PRODUCT(s) AFFECTED
- ACTEMRA SOLUTION 200 MG/10ML  -  ACTEMRA SOLUTION 400 MG/20ML
- ACTEMRA SOLUTION 80 MG/4ML

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Active infection (including TB). Concurrent therapy with other biologic agent(s).

REQUIRED MEDICAL INFORMATION
Screening for latent tuberculosis is required. If results are positive, patient must have completed treatment or must currently be receiving treatment for latent tuberculosis. Evaluate for HBV risk and initiate treatment if appropriate. Must have an inadequate response or intolerance/contraindication to one TNF antagonist therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For renewals, patient must have responded to Actemra therapy (e.g., condition improved or stabilized).
ACTHAR

PRODUCT(s) AFFECTED
- ACTHAR HP
- HP ACTHAR

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Supporting statement of diagnosis from the physician

AGE RESTRICTION
None

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
ACTIMMUNE

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
ADAGEN

PRODUCT(s) AFFECTED
ADAGEN

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Severe thrombocytopenia. Use in preparation for or in support of bone marrow transplantation.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Use for direct replacement for deficient enzyme (no benefit achieved in patients with immunodeficiency due to other causes).
ADCIRCA

PRODUCT(s) AFFECTED
ADCIRCA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Nitrate therapy

REQUIRED MEDICAL INFORMATION
PAH been confirmed by right heart catheterization.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
ALDURAZYME

PRODUCT(s) AFFECTED
ALDURAZYME

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis confirmed by measurement of alpha-L-iduronidase activity (enzymatic assay) or DNA testing. For Scheie form of MPS I, must have at least 2 moderate to severe symptoms. Must demonstrate improvement in lung function in patients who have received at least 26 weeks of Aldurazyme on re-authorization.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
ALPHA1-PROTEINASE INHIBITOR

PRODUCT(s) AFFECTED
- ARALAST
- GLASSIA
- ZEMAIRA

ARALAST NP

PROLASTIN-C

GLASSIA

ZEMAIRA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Patient has IgA deficiency with antibodies against IgA.

REQUIRED MEDICAL INFORMATION
Alpha1-proteinase inhibitor concentration is less than 11 micromoles per liter. The FEV1 level is between 35% and 60% predicted OR greater than 60% predicted. If the FEV1 is greater than 60% predicted, then the patient has experienced a rapid decline in lung function (ie, reduction of FEV1 more than 120 mL/year) that warrants treatment.

AGE RESTRICTION
18 years old and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
AMPHETAMINES

PRODUCT(s) AFFECTED
- AMPHETAMINE-DEXTROAMPHET ER
- DEXTROAMPHETAMINE SULFATE ER
- DEXTROAMPHETAMINE SULFATE TAB 10 MG
- DEXTROAMPHETAMINE SULFATE TAB 5 MG
- VYVANSE

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
MAOI concurrent use or within the last 14 days except if prescriber is a psychiatrist with experience prescribing both MAOI and amphetamine/dextroamphetamine drugs.

REQUIRED MEDICAL INFORMATION
Sleep studies for narcolepsy diagnosis

AGE RESTRICTION
3 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Consider benefits of use versus the potential risks of serious cardiovascular events
AMPYRA

PRODUCT(s) AFFECTED
AMPYRA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Moderate to severe renal impairment (CrCL less than or equal to 50 mL/min), history of seizures

REQUIRED MEDICAL INFORMATION
Patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting Ampyra.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
To continue therapy, the patient must experience an improvement in walking speed or other objective measure of walking ability since starting Ampyra.
ANABOLIC STEROIDS

PRODUCT(s) AFFECTED
- OXANDROLONE TAB 10 MG
- OXANDROLONE TAB 2.5 MG

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Known or suspected carcinoma of the prostate or breast (in male patients), carcinoma of the breast in women with hypercalcemia, pregnancy, nephrosis (the nephrotic phase of nephritis), hypercalcemia.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months

OTHER CRITERIA
N/A
**ARANESP**

**PRODUCT(s) AFFECTED**
- ARANESP (ALBUMIN FREE) SOLN PRSYR 100 MCG/0.5ML
- ARANESP (ALBUMIN FREE) SOLN PRSYR 200 MCG/0.4ML
- ARANESP (ALBUMIN FREE) SOLN PRSYR 300 MCG/0.6ML
- ARANESP (ALBUMIN FREE) SOLN PRSYR 500 MCG/ML
- ARANESP (ALBUMIN FREE) SOLUTION 100 MCG/ML
- ARANESP (ALBUMIN FREE) SOLUTION 200 MCG/ML
- ARANESP (ALBUMIN FREE) SOLUTION 300 MCG/ML
- ARANESP (ALBUMIN FREE) SOLUTION 60 MCG/ML

**COVERED USES**
All FDA approved indications not otherwise excluded from Part D

**EXCLUSION CRITERIA**
Uncontrolled hypertension, hemoglobin greater than or equal to 13 g/dL

**REQUIRED MEDICAL INFORMATION**
All patients must meet the following criteria: 1) The pretreatment hemoglobin level is less than 10 g/dL (or less than or equal to 11 g/dL with clinical symptoms of anemia). 2) Once on therapy for 12 weeks, the hemoglobin must increase at least 1 g/dL in response to Aranesp. 3) Once on therapy, the hemoglobin should be maintained to a level below 12 g/dL and if the level exceeds 12 g/dL, the prescriber must reduce the dose. Patients with chronic kidney disease or those treated with myelosuppressive chemotherapy must have adequate iron stores or be receiving concomitant iron
supplementation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 weeks

OTHER CRITERIA
Patient is instructed by the prescriber to report any signs or symptoms of adverse cardiovascular or thrombotic events.
PRODUCT(s) AFFECTED
ARCALYST

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Active or chronic infection. Concurrent therapy with other biologics.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
12 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For renewal, patient’s condition must have improved or stabilized.
BOSULIF

PRODUCT(s) AFFECTED
BOSULIF

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Signed statement of diagnosis from the physician, hepatic panel and CBC, trial and failure ofofimatinib or dasatinibi and documentation of a 90 day response

AGE RESTRICTION
None

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
BOTOX RECON SOLN 100 UNIT

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Cosmetic use. Hypersensitivity to any botulinum toxin preparation or any component of the formulation. Infection at the proposed injection site(s).

REQUIRED MEDICAL INFORMATION
For chronic migraine, initial treatment: inadequate response to at least 8 weeks of oral migraine preventative therapy unless contraindicated or not tolerated. For chronic migraine, continuation of treatment: 50 percent reduction in headache frequency since starting therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Chronic migraine, initial treatment: 12 weeks. Plan year for all other indications.

OTHER CRITERIA
Monitored for life-threatening symptoms of spread of toxin effect from the injection site (e.g., breathing, swallowing difficulties)
BUPRENORPHINE

PRODUCT(s) AFFECTED
- BUPRENORPHINE HCL SL TAB 2 MG
- BUPRENORPHINE HCL-NALOXONE HCL
- SUBOXONE FILM 8-2 MG

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Documentation that the member is not receiving other opioids

AGE RESTRICTION
For patients age 16 years and older, coverage determination is approved for FDA-approved indications not otherwise excluded from Part D. For patients age 0 to 15 years, drug is not covered.

PRESCRIBER RESTRICTION
Prescribers must be certified through CSAT (The Center for Substance Abuse Treatment) of SAMHSA (Substance Abuse and Mental Health Services Administration) to prescribe Suboxone and Subutex

COVERAGE DURATION
Buprenorphine - one month (12 months if pregnant). Buprenorphine-naloxone - 12 months.

OTHER CRITERIA
Buprenorphine and buprenorphine-naloxone should be part of an overall treatment program. The patient should be monitored periodically.
CAYSTON

PRODUCT(s) AFFECTED
CAYSTON

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of cystic fibrosis is confirmed by appropriate diagnostic or genetic testing. Confirmation of P. aeruginosa in cultures of the airways. For continuation of therapy in patients younger than 6 years of age, a clinical reason to continue therapy, such as symptomatic improvement, is required. For continuation of therapy in patients older than 6 years of age, pulmonary function tests have not deteriorated more than 10% from baseline or there is a clinical reason to continue therapy, such as symptomatic improvement.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
CELEBREX

PRODUCT(s) AFFECTED
- CELECOXIB CAP 100 MG - CELECOXIB CAP 200 MG
- CELECOXIB CAP 400 MG - CELECOXIB CAP 50 MG

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Post-operative pain following CABG surgery.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months for JRA, 12 months for dysmenorrhea, OA, RA, AS, 1 month for acute pain

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
CEREZYME

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Concurrent therapy with Zavesca.

REQUIRED MEDICAL INFORMATION
Diagnosis confirmed by bone marrow histology, DNA testing, or b-glucocerebrosidase enzyme assay (enzyme activity less than 30 percent). Must have at least one of following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly. Must demonstrate a decrease in liver and spleen volume and/or increase in platelet count and/or increase in Hgb concentration in patients who have received at least 24 months of Cerezyme therapy on re-authorization.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
- CIMZIA
- CIMZIA PREFILLED
- CIMZIA STARTER KIT

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Active infection (including TB). Concurrent therapy with other biologics.

REQUIRED MEDICAL INFORMATION
Screening for latent TB infection and assessment for Hep B risk. For positive latent TB, patient must have completed treatment or is currently receiving treatment for LTBI. HBV infection ruled out or treatment initiated for positive infection. Rheumatoid arthritis (RA) - Must have an inadequate response to either Enbrel or Humira and one of following: 1) inadequate response to methotrexate, 2) inadequate response to another nonbiologic DMARD (e.g., leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX or, 3) intolerance or contraindication to at least 2 nonbiologic DMARDs. Crohn’s Disease - Must have an inadequate response or contraindication/intolerance to at least one oral corticosteroid and Humira.

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 3 months for Crohn’s disease, 1 year for all other indications. Renewal: Plan Year

OTHER CRITERIA
For re-authorization, patient’s condition must have improved or stabilized.
PRODUCT(s) AFFECTED
DRONABINOL

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
A. The diagnosis is documented as anorexia associated with weight loss in a patient with AIDS a. AND the patient has had an involuntary weight loss of greater than 10% of pre-illness baseline body weight or a body mass index (BMI) less than 20kg/m2 in the absence of a concurrent illness or medical condition other than HIV that may cause weight loss b. AND the patient has failed to respond to a 30-day drug regimen of megestrol (Megace) c. AND if the patient has received previous dronabinol therapy, he/she must show a positive response to therapy by maintaining or increasing their initial weight and/or muscle mass before initiating dronabinol therapy. B. The diagnosis is documented as nausea and vomiting associated with cancer chemotherapy in a cancer patient a. AND the patient is receiving a chemotherapy or radiation regimen b. AND the patient has had a full trial and failure through at least one cycle of chemotherapy with IV ondansetron AND at least one of the following oral anti-emetic agents: metoclopramide, promethazine, prochlorperazine, meclizine, trimethobenzamide, oral 5-HT3 receptor antagonists e. AND if the patient has received previous dronabinol therapy, he/she must show a positive response by showing a reduced incidence of emesis and/or nausea.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
6 months

OTHER CRITERIA
B vs D coverage determination per CMS guidelines
ELAPRASE

PRODUCT(s) AFFECTED
ELAPRASE

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis confirmed by DNA testing or enzymatic analysis (deficiency of iduronate 2-sulfatase enzyme activity).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
- ENBREL
- ENBREL SURECLICK

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Concomitant use with another biologic, active infection (including TB).

REQUIRED MEDICAL INFORMATION
Screening for latent TB infection and assessment for Hep B risk. For positive latent TB, patient must have completed treatment or is currently receiving treatment for LTBI. HBV infection ruled out or treatment initiated for positive infection. Rheumatoid arthritis - Must have one of following: 1) inadequate response to methotrexate (MTX), 2) inadequate response to another nonbiologic DMARD (e.g., leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX, 3) intolerance or contraindication to at least 2 nonbiologic DMARDs or, 4) use Humira as first-line therapy with MTX for severely active RA. Polyarticular JIA - Must have an inadequate response to at least one nonbiologic DMARD or intolerance/contraindication to at least 2 nonbiologic DMARDs. Psoriatic arthritis with predominantly peripheral symptoms - Must have an inadequate response to at least an 8-week maximum tolerated dose trial of at least 1 nonbiologic DMARD unless contraindicated or intolerant to such therapy. For plaque psoriasis - Must have more than 5% BSA affected or has crucial body areas (e.g., feet, hands, face, or genitals) affected. Must have an inadequate response to at least a 60-day trial of 2 conventional therapies (e.g., phototherapy, calcipotriene, MTX, acitretin) unless contraindicated or intolerant to such therapies. Crohn's disease - Must have an inadequate response to at least a 60-day trial of 2 conventional therapies (e.g., sulfasalazine, mesalamine, azathioprine, corticosteroids) unless contraindicated or intolerant to such therapies OR an inadequate response or intolerance to either Remicade or Cimzia.

AGE RESTRICTION
For psoriasis, patient must be 18 years of age or older
Prior Authorization Criteria
Care N' Care Health Plan – Formulary ID: 16384 – Version 6
Effective Date: 1/1/2016

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
For continuation of therapy, patient's condition must have improved or stabilized.
PRODUCT(s) AFFECTED
- EPOGEN
- PROCRIT

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Uncontrolled hypertension

REQUIRED MEDICAL INFORMATION
For use in an anemic patient prior to surgery, the patient must also receive concomitant iron supplementation. For other indications, all of the following criteria are required: 1) The pretreatment Hgb is less than or equal to 10 g/dL for initial authorization. 2) The patient is receiving concomitant iron supplementation if iron stores are inadequate. 3) The Hgb is maintained at or below 12 g/dL once on therapy. 4) Once on therapy for 12 weeks, the hemoglobin must increase at least 1 g/dL in response to epoetin alfa.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 weeks

OTHER CRITERIA
N/A
ERWINAZE

PRODUCT(s) AFFECTED
ERWINAZE

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Supporting statement of diagnosis from the physician

AGE RESTRICTION
None

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
ESBRIET

PRODUCT(s) AFFECTED
ESBRIET

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Appropriate diagnosis (idopathic pulmonary fibrosis [IPF]), monitoring (hepatic function/LFTs)

AGE RESTRICTION
none

PRESCRIBER RESTRICTION
pulmonologist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
None
EXJADE

PRODUCT(s) AFFECTED
EXJADE

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Creatinine clearance less than 40 mL/min or evidence of overt proteinuria, platelet count less than 50 x 10^9/L, advanced malignancy, high-risk myelodysplastic syndrome (MDS) with poor performance status, or concurrent use of deferoxamine or iron-containing products.

REQUIRED MEDICAL INFORMATION
The patient must meet all of the following criteria: 1) Diagnosis of transfusion-dependent anemia with chronic iron overload due to blood transfusions, 2) Patient will have baseline and monthly monitoring of serum ferritin, serum creatinine, creatinine clearance, serum transaminases, and bilirubin. OR For the treatment of chronic iron overload in patients 10 years and older with nontransfusion-dependent thalassemia syndromes

AGE RESTRICTION
2 years of age and older

PRESCRIBER RESTRICTION
Hematologist

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A
**FABRAZYME**

**PRODUCT(s) AFFECTED**
FABRAZYME

**COVERED USES**
All FDA approved indications not otherwise excluded from Part D

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Diagnosis confirmed with an enzyme assay measuring a deficiency of alpha-galactosidase enzyme activity or DNA testing.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
N/A
PRODUCT(s) AFFECTED
FARYDAK

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
statement of diagnosis from physician

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12/31/16

OTHER CRITERIA
N/A
FULYZAQ

PRODUCT(s) AFFECTED
FULYZAQ

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
GILOTRIF

PRODUCT(s) AFFECTED
GILOTRIF

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Supporting statement of diagnosis from the physician in patients with EGFR exon 19 deletions or exon 21 (L858R) substitution as detected by an FDA-approved test.

AGE RESTRICTION
None

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
GONADOTROPIN

PRODUCT(s) AFFECTED
CHORIONIC GONADOTROPIN RECON SOLN 10000 UNIT

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Fertility indications in females are excluded.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
GROWTH HORMONE

PRODUCT(s) AFFECTED
- GENOTROPIN
- HUMATROPE RECON SOLN 12 MG
- NORDITROPIN FLEXPRO SOLUTION 10 MG/1.5ML
- NORDITROPIN FLEXPRO SOLUTION 5 MG/1.5ML
- NORDITROPIN NORDIFLEX PEN SOLUTION 5 MG/1.5ML
- NUTROPIN AQ NUSPIN 5
- OMNITROPE
- SAIZEN CLICK.EASY
- GENOTROPIN MINIQUICK
- HUMATROPE RECON SOLN 24 MG
- NORDITROPIN FLEXPRO SOLUTION 15 MG/1.5ML
- NORDITROPIN NORDIFLEX PEN SOLUTION 15 MG/1.5ML
- NUTROPIN AQ NUSPIN 20
- NUTROPIN AQ PEN SOLUTION 20 MG/2ML
- SAIZEN

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For pediatric GHD in neonate with hypoglycemia: patient has a randomly assessed GH level less than 20 ng/mL, other causes of hypoglycemia have been ruled out, and other treatments have been ineffective. For all pediatric patients: patients have short stature or slow growth velocity and have been evaluated for other causes of growth failure. For pediatric GHD, patient has delayed bone age. For pediatric GHD without pituitary disease, patient failed 2 stimulation tests. For pediatric GHD with a pituitary or CNS disorder, patient has clinical evidence of GHD and low IGF-1/IGFBP3. For TS and SHOX patients: diagnosis confirmed by genetic testing. For CRI patients: metabolic, endocrine and nutritional abnormalities have been treated or stabilized and patient has not had a kidney transplant. For SGA: patient has a low birth weight or length for gestational age. For ISS: pediatric GHD has been ruled out with one stimulation test. For adult GHD, patient was assessed for other causes of GHD-like symptoms. For adult GHD without pituitary disease, patient...
failed 2 stimulation tests. For adult GHD with at least 3 pituitary hormone deficiencies (PHD) or panhypopituitarism: have a low IGF-1. For adult GHD with less than 3 PHD, low IGF-1 and failed one stimulation test. For renewal for pediatric patients, growing more than 2 cm per year and for PWS only: improved body composition. For renewal for adult patients: patient has seen clinical improvement and IGF-1 will be monitored.

AGE RESTRICTION
For Turner syndrome and SGA, 2 years of age and older. For Noonan syndrome and SHOX, 3 years of age and older.

PRESCRIBER RESTRICTION
Endocrinologist, Pediatric Nephrologist, Gastroenterologist, Nutritional Support Specialist, Infectious Disease Specialist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
HARVONI

PRODUCT(s) AFFECTED
HARVONI

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

EXCLUSION CRITERIA
None

REQUIRED MEDICAL INFORMATION
Must submit documentation of chronic hepatitis C genotype (confirmed by HCV RNA level within the last 6 months) and subtype. Must submit laboratory results within 6 weeks of initiating therapy including: 1) CBC w Platelets, 2) AST/ALT, 3)Total Bilirubin, 4)Serum Albumin, 5)PT/INR, 6)Serum Creatinine, and 7)GFR.

AGE RESTRICTION
Patient must be age 18 or over

PRESCRIBER RESTRICTION
Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist

COVERAGE DURATION
24 wks: Post liver transplant, treatment-experienced or cirrhosis, 12 wks: all other indications

OTHER CRITERIA
None
PRODUCT(s) AFFECTED
ADEFOVIR DIPIVOXIL

COVERED USES
All FDA approved indications not otherwise excluded from Part D, prophylaxis against HBV infection with liver transplantation.

EXCLUSION CRITERIA
None

REQUIRED MEDICAL INFORMATION
A. The patient has been diagnosed with chronic hepatitis B. B. AND the patient has evidence of a positive HBsAg (+ or -) serological marker for greater than 6 months OR evidence by a liver biopsy showing chronic hepatitis. C. AND the patient has a Hepatitis B viral load greater than 20,000 IU/mL (100,000 copies per mL) except if for HBeAg-negative HBV, the viral load is greater than 2,000 IU per mL (10,000 copies per mL). D. AND the patient has elevations in liver aminotransferases (ALT or AST) that are two (2) times greater than normal OR normal liver aminotransferase (ALT or AST) levels with evidence of significant disease found on biopsy. E. AND the patient is not receiving Intron A. F. AND documented evidence of diagnosis, serological markers or liver biopsy, viral load and liver aminotransferases. G. If the patient has received previous Hepsera treatment, there is documented clinical improvement shown by a drop in viral load or reduction in the patient's liver aminotransferases. H. If patient has renal impairment dose to be reduced to 10mg every 48 hours for CrCl 30 to 49mL/min, 10mg every 72 hours for CrCl 10 to 29mL/min. I. Patient not to be taking tenofovir or PMPA concurrently.

AGE RESTRICTION
12 years and older

PRESCRIBER RESTRICTION
Gastroenterologist or infectious disease specialist or affiliated with an infectious disease or gastroenterology practice, or a primary care physician with experience in treating HBV.
COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
### PRODUCT(s) AFFECTED

<table>
<thead>
<tr>
<th>Product/Brand Name</th>
<th>Strength/Type</th>
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<tbody>
<tr>
<td>ALORA</td>
<td>AMITRIPTYLINE HCL TAB 10 MG</td>
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<td>AMITRIPTYLINE HCL TAB 100 MG</td>
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<td>ASCOMP-CODEINE</td>
<td>BENTYL SOLUTION 10 MG/ML</td>
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<tr>
<td>BENZTROPINE MESYLATE TAB 0.5 MG</td>
<td>BENZTROPINE MESYLATE TAB 1 MG</td>
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<tr>
<td>BENZTROPINE MESYLATE TAB 2 MG</td>
<td>BUTALBITAL-APAP-CAFF-COD CAP 50-325-40-30 MG</td>
</tr>
<tr>
<td>CARBINOXAMINE MALEATE SOLUTION 4 MG/5ML</td>
<td>CARBINOXAMINE MALEATE TAB 4 MG</td>
</tr>
<tr>
<td>CARISOPRODOL 350 MG</td>
<td>CARISOPRODOL TAB 350 MG</td>
</tr>
<tr>
<td>CARISOPRODOL-ASPIRIN</td>
<td>CARISOPRODOL-ASPIRIN-CODEINE</td>
</tr>
<tr>
<td>CHLORZOXAZONE TAB 500 MG</td>
<td>CLEMASTINE FUMARATE TAB 2.68 MG</td>
</tr>
<tr>
<td>CLIMARA PRO</td>
<td>CLOMIPRAMINE HCL CAP 25 MG</td>
</tr>
<tr>
<td>CLOMIPRAMINE HCL CAP 50 MG</td>
<td>CLOMIPRAMINE HCL CAP 75 MG</td>
</tr>
<tr>
<td>COMBIPATCH</td>
<td>CYCLOBENZAPRINE HCL TAB 10 MG</td>
</tr>
<tr>
<td>CYCLOBENZAPRINE HCL TAB 5 MG</td>
<td>CYCLOBENZAPRINE HCL TAB 7.5 MG</td>
</tr>
<tr>
<td>CYPROHEPTADINE HCL 4 MG</td>
<td>CYPROHEPTADINE HCL SYRUP 2 MG/5ML</td>
</tr>
<tr>
<td>CYPROHEPTADINE HCL TAB 4 MG</td>
<td>DICYCLOMINE HCL CAP 10 MG</td>
</tr>
<tr>
<td>DICYCLOMINE HCL SOLUTION 10 MG/5ML</td>
<td>DICYCLOMINE HCL TAB 20 MG</td>
</tr>
<tr>
<td>DIGITEK</td>
<td>DIGOX</td>
</tr>
<tr>
<td>DIGOXIN SOLUTION 0.05 MG/ML</td>
<td>DIGOXIN SOLUTION 0.25 MG/ML</td>
</tr>
<tr>
<td>DIGOXIN TAB 125 MCG</td>
<td>DIGOXIN TAB 250 MCG</td>
</tr>
<tr>
<td>DIPHENOXYLATE-ATROPINE</td>
<td>DIPYRIDAMOLE TAB 25 MG</td>
</tr>
<tr>
<td>DIPYRIDAMOLE TAB 50 MG</td>
<td>DIPYRIDAMOLE TAB 75 MG</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Drug Name</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td>INDOMETHACIN ER</td>
<td>JINTELI</td>
</tr>
<tr>
<td>LONOX</td>
<td>MEGACE ES</td>
</tr>
<tr>
<td>MEGESTROL ACETATE SUSPENSION 40 MG/ML</td>
<td>MEGESTROL ACETATE SUSPENSION 400 MG/10ML</td>
</tr>
<tr>
<td>MEGESTROL ACETATE TAB 20 MG</td>
<td>MEGESTROL ACETATE TAB 40 MG</td>
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<tr>
<td>MENEST</td>
<td>MENOSTAR</td>
</tr>
<tr>
<td>METAXALONE 800 MG</td>
<td>METAXALONE TAB 800 MG</td>
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<tr>
<td>METHOCARBAMOL TAB 500 MG</td>
<td>METHOCARBAMOL TAB 750 MG</td>
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<tr>
<td>METHYLDOPA-HYDROCHLOROTHIAZIDE</td>
<td>NITROFURANTOIN</td>
</tr>
<tr>
<td>NITROFURANTOIN MACROCRYSTAL CAP 100 MG</td>
<td>NITROFURANTOIN MACROCRYSTAL CAP 50 MG</td>
</tr>
<tr>
<td>NITROFURANTOIN MONOHYD MACRO</td>
<td>NORPACE CR</td>
</tr>
<tr>
<td>ORPHENADRINE CITRATE ER</td>
<td>PHENOBARBITAL ELIXIR 20 MG/5ML</td>
</tr>
<tr>
<td>PHENOBARBITAL SOLUTION 20 MG/5ML</td>
<td>PHENOBARBITAL TAB 100 MG</td>
</tr>
<tr>
<td>PHENOBARBITAL TAB 15 MG</td>
<td>PHENOBARBITAL TAB 16.2 MG</td>
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<tr>
<td>PHENOBARBITAL TAB 30 MG</td>
<td>PHENOBARBITAL TAB 32.4 MG</td>
</tr>
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<td>PHENOBARBITAL TAB 60 MG</td>
<td>PHENOBARBITAL TAB 64.8 MG</td>
</tr>
<tr>
<td>PHENOBARBITAL TAB 97.2 MG</td>
<td>PERPHENAZINE-AMITRIPTYLINE</td>
</tr>
<tr>
<td>PHENADOZ SUPPOS 12.5 MG</td>
<td>PREFEST</td>
</tr>
<tr>
<td>PREMARIN RECON SOLN 25 MG</td>
<td>PREMARIN TAB 0.3 MG</td>
</tr>
<tr>
<td>PREMARIN TAB 0.45 MG</td>
<td>PREMARIN TAB 0.625 MG</td>
</tr>
<tr>
<td>PREMARIN TAB 0.9 MG</td>
<td>PREMARIN TAB 1.25 MG</td>
</tr>
<tr>
<td>PREMPhASE</td>
<td>PREMPro</td>
</tr>
<tr>
<td>PROMETHAZINE HCL 25 MG/ML</td>
<td>PROMETHAZINE HCL 50 MG/ML</td>
</tr>
<tr>
<td>PROMETHAZINE HCL SOLUTION 25 MG/ML</td>
<td>PROMETHAZINE HCL SOLUTION 50 MG/ML</td>
</tr>
<tr>
<td>PROMETHAZINE HCL SOLUTION 6.25 MG/5ML</td>
<td>PROMETHAZINE HCL SUPPOS 12.5 MG</td>
</tr>
<tr>
<td>PROMETHAZINE HCL SUPPOS 25 MG</td>
<td>PROMETHAZINE HCL SUPPOS 50 MG</td>
</tr>
<tr>
<td>PROMETHAZINE HCL SYRUP 6.25 MG/5ML</td>
<td>PROMETHAZINE HCL TAB 12.5 MG</td>
</tr>
</tbody>
</table>
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- PROMETHAZINE HCL TAB 25 MG
- PROMETHAZINE VC PLAIN
- PROMETHEGAN SUPPOS 25 MG
- SILENOR TAB 6 MG
- SURMONTIL
- THIORIDAZINE HCL TAB 100 MG
- THIORIDAZINE HCL TAB 50 MG
- TRIMETHOBENZAMIDE HCL CAP 300 MG
- ZOLPIDEM TARTRATE
- PROMETHAZINE HCL TAB 50 MG
- PROMETHAZINE-PHENYLEPHRINE
- PROMETHEGAN SUPPOS 50 MG
- SOMA TAB 250 MG
- THIORIDAZINE HCL TAB 10 MG
- THIORIDAZINE HCL TAB 25 MG
- TRIHEXYPHENIDYL HCL
- ZALEPLON
- ZOLPIDEM TARTRATE ER

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For patients greater than or equal to 65 years, coverage determination is approved for FDA-approved indications not otherwise excluded from Part D AND prescriber must acknowledge that medication benefit outweighs potential risks.

AGE RESTRICTION
For patients less than or equal to 64 years, claim will automatically pay.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
HUMIRA

PRODUCT(s) AFFECTED
- HUMIRA
- HUMIRA PEN-CROHNS STARTER
- HUMIRA PEN-PSORIASIS STARTER

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Active infection (including TB), concurrent use with other biologics.

REQUIRED MEDICAL INFORMATION
Screening for latent TB infection and assessment for Hep B risk. For positive latent TB, patient must have completed treatment or is currently receiving treatment for LTBI. HBV infection ruled out or treatment initiated for positive infection. Rheumatoid arthritis - Must have one of following: 1) inadequate response to methotrexate (MTX), 2) inadequate response to another nonbiologic DMARD (e.g., leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX, 3) intolerance or contraindication to at least 2 nonbiologic DMARDs or, 4) use Humira as first-line therapy with MTX for severely active RA. Polyarticular JIA - Must have an inadequate response to at least one nonbiologic DMARD or intolerance/contraindication to at least 2 nonbiologic DMARDs. Psoriatic arthritis with predominantly peripheral symptoms - Must have an inadequate response to at least 1 nonbiologic DMARD unless contraindicated or intolerant to such therapy. For plaque psoriasis - Must have more than 5% BSA affected or has crucial body areas (e.g., feet, hands, face, or genitals) affected. Must have an inadequate response to at least a 60-day trial of 2 conventional therapies (e.g., phototherapy, calcipotriene, MTX, acitretin) unless contraindicated or intolerant to such therapies. Crohn's disease - Must have an inadequate response to at least a 60-day trial of 2 conventional therapies (e.g., sulfasalazine, mesalamine, azathioprine, corticosteroids) unless contraindicated or intolerant to such therapies OR an inadequate response or intolerance to either Remicade or Cimzia.

AGE RESTRICTION
For psoriasis, patient must be 18 years of age and older
PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 3 months for Crohn's disease and plan year for all other indications  Renewal: Plan Year

OTHER CRITERIA
For re-authorization, patient's condition must have improved or stabilized.
**HYSINGLA**

**PRODUCT(s) AFFECTED**
HYSINGLA ER

**COVERED USES**
All FDA approved indications not otherwise excluded from Part D.

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Must have severe pain requiring around the clock long term opioid, AND all of these: 1- ONE of the following formulary opioid options, hydrocodone IR, oxycodone IR, morphine IR, hydromorphone IR, methadone, OR oxymorphone IR are ineffective, not tolerated or inadequate for controlling pain AND fentanyl patches are ineffective, not tolerated, or inadequate for controlling pain 2-Must discontinue all other around-the-clock opioids when initiated 3-Care plan/agreement for opioid therapy has been established 4-Pt advised of risks and provides informed consent for chronic opioid therapy 5-Pt assessed for all these (i) pain severity (ii) suitability of non-opioids (iii) physical & emotional functional status (iv) risk of or current aberrant drug behavior 5-Prescriber will monitor for signs of misuse, abuse and addiction during therapy AND ONE of these: A-Opioid naive/non-tolerant must start at 10mg twice day for 7 days before titrating up OR B-Opioid tolerant, receiving one of these doses per day for at least 1 week: 60mg oral morphine, 25mcg transdermal fentanyl/hr, 30mg oral oxycodone, 8mg oral hydromorphone, 25mg oral oxymorphone

**AGE RESTRICTION**
Not covered if under 18 years of age.

**PRESCRIBER RESTRICTION**
Prescriber is knowledgeable in the use of potent opioids for the management of chronic pain

**COVERAGE DURATION**
90 days

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
IBRANCE

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Appropriate diagnosis (used in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12/31/16

OTHER CRITERIA
N/A
ICLUSIG

PRODUCT(s) AFFECTED
ICLUSIG

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

EXCLUSION CRITERIA
None

REQUIRED MEDICAL INFORMATION
diagnosis trial and failure of another formulary TKI

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
365 days

OTHER CRITERIA
N/A
IMBRUVICA

PRODUCT(s) AFFECTED
IMBRUVICA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Supporting statement of diagnosis from the physician

AGE RESTRICTION
None

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
INCRELEX

PRODUCT(s) AFFECTED
INCRELEX

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Epiphyseal closure, IV administration of Increlex, active malignancy, use in neonates, concurrent use with GH therapy, patient has secondary causes of IGF-1 deficiency.

REQUIRED MEDICAL INFORMATION
Prior to starting therapy, a height greater than 3 SD below the mean for chronological age and sex, and an IGF-1 level greater than or equal to 3 SD below the mean for chronological age and gender. One stimulation test showing patient has a normal or elevated GH level. For continuation of therapy, patient grew more than 2.5 cm/year.

AGE RESTRICTION
Between 2 and 20 years of age

PRESCRIBER RESTRICTION
Endocrinologist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
ITRACONAZOLE

PRODUCT(s) AFFECTED
ITRACONAZOLE CAP 100 MG

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
A. ventricular dysfunction (e.g., congestive heart failure (CHF) or history of CHF) do not use for onychomycosis. B. If the patient is taking/receiving any of the following: concomitant use with drugs metabolized by CYP3A4 (e.g., cisapride, dofetilide, pimozide, quinidine)

REQUIRED MEDICAL INFORMATION
Patients with a diagnosis of blastomycosis, pulmonary or extrapulmonary OR patients with a diagnosis of histoplasmosis, including chronic cavitary pulmonary disease or disseminated, non-meningeal histoplasmosis OR patients with a diagnosis of aspergillosis, pulmonary or extrapulmonary OR patients with a diagnosis of onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium) OR patients with a diagnosis of onychomycosis of the fingernail due to dermatophytes (tinea unguium). For onychomycosis, diagnosis has been confirmed with a fungal diagnostic test (e.g., KOH preparation, fungal culture, or nail biopsy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 weeks

OTHER CRITERIA
N/A
IVIG

PRODUCT(s) AFFECTED
- CARIMUNE NF
- GAMMAGARD S/D
- GAMMAPLEX
- GAMUNEX-C

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
IgA deficiency with antibody formation and a history of hypersensitivity. History of anaphylaxis or severe systemic reaction to human immune globulin. Presence of risk factor(s) for acute renal failure, unless the patient will receive IGIV products at the minimum concentration available and at the minimum rate of infusion practicable OR Gamunex/Gamunex-C is administered SC for PID.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
CIDP diagnosis by a neurologist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Gamunex/Gamunex-C: if administered SC outside of a controlled healthcare setting, appropriate treatment (eg, anaphylaxis kit) should be available for managing an acute hypersensitivity reaction.
PRODUCT(s) AFFECTED
KALYDECO

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Cystic Fibrosis (Initial): Diagnosis of CF. Confirmed G551D mutation. (Reauthorization): Documentation of one of the following while on Kalydeco therapy: Improved lung function or stable lung function.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12/31/16

OTHER CRITERIA
N/A
KEYTRUDA

PRODUCT(s) AFFECTED
KEYTRUDA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
None

REQUIRED MEDICAL INFORMATION
appropriate diagnosis, trial/failure of Yervoy, and if BRAF V600 mutation positive must also try a BRAF inhibitor.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
365 days

OTHER CRITERIA
N/A
KINERET

PRODUCT(s) AFFECTED
KINERET

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Active infection, concurrent therapy with other biologics.

REQUIRED MEDICAL INFORMATION
Must have one of following: 1) inadequate response to methotrexate (MTX), 2) inadequate response to another nonbiologic DMARD (e.g., leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX, 3) intolerance or contraindication to at least 2 nonbiologic DMARDs or, 4) use Kineret as first-line therapy with MTX for severely active RA. For Diagnosis of CAPs, Kineret will be approved.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For re-authorization, patient's condition must have improved or stabilized.
PRODUCT(s) AFFECTED
KORLYM

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

EXCLUSION CRITERIA
Pregnancy

REQUIRED MEDICAL INFORMATION
Supporting statement of diagnosis and relevant medical information from physician

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
- KUVAN PACKET 500 MG
- KUVAN TAB SOL 100 MG

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Blood phenylalanine (Phe) levels. Pretreatment blood phenylalanine (Phe) levels greater than 10mg/dL if the patient is older than 12 years of age or greater than 6mg/dL if less than or equal to 12 years of age. Response to a therapeutic trial (greater than or equal to a 30% reduction in blood Phe levels) is required for long-term authorization.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
1 month initial, plan year on renewal

OTHER CRITERIA
Blood Phe levels should be checked after 1 week of therapy and periodically up to one month during a therapeutic trial.
LETAIRIS

PRODUCT(s) AFFECTED
LETAIRIS

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Pregnancy

REQUIRED MEDICAL INFORMATION
NYHA class II or III symptoms. PAH been confirmed by right heart catheterization.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
UD or two appropriate contraceptive methods will be used for women of childbearing potential.
LEUKINE

PRODUCT(s) AFFECTED
- LEUKINE 250 MCG
- LEUKINE RECON SOLN 250 MCG

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Administration within 24 hours preceding or following chemotherapy or radiotherapy, hypersensitivity to yeast-derived products. For prophylaxis of febrile neutropenia: use to increase the chemotherapy dose intensity or dose schedule above established regimens. For treatment of febrile neutropenia, when patient receives Neulasta during the current chemotherapy cycle. For AML only, excessive (greater than or equal to 10%) leukemic myeloid blasts in the bone marrow or peripheral blood.

REQUIRED MEDICAL INFORMATION
For patients with nonmyeloid malignancies receiving myelosuppressive chemotherapy: Leukine may be used for the prevention of chemotherapy-induced febrile neutropenia if the patient experienced febrile neutropenia with a prior chemotherapy cycle OR the patient is at high risk (greater than 20%) or intermediate risk (10-20%) for developing febrile neutropenia. Patients at low risk (less than 10%) for developing febrile neutropenia may also receive Leukine for prophylaxis if there is a significant risk for serious medical consequences due to febrile neutropenia and the intent of chemotherapy is to prolong survival or cure the disease. Leukine is allowable for the treatment of febrile neutropenia in patients who have received prophylaxis with Leukine (or Neupogen) OR in patients at risk for infection-related complications. All patients must receive baseline and regular monitoring of complete blood counts and platelet counts.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
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**COVERAGE DURATION**
6 months

**OTHER CRITERIA**
N/A
LIDOCAINE TD

PRODUCT(s) AFFECTED
LIDOCAINE PATCH 5 %

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

EXCLUSION CRITERIA
None

REQUIRED MEDICAL INFORMATION
Supporting statement of diagnosis from the physician

AGE RESTRICTION
None

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
12/31/16

OTHER CRITERIA
For the FDA-labeled indication of post-herpetic neuralgia, no additional criteria are required to be met. For diabetic neuropathy: the patient must have previous use and inadequate response or intolerance to any ONE neuropathic pain medication, including (but not limited to) Cymbalta and Lyrica that are labeled for neuropathic pain.
PRODUCT(s) AFFECTED
- LEUPROLIDE ACETATE KIT 1 MG/0.2ML - LUPRON DEPOT
- LUPRON DEPOT-PED KIT 11.25 MG - LUPRON DEPOT-PED KIT 15 MG

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Drug is excluded in Pregnant or breast feeding female patients.

REQUIRED MEDICAL INFORMATION
For prostate cancer: 1) allow therapy for locally advanced, recurrent or metastatic disease, 2) allow initial long-term neoadjuvant/concurrent/adjuvant ADT in combination with radiation therapy for clinically localized disease with high risk of recurrence, 3) allow initial short-term neoadjuvant/concurrent/adjuvant ADT in combination with radiation therapy for clinically localized disease with intermediate risk of recurrence or with brachytherapy for clinically localized disease with high risk of recurrence, or 4) allow neoadjuvant therapy in conjunction with brachytherapy in patients with a large prostate to shrink the prostate to an acceptable size for brachytherapy. For endometriosis: patient must have completed a trial and failure of at least 2 of the following therapies: oral contraceptives, medroxyprogesterone, or danazol.

AGE RESTRICTION
For CPP, patient must be less than 12 years old if female and less than 13 years old if male.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Prostate CA: 1 yr but 6 mos for short term use, Fibroids: 3 mos, Endometriosis: 6 mos, CPP: 1 yr

OTHER CRITERIA
N/A
LYNPARZA

PRODUCT(s) AFFECTED
LYNPARZA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Appropriate diagnosis and testing for BRCA mutation (deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA approved test) advanced ovarian cancer that has been treated with 3 or more prior lines of chemotherapy)

AGE RESTRICTION
none

PRESCRIBER RESTRICTION
none

COVERAGE DURATION
12/31/16

OTHER CRITERIA
none
METHYLPHENIDATES

PRODUCT(s) AFFECTED
- DAYTRANA PATCH 15 MG/9HR
- METADATE CD CAP ER 30 MG
- METADATE ER
- METHYLPHENIDATE HCL ER (CD) CAP ER 20 MG
- METHYLPHENIDATE HCL ER (CD) CAP ER 40 MG
- METHYLPHENIDATE HCL ER TAB ER 20 MG
- METHYLPHENIDATE HCL ER TAB ER 24H 27 MG
- METHYLPHENIDATE HCL ER TAB ER 24H 54 MG
- METHYLPHENIDATE HCL SOLUTION 5 MG/5ML
- METHYLPHENIDATE HCL TAB 20 MG
- METADATE CD CAP ER 20 MG
- METADATE CD CAP ER 40 MG
- METHYLPHENIDATE HCL ER (CD) CAP ER 10 MG
- METHYLPHENIDATE HCL ER (CD) CAP ER 30 MG
- METHYLPHENIDATE HCL ER (LA)
- METHYLPHENIDATE HCL ER TAB ER 24H 18 MG
- METHYLPHENIDATE HCL ER TAB ER 24H 36 MG
- METHYLPHENIDATE HCL SOLUTION 10 MG/5ML
- METHYLPHENIDATE HCL TAB 10 MG
- METHYLPHENIDATE HCL TAB 5 MG

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
MAOI concurrent use or within the last 14 days

REQUIRED MEDICAL INFORMATION
Sleep studies for narcolepsy diagnosis

AGE RESTRICTION
6 years of age and older
**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

Consider benefits of use versus the potential risks of serious cardiovascular events.
MOZOBIL

PRODUCT(s) AFFECTED
MOZOBIL

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months

OTHER CRITERIA
Mozobil is given in combination with granulocyte-colony stimulating factor
MYOZYME

PRODUCT(s) AFFECTED
MYOZYME

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis confirmed by DNA testing or an enzymatic assay showing a deficiency in acid alpha glucosidase.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
NAGLAZYME

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis confirmed by DNA testing or an enzymatic assay showing a deficiency in N-acetylgalactosamine activity. Patient must have at least one MPS VI symptom. For re-authorization of Naglazyme, patient must demonstrate improvement in walking and/or stair-climbing capacity.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
NEULASTA

PRODUCT(s) AFFECTED
- NEULASTA - NEULASTA DELIVERY KIT

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Treatment for febrile neutropenia, known hypersensitivity to filgrastim, use in the period 14 days before and 24 hours after administration of chemotherapy, use in patients with myeloid malignancy, use to increase the chemotherapy dose intensity or dose schedule beyond established regimens.

REQUIRED MEDICAL INFORMATION
For patients with non-myeloid malignancies receiving myelosuppressive chemotherapy: Neulasta may be used for the prevention of chemotherapy-induced febrile neutropenia if the patient experienced febrile neutropenia with a prior chemotherapy cycle OR the patient is at high risk (greater than 20%) or intermediate risk (10-20%) for developing febrile neutropenia. Patients at low risk (less than 10%) for developing febrile neutropenia may also receive Neulasta prophylaxis if there is a significant risk for serious medical consequences due to febrile neutropenia and the intent of chemotherapy is to prolong survival or cure the disease. All patients must receive baseline and regular monitoring of complete blood counts and platelet counts.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months

OTHER CRITERIA
N/A
NEUPOGEN

PRODUCT(s) AFFECTED
NEUPOGEN

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Administration within 24 hours preceding or following chemotherapy or radiotherapy, E coli hypersensitivity. For prophylaxis of febrile neutropenia: use to increase the chemotherapy dose intensity or dose schedule beyond established regimen. For treatment of febrile neutropenia, when patient receives Neulasta during the current chemotherapy cycle.

REQUIRED MEDICAL INFORMATION
For patients with nonmyeloid malignancies receiving myelosuppressive chemotherapy: Neupogen may be used for the prevention of chemotherapy-induced febrile neutropenia if the patient experienced febrile neutropenia with a prior chemotherapy cycle OR the patient is at high risk (greater than 20%) or intermediate risk (10-20%) for developing febrile neutropenia. Patients at low risk (less than 10%) for developing febrile neutropenia may receive Neupogen for prophylaxis if there is a significant risk for serious medical consequences due to febrile neutropenia and the intent of chemotherapy is to prolong survival or cure the disease. Neupogen is allowable for the treatment of febrile neutropenia in patients who have received prophylaxis with Neupogen (or Leukine) OR in patients at risk for infection-related complications. All patients must receive baseline and regular monitoring of complete blood counts and platelet counts.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Prior Authorization Criteria
Care N' Care Health Plan – Formulary ID: 16384 – Version 6
Effective Date: 1/1/2016

6 months

OTHER CRITERIA
N/A
NORTHERA

PRODUCT(s) AFFECTED
NORTHERA

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

EXCLUSION CRITERIA
None

REQUIRED MEDICAL INFORMATION
statement of diagnosis

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
365 days

OTHER CRITERIA
N/A
NUDEXTA

PRODUCT(s) AFFECTED
NUDEXTA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient has amyotrophic lateral sclerosis (ALS) OR multiple sclerosis (MS)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
NUVIGIL

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
If diagnosis of Shift Work Sleep Disorder frequently (5 times or more per month) AND experience excessive sleepiness while working. If diagnosis of mild obstructive sleep apnea/hypopnea syndrome and whether patient is using and compliant with an oral appliance

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
OCTREOTIDE

PRODUCT(s) AFFECTED
OCTREOTIDE ACETATE

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
**OPDIVO**

**PRODUCT(s) AFFECTED**
OPDIVO

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

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Diagnosis of unresectable or metastatic melanoma and disease progression following ipilimumab [Yervoy]) and testing for BRAF V600 mutation OR Diagnosis of metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy.

**AGE RESTRICTION**
none

**PRESCRIBER RESTRICTION**
none

**COVERAGE DURATION**
12/31/16

**OTHER CRITERIA**
none
OPSUMIT

PRODUCT(s) AFFECTED
OPSUMIT

COVERED USES
All FDA approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Supporting statement of diagnosis and relevant medical information from physician

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
ORAL FENTANYL

PRODUCT(s) AFFECTED
- ABSTRAL
- FENTANYL CITRATE LOZ HANDLE 1600 MCG
- FENTANYL CITRATE LOZ HANDLE 400 MCG
- FENTANYL CITRATE LOZ HANDLE 800 MCG
- LAZANDA
- FENTORAZY LAZANDA
- SUBSYS

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Patients taking strong or moderate cytochrome P450 3A4 inhibitor(s) (e.g., aprepitant, clarithromycin, diltiazem, erythromycin, fosamprenavir, fluconazole,itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, verapamil) who will not be monitored or have dosing adjustments made if necessary.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
16 years of age and older (Actiq), 18 years of age and older all others

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 months
OTHER CRITERIA

N/A
ORENCEIA

PRODUCT(s) AFFECTED
ORENCEIA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Active infection (including TB). Concurrent therapy with other biologics.

REQUIRED MEDICAL INFORMATION
Screening for latent TB infection and assessment for Hep B risk. For positive latent TB, patient must have completed treatment or is currently receiving treatment for LTBI. HBV infection ruled out or treatment initiated for positive infection. Rheumatoid arthritis - Must have one of following: 1) inadequate response to methotrexate (MTX), 2) inadequate response to another nonbiologic DMARD (e.g., leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX, 3) intolerance or contraindication to at least 2 nonbiologic DMARDs or, 4) use Orenicia as first-line therapy with MTX for severely active RA. Polyarticular JIA - Must have an inadequate response to at least one nonbiologic DMARD or intolerance/contraindication to at least 2 nonbiologic DMARDs.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For re-authorization, patient's condition must have improved or stabilized.
OSTEOPOROSIS

PRODUCT(s) AFFECTED
FORTEO

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient meets one of the following criteria: 1) Patient has experienced a prior fragility fracture, or 2) Patient had an inadequate response to an adequate trial of a bisphosphonate (one year) or patient has a contraindication or intolerance to bisphosphonate trial, or 3) Patient has 2 of the following risk factors for fracture: advanced age, parental history of fracture, low body mass index, current smoker, chronic alcohol use, rheumatoid arthritis, chronic steroid use, or other secondary cause of osteoporosis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
METHOXSALEN RAPID

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Aphakia, melanoma, or invasive squamous cell carcinoma

REQUIRED MEDICAL INFORMATION
The patient must be diagnosed with cutaneous T-cell lymphoma OR psoriasis AND if the diagnosis is psoriasis, the patient must have previous inadequate treatment response or intolerance or contraindication to at least one topical steroid.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Dermatologist or Oncologist or affiliated with a dermatologist/oncologist practice

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
<table>
<thead>
<tr>
<th>PRODUCT(s) AFFECTED</th>
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<tbody>
<tr>
<td>ABELCET</td>
<td>ABRAXANE</td>
</tr>
<tr>
<td>ACETYLHYDROISOLEN SOLUTION 10 %</td>
<td>ACETYLHYDROISOLEN SOLUTION 20 %</td>
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<td>ACETYLHYDROISOLEN SOLUTION 20 %</td>
<td>ACETYLHYDROISOLEN SOLUTION 50 MG/ML</td>
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<td>AMBISOME</td>
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<td>AMIFOSTINE</td>
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<td>AMINOSYN II/ELECTROLYTES</td>
<td>AMINOSYN M</td>
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<td>AZACITIDINE</td>
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<td>BICNU</td>
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<td>Product Code</td>
<td>Description</td>
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<td>COLISTIMETHATE SODIUM RECON SOLN 150 MG</td>
<td>COSMEGEN</td>
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<td>CROMOLYN SODIUM NEBU SOLN 20 MG/2ML</td>
<td>CYCLOSPORINE 100 MG</td>
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<td>CYCLOSPORINE CAP 100 MG</td>
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<td>CYCLOSPORINE SOLUTION 50 MG/ML</td>
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<td>DAUNORUBICIN HCL</td>
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<td>DACARBAZINE RECON SOLN 200 MG</td>
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<td>DAUNOXOME</td>
<td>DECITABINE</td>
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<td>DEPO-PROVERA SUSPENSION 400 MG/ML</td>
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- DEXTROSE SOLUTION 10 %
- DEXTROSE SOLUTION 5 %
- DOXIL
- DURAMORPH
- ELIGARD
- ELITEK
- ELLENCE
- EMEND CAP 80 & 125 MG
- ENGERIX-B
- EPIRUBICIN HCL SOLUTION 200 MG/100ML
- EPIRUBICIN HCL SOLUTION 50 MG/25ML
- EPIRUBICIN HCL SOLUTION 200 MG/100ML
- ETOPOPHOS
- ETOPOSIDE SOLUTION 1 GM/50ML
- ETOPOSIDE SOLUTION 100 MG/5ML
- ETOPOSIDE SOLUTION 500 MG/25ML
- FASLODEX
- FIRMAGON
- FLEBOGAMMA DIF SOLUTION 10 GM/100ML
- FLEBOGAMMA DIF SOLUTION 20 GM/200ML
- FLEBOGAMMA DIF SOLUTION 5 GM/50ML
- FLEBOGAMMA DIF SOLUTION 5 GM/50ML
- FLEBOGAMMA DIF SOLUTION 20 GM/200ML
- FLUDARABINE PHOSPHATE
- FLUOROURACIL SOLUTION 1 GM/20ML
- FLUOROURACIL SOLUTION 2.5 GM/50ML
- FLUOROURACIL SOLUTION 5 GM/100ML
- FLUOROURACIL SOLUTION 500 MG/10ML
- FOSCARNET SODIUM
- FREAMINE HBC
- GAMMAKED
- GANCICLOVIR SODIUM
- GENGRAF
- GRANISETRON HCL
- HYDROMORPHONE HCL PF
- HYDROMORPHONE HCL SOLUTION 10 MG/ML
- HYDROMORPHONE HCL SOLUTION 50 MG/5ML
- HYDROMORPHONE HCL SOLUTION 10 MG/ML
- HYDROMORPHONE HCL SOLUTION 50 MG/5ML
- HEPATAMINE
- HERCEPTIN
- IDARUBICIN HCL
- IBANDRONATE SODIUM SOLUTION 3 MG/3ML
- IDAMYCIN PFS
- IFOSFAMIDE
- IMOVAX RABIES
- INTRALIPID
- INTRON A
- IPRATROPIUM BROMIDE SOLUTION 0.02 %
- IPRATROPIUM-ALBUTEROL
- IRINOPHARM HCL SOLUTION 100 MG/5ML
- IRINOCAN HCL SOLUTION 40 MG/2ML
- ISTODAX
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<th>Medication</th>
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<tr>
<td>IXEMPRA KIT</td>
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<td>LEUCOVORIN CALCIUM RECON SOLN 100 MG</td>
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<tr>
<td>LEVOLEUCOVORIN CALCIUM</td>
<td>MELPHALAN HCL</td>
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<tr>
<td>MESNA</td>
<td>METHOTREXATE SODIUM</td>
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<td>MIRCERA SOLN PRSRY 100 MCG/0.3ML</td>
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<td>MITOXANTRONE HCL</td>
<td>MUSTARGEN</td>
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<td>MYCOPHENOLATE MOFETIL</td>
<td>MYCOPHENOLIC ACID</td>
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<td>NEPHRAMINE</td>
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<td>NULOJIX</td>
<td>ONCASPAR</td>
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<tr>
<td>ONDANSETRON</td>
<td>ONDANSETRON HCL 4 MG</td>
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<td>OXALIPLATIN</td>
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<td>PAMIDRONATE DISODIUM</td>
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<td>PREMASOL</td>
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- PROGRAF SOLUTION 5 MG/ML
- PROSOL
- PULMOZYME
- RAPAMUNE SOLUTION 1 MG/ML
- REMODULIN
- SANDIMMUNE CAP 25 MG
- SIMULECT
- SIROLIMUS TAB 1 MG
- TPN ELECTROLYTES
- TACROLIMUS CAP 1 MG
- TAXOTERE
- THYMAGLOBULIN
- TOPOSAR
- TORISEL
- TREANDA
- TRELSTAR DEPOT MIXJECT
- TRELSTAR MIXJECT
- TRISEREX
- UVADEX
- VELCADE
- VINBLASTINE SULFATE RECON SOLN 10 MG
- VINCRIKTION SULFATE SOLUTION 1 MG/ML
- VINORELBINE TARTRATE
- ZOLEDRONIC ACID CONC 4 MG/5ML

**DETAILS**
This drug may be covered under Medicare Part B or D depending on the circumstances. Information may need to be submitted describing the use and setting of the drug to make the
determination.
PRODUCT(s) AFFECTED
- PEGASYS
- PEGASYS PROCLICK

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Decompensated liver disease. Autoimmune hepatitis. Concomitant administration of didanosine with ribavirin in patients coinfected with HIV.

REQUIRED MEDICAL INFORMATION
Diagnosis of hepatitis C for initial therapy with Sovaldi in patients with genotype 3, 4, 5, or 6 OR retreatment of genotypes 2,3,4,5, or 6. OR Diagnosis of chronic hepatitis B and evidence of hepatitis B viral replication and patient has been serum hepatitis B surface antigen (HBsAg)-positive for at least 6 months.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ID specialist, Gastroenterologist, Oncologist

COVERAGE DURATION
HCV: 12 weeks to 72 weeks total depending on genotype and initial vs. renewal therapy. HBV: 48 weeks.

OTHER CRITERIA
Monitor for evidence of depression.
PEGINTRON

PRODUCT(s) AFFECTED
- PEG-INTRON
- PEG-INTRON REDIPEN
- PEG-INTRON REDIPEN PAK 4
- PEGINTRON

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Decompensated liver disease. Autoimmune hepatitis. Concomitant administration of didanosine with ribavirin in patients coinfected with HIV.

REQUIRED MEDICAL INFORMATION
Diagnosis of hepatitis C for initial therapy with Sovaldi in patients with genotype 3, 4, 5, or 6 OR retreatment of genotypes 2,3,4,5, or 6. HCV: Prior to initiating therapy, detectable levels of HCV RNA in the serum.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ID specialist, Gastroenterologist, Oncologist

COVERAGE DURATION
12 weeks to a total 72 weeks depending on genotype and initial vs. renewal therapy.

OTHER CRITERIA
Monitor for evidence of depression.
PROLIA

PRODUCT(s) AFFECTED
PROLIA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Hypocalcemia

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Patient will be adequately supplemented with calcium and vitamin D.
PRODUCT(s) AFFECTED
PROMACTA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For new starts, at the time of diagnosis of ITP or hepatitis C infection associated thrombocytopenia, one of the following are required: 1) a pretreatment platelet count less than 30,000/microL or 2) a platelet count less than or equal to 50,000/microL with significant mucous membrane bleeding or risk factors for bleeding. Patients must be evaluated for other causes of thrombocytopenia and have had an insufficient response or intolerance to corticosteroids, or immunoglobulins, or splenectomy. For continuation of therapy, one of the following are required: 1) an increase in platelet count to greater than or equal to 50,000/microL or 2) an increase in platelet level that is sufficient to avoid clinically important bleeding after at least 4 weeks of Promacta at the maximum dose. For all patients receiving Promacta therapy, if platelets increase above 200,000/microL, therapy will be adjusted to maintain the minimal platelet count needed to reduce the risk for bleeding. Liver function must be assessed pretreatment and regularly throughout therapy. To continue Promacta therapy, alanine aminotransferase levels must not be greater than or equal to 3 times the upper limit of normal with any of the following characteristics: progressive, persistent, accompanied by increased bilirubin or symptoms of liver injury or evidence of hepatic decompensation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
6 month initial, 12 month renewal if adequate platelet response, 3 month w/o platelet response

OTHER CRITERIA
N/A
PROVIGIL

PRODUCT(s) AFFECTED
- MODAFINIL TAB 100 MG - MODAFINIL TAB 200 MG

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
If diagnosis of Shift Work Sleep Disorder frequently (5 times or more per month) AND experience excessive sleepiness while working. If diagnosis of mild obstructive sleep apnea/hypopnea syndrome and whether patient is using and compliant with an oral appliance

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
**PRODUCT(s) AFFECTED**
REGRANEX

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

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Diabetic Neuropathic Ulcers: Diabetic patient with ulcer wound. Treatment will be given in combination with ulcer wound care (eg, debridement, infection control, and/or pressure relief).

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Diabetic Neuropathic Ulcers: Maximum 5 months.

**OTHER CRITERIA**
N/A
RELISTOR

PRODUCT(s) AFFECTED
RELISTOR

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Mechanical gastrointestinal obstruction, known or suspected.

REQUIRED MEDICAL INFORMATION
A. Relistor is being prescribed for treatment of 1) opioid-induced constipation in adult patients with chronic non-cancer pain OR 2) opioid-induced constipation in adult patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. AND B. patient must have previous trial/failure of polyethylene glycol.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
4 Months

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
SILDENAFIL CITRATE TAB 20 MG

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Nitrate therapy

REQUIRED MEDICAL INFORMATION
Diagnosis of pulmonary arterial hypertension (PAH), (WHO Group 1). PAH been confirmed by right heart catheterization. If patient is an infant, PAH diagnosed by Doppler echocardiogram. The patient has had an inadequate response or intolerance to Adcirca.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
REVLIMID

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Pregnancy

REQUIRED MEDICAL INFORMATION
For active myeloma, patient meets one of the following: 1) Revlimid is used after at least one prior therapy or as salvage therapy. 2) Revlimid is used with dexamethasone as primary induction therapy or in combination with melphalan and prednisone in nontransplant candidates. 3) Revlimid is used as maintenance monotherapy following response to either stem cell transplant or primary induction therapy. For Low or Intermediate-1 Risk myelodysplastic syndrome (MDS): for those with 5q deletion, patients should have transfusion-dependent anemia or symptomatic anemia with clinically significant cytopenias. For those with non-5q deletion MDS and symptomatic anemia, patients should have failed to respond to epoetin alfa or darbepoetin or have a pretreatment serum erythropoietin levels greater than 500 mU/mL and a low probability of response to immunosuppressive therapy. For female patients of childbearing potential, pregnancy is excluded by 2 negative serum or urine pregnancy tests. For all patients, complete blood counts are monitored for hematologic toxicity while receiving Revlimid.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year
OTHER CRITERIA
Male and female patients of child-bearing potential should be instructed on the importance of proper utilization of appropriate contraceptive methods for Revlimid use. Patients should be monitored for signs and symptoms of thromboembolism.
RIBAVIRIN

PRODUCT(s) AFFECTED
- REBETOL SOLUTION 40 MG/ML
- RIBASPHERE
- RIBASPHERE RIBAPAK TAB 400 MG
- RIBAVIRIN CAP 200 MG
- RIBATAB TAB 600 MG
- RIBASPHERE RIBAPAK TAB 400 & 600 MG
- RIBASPHERE RIBAPAK TAB 600 MG
- RIBAVIRIN TAB 200 MG

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Hemoglobin less than 8.5 g/dL. Hemoglobinopathy. History of unstable heart disease. Creatinine clearance less than 50 mL/minute and unwilling to use modified dose of ribavirin. Pregnancy (self or partner). Unwilling to use effective contraception. Coadministration with didanosine in HIV coinfection patients.

REQUIRED MEDICAL INFORMATION
Chart notes / written medical summary documenting diagnosis of Chronic HCV are required. Recent lab reports documenting elevated HCV RNA are required, along with genotype.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
ID specialist, gastroenterologist, or oncologist

COVERAGE DURATION
12 weeks to a total 72 weeks depending on genotype and initial vs. renewal therapy.

OTHER CRITERIA
Patient has been instructed to practice effective contraception during therapy and for six months after stopping ribavirin therapy.
RITUXAN

PRODUCT(s) AFFECTED
RITUXAN

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
History of severe skin or infusion reaction with Rituxan than cannot be appropriately managed, use in combination with another biologic agent

REQUIRED MEDICAL INFORMATION
For rheumatoid arthritis (RA): an inadequate response to MTX or another nonbiologic DMARD if MTX is contraindicated or not tolerated except when RA is severely active and frontline Rituxan therapy is warranted AND an inadequate response to a TNF antagonist (unless contraindicated). For continuation of RA therapy, improvement in clinical symptoms (may include improvement in tender and swollen joint count, mobility, or stiffness, or delay in progression of disease) is required from the last treatment course, which was at least 16 weeks earlier. Hematologic malignancies must be positive for CD20. Rituxan must be used in combination with chemotherapy for mantle cell lymphoma (or other agents), Burkitt's lymphoma, lymphoblastic lymphoma, and AIDS-related B-cell lymphoma. Induction therapy for Burkitt's lymphoma. Prior to initiating therapy, prescriber must have assessed the patient's risk for hepatitis B and, if appropriate, ruled out or initiated treatment for hepatitis B.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year
OTHER CRITERIA
Monitored for pulmonary toxicity
SAMSCA

PRODUCT(s) AFFECTED
SAMSCA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Patients with anuria, patients requiring an urgent increase in serum sodium, patients unable to sense and respond to thirst, concomitant use of a strong CYP 3A inhibitor (e.g., clarithromycin, ketoconazole).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Samsca must be initiated or re-initiated in a hospital setting.
SANDOSTATIN LAR

PRODUCT(s) AFFECTED
SANDOSTATIN LAR DEPOT

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient received initial treatment with Sandostatin Injection (not the Depot form) for at least 2 weeks and treatment with Sandostatin Injection was effective and tolerable.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
SEROSTIM

PRODUCT(s) AFFECTED
SEROSTIM

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Acute critical illness, active malignancy.

REQUIRED MEDICAL INFORMATION
Patient is on concurrent antiretroviral therapy and alternative causes of wasting have been ruled out or treated appropriately. For continuation of therapy, patients treated for 12 or more weeks with Serostim must show a response to therapy (body mass index has improved or stabilized).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 weeks

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
SIMPONI SOLN PRSYR 50 MG/0.5ML

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Active infection (including TB). Concurrent therapy with other biologics.

REQUIRED MEDICAL INFORMATION
Screening for latent TB infection and assessment for Hep B risk. For positive latent TB, patient must have completed treatment or is currently receiving treatment for LTBI. HBV infection ruled out or treatment initiated for positive infection. Rheumatoid arthritis - Must have one of following: 1) inadequate response to methotrexate (MTX), 2) inadequate response to another nonbiologic DMARD (e.g., leflunomide, hydroxychloroquine, sulfasalazine) if contraindicated or intolerant to MTX, 3) intolerance or contraindication to at least 2 nonbiologic DMARDs or, 4) use Simponi as first-line therapy with MTX for severely active RA. Ankylosing spondylitis - Inadequate response or intolerance/contraindication to at least 2 NSAIDs.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For re-authorization, patient's condition must have improved or stabilized.
PRODUCT(s) AFFECTED
SOVALDI

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

EXCLUSION CRITERIA
None

REQUIRED MEDICAL INFORMATION
Must have genotype 1,2,3,4,5, or 6

AGE RESTRICTION
Patient must be age 18 or over.

PRESCRIBER RESTRICTION
Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist

COVERAGE DURATION
12,16,24, or 48 wks based on genotype, cirrhosis status, transplant status, & previous/concurrent tx

OTHER CRITERIA
For genotypes 2,3, 4, 5, and 6 patient must be taking ribavirin with Sovaldi.
SOMATULINE DEPOT

PRODUCT(s) AFFECTED
SOMATULINE DEPOT

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
SOMAVERTR

PRODUCT(s) AFFECTED
- SOMAVERTR RECON SOLN 10 MG
- SOMAVERTR RECON SOLN 15 MG
- SOMAVERTR RECON SOLN 20 MG

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
IV administration of Somavert, concomitant use of Sandostatin or Somatuline.

REQUIRED MEDICAL INFORMATION
Diagnosis of acromegaly was confirmed by an elevated IGF-1 level or elevated GH level with a glucose tolerance test. Patient has tried and failed at least a 3 month trial of Sandostatin or Somatuline. For renewal, reduction in IGF-1 level from baseline.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Endocrinologist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
SORIATANE

PRODUCT(s) AFFECTED
ACITRETIN

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Severely impaired liver function, severely impaired kidney function, chronic abnormally elevated blood lipid values, currently taking methotrexate or tetracycline.

REQUIRED MEDICAL INFORMATION
1. If the patient is female and able to bear children (e.g., no hysterectomy, not reached menopause, has achieved menses). AND 2. the patient is unresponsive to other therapies for this diagnosis OR the other therapies for the treatment of this diagnosis are contraindicated due to the clinical condition of the patient AND 3. pregnancy has been excluded as confirmed by 2 negative urine or serum pregnancy tests with a sensitivity of at least 25 mIU/mL. AND 4. the patient has chosen to use any of the following methods of contraception: one primary form (e.g., tubal ligation, partner’s vasectomy, intrauterine devices, birth control pills, injectable/implantable/insertable/topical hormonal birth control products) plus one secondary form (e.g., diaphragms, latex condoms, cervical caps) used in combination with a spermicide OR absolute abstinence AND 5. the patient has agreed to use her chosen form of contraception for at least 1 month before initiation of acitretin therapy, during acitretin therapy, and for at least 3 years after discontinuation of therapy AND 6. the patient has been advised that ethanol must not be ingested by female patients during acitretin treatment and for 2 months following therapy AND 7. the patient will have a negative pregnancy test on a monthly basis.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
Plan Year

OTHER CRITERIA
Female patient or guardian signed a Patient Agreement/Informed Consent.
STELARA

PRODUCT(s) AFFECTED
- STELARA SOLN PRSYR 45 MG/0.5ML
- STELARA SOLN PRSYR 90 MG/ML

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Active infection (including tuberculosis), concurrent use with other biologics

REQUIRED MEDICAL INFORMATION
Screening for latent tuberculosis. If results are positive, patient must have completed treatment or is currently receiving treatment for latent tuberculosis. Must have more than 10% BSA affected or has crucial body areas (e.g., feet, hands, face) affected. Patient must have an inadequate response to at least a 60-day trial of 2 conventional therapies (e.g., phototherapy, calcipotriene, methotrexate, acitretin) unless contraindicated or intolerant to such therapies. Approved for diagnosis of active psoriatic arthritis.

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For renewal, patient's condition must have improved or stabilized.
STIVARGA

PRODUCT(s) AFFECTED
STIVARGA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Supporting statement of diagnosis from the physician

AGE RESTRICTION
None

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
STRATTERA

PRODUCT(s) AFFECTED
STRATTERA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
MAOI concurrent use or within the last 14 days

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
6 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Monitor for suicidality, clinical worsening, changes in behavior, blood pressure changes, heart rate changes, liver injury.
SYMLIN

PRODUCT(s) AFFECTED
- SYMLINPEN 120
- SYMLINPEN 60

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Severe hypoglycemia that required assistance during the past 6 months, gastroparesis, patient requires drug therapy to stimulate gastrointestinal motility, the presence of hypoglycemia unawareness (i.e., inability to detect and act upon the signs or symptoms of hypoglycemia).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
The patient must have inadequate glycemic control (HbA1c greater than 7% but less than 9%) at initiation of therapy, patient currently receiving optimal mealtime insulin therapy. If taking Symlin in previous 6 months, patient demonstrated a reduction in HbA1c since initiating Symlin therapy.
TESTOSTERONES

PRODUCT(s) AFFECTED
- ANDRODERM
- FORTESTA
- TESTOSTERONE GEL 25 MG/2.5GM (1%)
- AXIRON
- TESTIM

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Female, prostate cancer, breast cancer.

REQUIRED MEDICAL INFORMATION
Before the start of testosterone therapy patient has (or patient currently has) a confirmed low testosterone level (i.e. total testosterone less than 300 ng/dL, free or bioavailable, testosterone less than 5 ng/dL) or absence of endogenous testosterone.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
THALOMID

PRODUCT(s) AFFECTED
THALOMID

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Pregnancy

REQUIRED MEDICAL INFORMATION
For active myeloma, patient meets one of the following: 1) Thalomid is used as salvage or palliative therapy. 2) Thalomid is used for newly diagnosed disease or as primary induction therapy in combination with dexamethasone or in combination with melphalan and prednisone in nontransplant candidates. 3) Thalomid is used as maintenance monotherapy following response to either stem cell transplant or primary induction therapy. For female patients of childbearing potential, pregnancy is excluded by a negative pregnancy test.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Patients are monitored for signs and symptoms of thromboembolism. Male and female patients of child-bearing potential are instructed on the importance of proper utilization of appropriate contraceptive methods.
TOPICAL IMMUNOSUPPRESSANT

PRODUCT(s) AFFECTED
- ELIDEL - TACROLIMUS OINTMENT 0.03 %
- TACROLIMUS OINTMENT 0.1 %

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
A. The diagnosis is documented as atopic dermatitis or eczema. B. AND patients must be at least 2 years of age C. AND patients who have completed a documented trial and failure of at least two medium or higher potency topical steroids or have documented intolerance or unresponsiveness to medium or higher potency topical steroids D. AND patients have been advised that Elidel and tacrolimus should only be used to treat the immediate problem and then should be stopped when the condition improves.

AGE RESTRICTION
Elidel and tacrolimus 0.03%: 2 years of age and older, tacolimus 0.1%: 16 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
TRACLEER

PRODUCT(s) AFFECTED
TRACLEER

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
AST/ALT level greater than 3 times upper limit of normal (ULN). Pregnancy. Concomitant use of cyclosporine A or glyburide.

REQUIRED MEDICAL INFORMATION
PAH confirmed by right heart catheterization. NYHA Class II-IV symptoms.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Female patients of childbearing potential must use more than one method of contraception concurrently.
TYSABRI

PRODUCT(s) AFFECTED
TYSABRI

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Tysabri will be used as monotherapy. For MS, inadequate response or intolerance to other MS therapies.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
MS - 12 months. CD, initial - 3 months, renewal - 12 months.

OTHER CRITERIA
For Crohn's disease renewal, patient's condition has improved or stabilized on treatment.
TYZEKA

PRODUCT(s) AFFECTED
TYZEKA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
A. The patient has been diagnosed with chronic hepatitis B. B. AND the patient has evidence of a positive HBsAg (+ or -) serological marker for greater than 6 months OR evidence by a liver biopsy showing chronic hepatitis. C. AND the patient has a Hepatitis B viral load greater than 20,000 IU/mL (100,000 copies per mL) except if for HBeAg-negative HBV, the viral load is greater than 2,000 IU per mL (10,000 copies per mL). D. AND the patient has elevations in liver aminotransferases (ALT or AST) that are two (2) times greater than normal OR normal liver aminotransferase (ALT or AST) levels with evidence of significant disease found on biopsy. E. AND the patient has been tested for HIV and is negative. F. AND if the patient has received previous Tyzeka treatment, there is documented clinical improvement shown by a drop in viral load or reduction in the patient's liver aminotransferases. G. AND the patient is not receiving duplicate therapy that includes Baraclude, Epivir and/or Intron A. H. AND evidence of diagnosis, serological markers or liver biopsy, viral load, and liver aminotransferases is documented in patient's chart.

AGE RESTRICTION
16 years of age and older

PRESCRIBER RESTRICTION
Infectious Disease specialist or Gastroenterologist or affiliated with an infectious disease or gastroenterology practice or a primary care physician with experience in treating HBV
Prior Authorization Criteria
Care N' Care Health Plan – Formulary ID: 16384 – Version 6
Effective Date: 1/1/2016

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
N/A
VIMPAT

PRODUCT(s) AFFECTED
VIMPAT

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Supporting statement of diagnosis from the physician

AGE RESTRICTION
None

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
VPRIV

PRODUCT(s) AFFECTED
VPRIV

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Concomitant use of miglustat (Zavesca)

REQUIRED MEDICAL INFORMATION
Diagnosis confirmed by bone marrow histology, DNA testing, or measurement of beta-glucocerebrosidase enzyme activity of less than 30 percent. Patient must have at least one of the following conditions as a result of Type 1 Gaucher disease: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly. Patients who have previously received 24 months of VPRIV therapy must have one of the following responses to continue therapy: 1) A decrease in liver and spleen volume 2) An increase in platelet count, or 3) An increase in hemoglobin concentration.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
XENAZINE

PRODUCT(s) AFFECTED
XENAZINE

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Patients with untreated or inadequately treated depression or who are actively suicidal, history of hepatic disease, use in combination with MAO inhibitors or reserpine (or it has been less than 20 days since reserpine was discontinued).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
XGEVA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Uncorrected hypocalcemia

REQUIRED MEDICAL INFORMATION
1.) Patient has bone metastases from a solid tumor. To prevent hypocalcemia, patients will receive concurrent calcium and vitamin D supplementation as needed. OR 2.) Patient has or giant cell tumor of the bone that is unresectable or where surgical resection is likely to result in severe morbidity. OR 3.) Patient has hypercalcemia of malignancy refractory to bisphosphonate therapy

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
XIFAXAN

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years of age and older (Xifaxan 550mg)

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Hepatic encephalopathy-6 months

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
XOLAIR

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient must meet all of the following criteria for Xolair use: 1) Patient has evidence of reversible disease (demonstrates at least 20 percent improvement in PEF with a short-acting bronchodilator challenge). 2) Patient has experienced two or more asthma exacerbations per month within the last three months. 3) Patient had a positive skin test to at least one perennial aeroallergen. 4) Baseline IgE level at or above 30 IU/mL. 5) Patient's asthma is inadequately controlled despite adherent use of inhaled corticosteroids. 6) Patient had an inadequate response to a trial of a leukotriene modifier or long-acting beta2-agonist (unless patient demonstrates intolerance to the therapeutic trial).

AGE RESTRICTION
12 years of age and older

PRESCRIBER RESTRICTION
Pulmonologist, allergist or immunologist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
To continue therapy, patients must demonstrate an improvement in asthma control with use of Xolair.
XTANDI

PRODUCT(s) AFFECTED
XTANDI

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Supporting statement of diagnosis from the physician and prior trial and failure of docetaxel

AGE RESTRICTION
None

PRESCRIBER RESTRICTION
None

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
XYREM

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
If the patient is taking/receiving any of the following: anxiolytics, sedatives, hypnotics, barbiturates, benzodiazepines or ethanol.

REQUIRED MEDICAL INFORMATION
A. The diagnosis is documented as excessive daytime sleepiness with symptoms that limit their ability to perform normal daily activities OR the diagnosis is documented as cataplexy (a condition characterized by weak or paralyzed muscles) in patients with narcolepsy. C. AND if the patient has received prior treatment with Xyrem, the patient must experience a decrease in daytime sleepiness and/or cataplexy in a narcoleptic patient.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
3 months

OTHER CRITERIA
N/A
ZAVESCA

PRODUCT(s) AFFECTED
ZAVESCA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Severe renal impairment. Pregnancy.

REQUIRED MEDICAL INFORMATION
Diagnosis confirmed by bone marrow histology, DNA testing, or b-glucocerebrosidase enzyme assay (enzyme activity less than 30 percent). Trial of enzyme replacement therapy (ERT) or ERT is not a therapeutic option (eg, allergy, poor venous access). Female patients of childbearing age will use an effective method of contraception. Female patients of childbearing age will be educated about the potential hazards associated with Zavesca use in pregnancy (ie, potential harm to fetus). Must demonstrate a decrease in liver and spleen volume and/or increase in platelet count and/or increase in Hgb concentration in patients who received at least 24 months of Zavesca therapy.

AGE RESTRICTION
18 years of age and older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
ZORBTIVE

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
Active malignancy (newly diagnosed or recurrent), acute critical illness due to complications following open heart or abdominal surgery, accidental trauma or acute respiratory failure

REQUIRED MEDICAL INFORMATION
For continuation of therapy, patient show a response to Zorbtive therapy (e.g., requirements for nutritional support have decreased or the patient's weight has stabilized or increased).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
4 weeks initial, 4 weeks renewal (up to a lifetime maximum of 8 weeks)

OTHER CRITERIA
N/A
ZYTIGA

PRODUCT(s) AFFECTED
ZYTIGA

COVERED USES
All FDA approved indications not otherwise excluded from Part D

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Used in combination with prednisone. Received prior chemotherapy containing docetaxel.