factor 1 (IGF-1) level for age and gender has normalized/improved

SILDENAFIL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. For Revatio injection only (Initial): Patient is temporarily unable to take oral medications. For Revatio oral suspension only (initial, reauth): One of the following: A) Intolerance to generic Revatio tablets, OR B) Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following: age, oral-motor difficulties, or dysphagia.

AGE RESTRICTIONS:

MD RESTRICTIONS: PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION: PAH: Initial: 6 months. Reauth: 12 months.

OTHER CRITERIA: PAH (Reauth): Documentation of positive clinical response to therapy

SIMPONI

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall) OR trial and failure, contraindication, or intolerance (TF/C/I) to methotrexate (Rheumatrex/Trexall). One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi therapy. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Patient is corticosteroid dependent (ie, an inability to successfully taper corticosteroids without a return of the symptoms of UC), OR TF/C/I to one of the following: oral aminosalicylate, oral corticosteroid, azathioprine, 6-mercaptopurine. One of the following: TF/C/I to Humira (adalimumab), OR for continuation of prior Simponi therapy. All indications (Initial, reauth): Patient is not receiving Simponi in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]. Patient is not receiving Simponi in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. UC (Initial): Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION: UC (Initial): 12 weeks. UC (Reauth): 12 months. RA, AS, PsA (Initial,

OTHER CRITERIA: All indications (Reauth): Documentation of positive clinical response to Simponi therapy.

SIMPONI ARIA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), OR trial and failure, contraindication, or intolerance to methotrexate (Rheumatrex/Trexall). One of the following: trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR for continuation of prior Simponi Aria therapy. Patient is not receiving Simponi Aria in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]. Patient is not receiving Simponi Aria in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

AGE RESTRICTIONS:

MD RESTRICTIONS: RA (Initial): Prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION: RA (Initial, reauth): 12 months

OTHER CRITERIA: RA (Reauth): Documentation of positive clinical response to Simponi Aria therapy. Patient is not receiving Simponi Aria in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]. Patient is not receiving Simponi Aria in combination with a Janus kinase inhibitor [eg, Xeljanz (tofacitinib)].

SIMVASTATIN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient has been taking simvastatin 80 mg per day chronically (12 months or more) and no evidence of muscle toxicity/myopathy (eg, muscle pain, muscle tenderness, muscle weakness) on simvastatin 80 mg per day.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

SOMATULINE DEPOT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) Failure to one of the following: surgery or radiotherapy, OR B) not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (initial): Diagnosis of unresectable, well- or moderately-differentiated, locally advanced or metastatic GEP-NETs

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: All Indications (Initial and reauth): 12 months

OTHER CRITERIA: Approve for continuation of prior therapy.

SOMAVERT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Acromegaly (initial): Diagnosis of acromegaly AND Failure to surgery and/or radiation therapy and/or other medical therapies (such as dopamine agonists [e.g., bromocriptine, cabergoline]) unless patient is not a candidate for these treatment options AND trial and failure or intolerance to generic octreotide (a somatostatin analogue)

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Initial and reauth: 12 months

OTHER CRITERIA: Acromegaly (reauth): Patient has experienced an objective response to therapy (biochemical control, decrease or normalization of IGF-1 levels).

SOVALDI

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Criteria will be applied consistent with current AASLD/IDSA guideline. For genotype (GT) 1 patients, Sovaldi plus Olysio: Patient is without decompensated liver disease (defined as Child-Pugh Class B or C). All GT1 (except Sovaldi plus Olysio therapy, or Sovaldi plus Daklinza therapy in post-liver transplant (tx) patients) and GT4: 1) trial and failure, intolerance or contraindication (TF/I/C) to both of the following: Harvoni and Zepatier therapy OR 2) For continuation of prior Sovaldi therapy. For GT2 (except in 1) post-liver tx patients, or 2) patients 12 to 17 years of age or 3) both of the following: a) patients weighing at least 35 kg and b) less than 18 years of age) or GT3 patients (except in 1) patients 12 to 17 years of age or 2) both of the following: a) patients weighing at least 35 kg and b) less than 18 years of age), using Sovaldi plus ribavirin: TF/I/C to Epclusa OR for continuation of prior Sovaldi therapy. All Sovaldi plus Olysio therapy: one of the following: 1) TF/I/C to Harvoni and Zepatier OR 2) both of the following: a) trial and failure of a NS5A-containing regimen (e.g., Harvoni, Epclusa, OR Zepatier) AND b) the patient has NS5A inhibitor resistant-associated variants detected using commercially available assays, OR 3) For continuation of prior Sovaldi plus Olysio therapy. All Sovaldi plus Daklinza therapy: One of the following: 1) Patient has not failed a prior HCV NS5A-containing regimen (eg, Daklinza) therapy, OR 2) patient has failed prior therapy with an NS5A-containing regimen AND submission of medical records (eg, chart notes) documenting that the patient does not have NS5A inhibitor resistance-associated variants detected using commercially available assays. For GT2 and GT3 (except post-liver tx patients) patients, using Sovaldi plus Daklinza: TF/I/C to Epclusa OR for continuation of prior Sovaldi therapy. For GT1 post-liver tx patients using Sovaldi plus Daklinza, TF/I/C to Harvoni OR for continuation of prior Sovaldi therapy.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine

COVERAGE DURATION: 12 to 48 wks. Criteria will be applied consistent with current AASLD/I

OTHER CRITERIA:

SPORANOX

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: 1) patient has a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), OR 2) patient is resistant to topical antifungal treatment and has one of the following diagnoses: a) tinea corporis (ringworm), OR b) tinea cruris (jock itch), OR c) tinea pedis (athleteÂ¿s foot), OR d) tinea capitis (scalp ringworm), OR e) pityriasis versicolor, OR 3) all of the following: a) patient has a diagnosis of onychomycosis confirmed by one of the following (CAPSULE ONLY): i) positive potassium hydroxide (KOH) preparation, OR ii) culture, OR iii) histology, AND b) patient has had a trial and inadequate response, intolerance or hypersensitivity to oral terbinafine, OR 4) patient has a diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole (ORAL SOLUTION ONLY).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: systemic fungal infxn:6mo.(candidiasis,fingernail onycho.):1 mo.(toe

OTHER CRITERIA:

STELARA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Diagnosis of moderately to severely active Crohn's disease. One of the following: a) trial and failure, contraindication, or intolerance to Humira (adalimumab), or (b) trial and failure, contraindication, or intolerance to treatment with at least one immunomodulator or corticosteroid [e.g., Purinethol (6-mercaptopurine), Imuran (azathioprine), Sandimmune (cyclosporine A), Prograf (tacrolimus), MTX (methotrexate)]. Patient is not receiving Stelara in combination a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION: One time

OTHER CRITERIA: Stelara is to be administered as an intravenous induction dose. Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg.

STRENSIQ

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypophosphatasia: Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia AND for patients requesting the 80 mg/0.8 mL vial only: Patient's weight is greater than or equal to 40 kg

AGE RESTRICTIONS:

MD RESTRICTIONS: Hypophosphatasia: Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism or endocrinologist

COVERAGE DURATION: Hypophosphatasia: 12 months

OTHER CRITERIA:

STRIANT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reaut

OTHER CRITERIA: HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

SYLVANT

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multicentric Castleman's disease (MCD) (Initial): Diagnosis of MCD. Patient is human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

AGE RESTRICTIONS:

MD RESTRICTIONS: MCD (Initial): Prescribed by or in consultation with hematologist/oncologist or rheumatologist.

COVERAGE DURATION: MCD (initial, reauth): 6 months

OTHER CRITERIA: MCD (reauth): Documentation of positive clinical response to Sylvant therapy. Patient is HIV negative and HHV-8 negative.

SYMLINPEN 120

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Gastroparesis.

REQUIRED INFO: One of the following diagnoses: A) Type 1 diabetes OR B) Type 2 diabetes.

AGE RESTRICTIONS: 18 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

SYMLINPEN 60

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA: Gastroparesis.

REQUIRED INFO: One of the following diagnoses: A) Type 1 diabetes OR B) Type 2 diabetes.

AGE RESTRICTIONS: 18 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

SYNAGIS

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Patient will use palivizumab for immunoprophylaxis of respiratory syncytial virus (RSV) during the peak months of infection in the patientÂ¿s geographic region AND Patient meets one of the following criteria: 1) Infants born at 28 weeks, six days gestation or earlier and who are younger than 12 months of age at the start of the RSV season OR 2) Diagnosis of chronic lung disease of prematurity, born before 32 weeks, 0 days gestation, received greater than 21% oxygen for at least the first 28 days after birth, and one of the following: a) 12 months of age or younger at the start of the RSV season OR b) greater than 12 months of age to 24 months of age at the start of the RSV season and received medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season. OR 3) Patient is 12 months of age or younger at the start of the RSV season and has one of the following: a) acyanotic heart failure that will require a cardiac surgical procedure and the patient is receiving medication to control congestive heart failure, OR b) moderate to severe pulmonary hypertension OR c) cyanotic heart defect. OR 4) patient is younger than 24 months of age and will or has undergone a cardiac transplantation during the RSV season. OR 5) Patient is 12 months of age or younger at the start of the RSV season with a congenital abnormality or neuromuscular disorder and has an impaired ability to clear secretions from the upper airway due to an ineffective cough. OR 6) Patient is younger than 24 months of age with a lymphocyte count below the normal range for patientÂ¿s age and has received or will receive a solid organ transplant, hematopoietic stem cell transplant recipient, or chemotherapy during the RSV season.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with a pediatric specialist (i.e., pulmonologist, neonatologist, neurologist, cardiologist, pediatric intensivist, or infectious disease specialist).

COVERAGE DURATION: 12 months

OTHER CRITERIA: Approve 5 doses based on patient body weight for all other indications.

TALTZ

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance to both Cosentyx (secukinumab) and either Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Taltz therapy. Patient is not receiving Taltz in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

AGE RESTRICTIONS:

MD RESTRICTIONS: Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION: Initial, reauth: 12 months

OTHER CRITERIA: Plaque psoriasis (Reauth): Documentation of positive clinical response to Taltz therapy. Patient is not receiving Taltz in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

TAZORAC

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Acne vulgaris (initial): Diagnosis of acne vulgaris AND History of failure or intolerance to at least two topical acne products (e.g., tretinoin, adapalene, benzoyl peroxide, clindamycin, erythromycin, or azelaic acid). Plaque psoriasis (initial): Diagnosis of stable moderate to severe plaque psoriasis AND Patient has body surface area (BSA) involvement of less than 20 percent AND History of failure or intolerance to at least two topical psoriasis product (e.g., medium to high potency corticosteroids and/or vitamin D analogs).

AGE RESTRICTIONS: Acne (initial): 12 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: All uses (Initial and reauth): 12 months

OTHER CRITERIA: Acne, Plaque psoriasis (reauth): Documentation of positive clinical response to therapy .

TECFIDERA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

TECFIDERA STARTER PACK

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

TECHNIVIE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: All of the following: A) Criteria will be applied consistent with current AASLD/IDSA guideline, AND B) Patient is not receiving Technivie in combination with another HCV direct acting antiviral agent [eg, Harvoni (ledipasvir-sofosbuvir), Sovaldi (sofosbuvir), Olysio (simeprevir)], AND C) ONE of the following: Trial and failure, intolerance or contraindication to Harvoni and Zepatier therapy OR patient is currently on Technivie therapy.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine

COVERAGE DURATION: 12 wks. Criteria will be applied consistent with current AASLD/IDSA

OTHER CRITERIA:

TESTOSTERONE CYPIONATE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reaut

OTHER CRITERIA: HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

TESTOSTERONE ENANTHATE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC,

OTHER CRITERIA: HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

TETRABENAZINE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Chorea associated with Huntington's Disease (HD) (Initial): Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia (Initial): Patient has stereotypies associated with tardive dyskinesia. Tourette's syndrome (Initial): Patient has tics associated with Tourette's syndrome. Failure, contraindication, or intolerance to Haldol (haloperidol).

AGE RESTRICTIONS: Tardive dyskinesia (Initial): Age greater than or equal to 18 years.

MD RESTRICTIONS: HD (Initial): Prescribed by or in consultation with a neurologist. Tardive dyskinesia, Tourette's syndrome (Initial): Prescribed by or in consultation with neurologist or psychiatrist.

COVERAGE DURATION: All indications: (Initial) 3 months, (Reauth) 12 months.

OTHER CRITERIA: All indications (Reauth): Documentation of clinical response and benefit from therapy.

TRETINOIN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: Acne: Diagnosis of acne.

AGE RESTRICTIONS: PA applies to members 26 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

TRETINOIN MICROSPHERE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: Acne: Diagnosis of acne.

AGE RESTRICTIONS: PA applies to members 26 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

TYSABRI

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses). Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone or Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Rebif (interferon beta-1a), or Tecfidera (dimethyl fumarate). Patient is not taking Tysabri in combination with another MS agent [eg, Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone (glatiramer acetate), Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Rebif (interferon beta-1a), or Tecfidera (dimethyl fumarate)]. Crohn's Disease (CD) (initial): Diagnosis of moderate to severe CD with evidence of inflammation (eg, elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes). Inadequate response or intolerance to one of the following conventional therapies: corticosteroids, 6-mercaptopurine (6MP [Purinethol], azathioprine (Imuran), methotrexate, aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). Inadequate response or intolerance to a TNF-inhibitor (eg, Cimzia [certolizumab pegol], Humira [adalimumab], Remicade [infliximab]). CD (initial and reauth): Patient is not taking Tysabri in combination with an immunosuppressant (eg, 6-MP, azathioprine, cyclosporine, or methotrexate) or a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or Remicade [infliximab]).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: MS: 12mo. CD (Init): 3 mo. CD (Reauth): 6 mo if not on steroids. Ot

OTHER CRITERIA: CD (reauth): Diagnostic and/or clinical documentation (eg, improved disease activity index) that indicates patient has experienced clinical benefit from receiving (induction) Tysabri therapy by week 12.

UPTRAVI

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Pulmonary arterial hypertension (PAH) (initial): Diagnosis of PAH AND Patient is symptomatic AND One of the following: a) Diagnosis of PAH was confirmed by right heart catheterization OR b) patient is currently on any therapy for the diagnosis of PAH. One of the following: a) History of trial and failure, contraindication, or intolerance to a PDE5 inhibitor (ie, Adcirca, Revatio) or Adempas (riociguat), and History of trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g. Letairis (ambrisentan), Opsumit (macitentan), or Tracleer (bosentan)] OR b) For continuation of prior Uptravi therapy. Not taken in combination with a prostanoid/prostacyclin analogue (eg, epoprostenol, iloprost, treprostinil).

AGE RESTRICTIONS:

MD RESTRICTIONS: PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist

COVERAGE DURATION: Initial: 6 months Reauth: 12 months

OTHER CRITERIA: PAH (Reauth): Documentation of positive clinical response to Uptravi therapy. Not taken in combination with a prostanoid/prostacyclin analogue (eg, epoprostenol, iloprost, treprostinil)

VENTAVIS

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.

AGE RESTRICTIONS:

MD RESTRICTIONS: PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.

COVERAGE DURATION: PAH (Initial): 6 months. (Reauth): 12 months

OTHER CRITERIA: Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.

VIVITROL

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Alcohol dependence (init): History of alcohol dependence and confirmed abstinence at treatment initiation. Opioid dependence (init): History of opioid dependence and confirmed opioid detoxification at treatment initiation.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Alcohol dependence, opioid dependence (init, reauth): 24 weeks

OTHER CRITERIA: Alcohol dependence, opioid dependence (reauth): Confirmation of clinical benefit to the patient.

VPRIV

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Gaucher disease: Diagnosis of type 1 Gaucher disease. Patient has evidence of symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Gaucher disease: 12 months

OTHER CRITERIA:

XELJANZ

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29 for specific phobia diagnostic criteria), OR for continuation of prior tofacitinib therapy. Patient is not receiving tofacitinib in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).

AGE RESTRICTIONS:

MD RESTRICTIONS: RA (Initial): Prescribed by or in consultation with a rheumatologist

COVERAGE DURATION: RA (initial, reauth): 12 months

OTHER CRITERIA: RA (Reauth): Documentation of positive clinical response to tofacitinib therapy. Patient is not receiving tofacitinib in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).

XELJANZ XR

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29 for specific phobia diagnostic criteria), OR for continuation of prior tofacitinib therapy. Patient is not receiving tofacitinib in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).

AGE RESTRICTIONS:

MD RESTRICTIONS: RA (Initial): Prescribed by or in consultation with a rheumatologist

COVERAGE DURATION: RA (initial, reauth): 12 months

OTHER CRITERIA: RA (Reauth): Documentation of positive clinical response to tofacitinib therapy. Patient is not receiving tofacitinib in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).

XEOMIN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Cervical Dystonia (CD) (init): Diagnosis of CD (also known as spasmodic torticollis). Blepharospasm (initial): Diagnosis of blepharospasm. History of previous use of Botox (onabotulinumtoxinA) for the treatment of blepharospasm. Upper limb spasticity (ULS) (init): Diagnosis of upper limb spasticity.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: All indications (init, reauth): 3 months (for 1 dose)

OTHER CRITERIA: All indications (reauth): Confirmed improvement in symptoms with initial Xeomin treatment. At least 3 months have elapsed since the last treatment with Xeomin

XGEVA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Bone metastasis from solid tumors (BMST): Both of the following: 1) diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer), AND 2) documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Both of the following: 1) diagnosis of giant cell tumor of bone AND 2) One of the following: a) tumor is unresectable, OR b) surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM): Both of the following: 1) diagnosis of hypercalcemia of malignancy, AND 2) Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (eg, Aredia (pamidronate), Zometa (zoledronic

AGE RESTRICTIONS:

MD RESTRICTIONS: GCTB, HCM: Prescribed by or in consultation with an oncologist

COVERAGE DURATION: BMST, GCTB: 12 mo. HCM: 2 mo.

OTHER CRITERIA: Approve for continuation of prior therapy.

XIFAXAN

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Travelers' diarrhea (TD) (200 mg strength only): Diagnosis of travelers' diarrhea, AND one of the following: a) Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR b) resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin). Prophylaxis of hepatic encephalopathy (HE) recurrence (550mg strength only): Used for the prophylaxis of hepatic encephalopathy recurrence, AND trial and failure, contraindication or intolerance to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (550mg strength only) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide].

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: TD: One time only. HE: 6 months. IBS-D (initial, reauth): 2 weeks.

OTHER CRITERIA: IBS-D (reauth): Patient experiences IBS-D symptom recurrence AND patient has not already received 3 treatment courses of Xifaxan for IBS-D in their lifetime.

XIIDRA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Initial: Diagnosis of dry eye disease. Patient has suppressed tear production due to ocular inflammation as determined by at least one of the following diagnostic tests: Schirmer test (aqueous tear production and clearance), tear break-up time, ocular surface dye staining, tear film osmolarity, or fluorescein clearance test/tear function test. Failure, contraindication, or intolerance to Restasis at an optimal dose and frequency for at least 2 weeks

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Initial, reauth: 12 months

OTHER CRITERIA: Reauth: Documentation of positive clinical response to Xiidra therapy (e.g., increased tear production or improvement in dry eye symptoms).

XYREM

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND trial and failure, contraindication, or intolerance to one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: All uses (initial, reauth): 12 months

OTHER CRITERIA: Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with Xyrem therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy.

ZARXIO

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with a history of FN during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) Patient is receiving National Cancer InstituteÂ¿s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia (ANC less than or equal to 500 cells/mm^3), AND 2) patients with FN at high risk for infection-associated complications.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by hematologist/oncologist except HIVN: Prescribed by hematologist/oncologist or infectious disease specialist

COVERAGE DURATION: BMSCT, AML, CFN, secondary prophy of FN, NDDC:3mo or duratio

OTHER CRITERIA:

ZAVESCA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease. Patient is unable to receive enzyme replacement therapy due to one of the following conditions: allergy or hypersensitivity to enzyme replacement therapy, poor venous access, unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV).

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: Gaucher disease: 12 months

OTHER CRITERIA:

ZEMAIRA

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency: All of the following: A) Patient has an alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency AND B) Diagnosis of emphysema AND C) One of the following: 1) Patient has a high risk phenotype: PiZZ, PiZ(null), or Pi(null)(null) OR 2) Patient has serum alpha-1 antitrypsin concentrations of less than 11 Â¿M/L (80 mg/dL), AND D) One of the following: FEV1 level is between 30% and 65% of predicted OR the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment, AND E) Trial and failure, or intolerance to Prolastin-C.

AGE RESTRICTIONS:

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

ZENATANE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Acne (initial): Diagnosis of acne. Trial and failure, contraindication or intolerance to an adequate trial (at least 6 weeks) on both of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin)] AND b) combination therapy with benzoyl peroxide and one of the following: 1) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)] OR 2) topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)].

AGE RESTRICTIONS:

MD RESTRICTIONS: Acne (Initial): Prescribed by a dermatologist

COVERAGE DURATION: Acne (initial, reauth): 5 months

OTHER CRITERIA: Acne (reauth): One of the following: A) After more than 2 months off therapy, persistent or recurring severe recalcitrant nodular acne is still present, OR B) the total cumulative dose is less than 150 mg/kg (will be approved up to a total of 150 mg/kg).

ZENZEDI

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AGE RESTRICTIONS: PA applies to members 19 years of age or older

MD RESTRICTIONS:

COVERAGE DURATION: 12 months

OTHER CRITERIA:

ZORBTIVE

COVERED USES: All medically accepted indications not otherwise excluded from Part D.

EXCLUSION CRITERIA:

REQUIRED INFO: Short Bowel Syndrome (SBS): Diagnosis of SBS. Patient is currently receiving specialized nutritional support (eg, intravenous parenteral nutrition, fluid, and micronutrient supplements). Patient has not previously received 4 weeks of treatment with Zorbtive.

AGE RESTRICTIONS:

MD RESTRICTIONS: Prescribed by or in consultation with a gastroenterologist.

COVERAGE DURATION: SBS: 4 weeks.

OTHER CRITERIA: