ACITRETIN

PRODUCT(s) AFFECTED
ACITRETIN

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Prevention of non-melanoma skin cancers in high risk individuals.

EXCLUSION CRITERIA
Severely impaired liver function or kidney function. Chronic abnormally elevated blood lipid values. Concomitant use of methotrexate or tetracycline.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
If the patient is female and able to bear children, female patient and/or guardian signed a Patient Agreement/Informed Consent (e.g., Do Your P.A.R.T) which includes confirmation of 2 negative pregnancy tests.
ACTHAR

PRODUCT(s) AFFECTED

- ACTHAR HP

- HP ACTHAR

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

Acute exacerbation of MS, prescribed by neurologist or MS specialist.

COVERAGE DURATION

Acute exacerbation of MS, authorization for 3 weeks. For infantile spasms, 4 weeks.

OTHER CRITERIA

Acute exacerbation of MS, must have documented failure or cannot tolerate high-dose glucocorticoids (e.g. IV methylprednisolone 1000 mg daily for five days).
ACTIMMUNE

PRODUCT(s) AFFECTED
ACTIMMUNE

COVERED USES
All FDA-approved indications not otherwise excluded from Part D, mycosis fungoides, Sezary syndrome, atopic dermatitis.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For chronic granulomatous disease, Actimmune is used for reducing the frequency and severity of serious infections associated with chronic granulomatous disease. For atopic dermatitis, the condition is resistant to conservative treatments (eg, topical medications, phototherapy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
PRODUCT(s) AFFECTED
ADAGEN

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Severe combined immunodeficiency disease (SCID) is due to adenosine deaminase (ADA) deficiency. Condition failed to respond to bone marrow transplantation or patient is not currently a suitable candidate for bone marrow transplantation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
ADEMPAS

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

EXCLUSION CRITERIA
Patient is taking a nitrate or nitric oxide donor medication (eg, amyl nitrite) on a regular or intermittent basis. Patient is taking a phosphodiesterase inhibitor (eg, sildenafil, tadalafil, vardenafil, dipyridamole, theophylline).

REQUIRED MEDICAL INFORMATION
For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg AND 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg AND 3) pretreatment pulmonary vascular resistance is greater than 3 Wood units. For chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4): 1) CTEPH was confirmed by right heart catheterization AND by CT, MRI or pulmonary angiography AND 2) Patient has inoperable CTEPH or persistent or recurrent CTEPH after pulmonary endarterectomy. For pulmonary arterial hypertension (PAH) (WHO Group 1): 1) PAH was confirmed by right heart catheterization AND 2) NYHA Functional Class II or III symptoms.

AGE RESTRICTION
18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year
OTHER CRITERIA
N/A
AFINITOR

PRODUCT(s) AFFECTED
- AFINITOR
- AFINITOR DISPERZ

COVERED USES
All FDA-approved indications not otherwise excluded from Part D, lung neuroendocrine tumors, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, soft tissue sarcoma with one of the following three histologic subtypes: perivascular epithelioid cell tumors (PEComa), angiomyolipoma, lymphangioleiomyomatosis, Classical Hodgkin lymphoma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For RCC, the disease is relapsed or medically unresectable. Afinitor will be used as a single agent. The tumor expresses clear cell or non-clear cell histology. If clear cell histology, the patient has previous tried Votrient (pazopanib) or Sutent (sunitinib). For classical Hodgkin lymphoma, Afinitor will be used as a single agent. For advanced breast cancer, patient has advanced hormone receptor positive, HER2 negative disease. Afinitor will be used in combination with exemestane. Patient's disease has progressed within 12 months, was previously treated with a nonsteroidal aromatase inhibitor, or was previously treated with tamoxifen. For subependymal giant cell astrocytoma associated with tuberous sclerosis complex (TSC), patient is not a candidate for curative surgical resection. For renal angiomyolipoma with TSC, patient does not require immediate surgery.

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 of MPS I was confirmed by an enzyme assay demonstrating a deficiency of alpha-L-iduronidase enzyme activity or by DNA testing. Patients with Scheie syndrome must have moderate to severe symptoms of MPS I.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
N/A
ALECENSA

PRODUCT(s) AFFECTED
ALECENSA

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
ALPHA-1 PROTEINASE INHIBITORS

PRODUCT(s) AFFECTED
- ARALAST
- GLASSIA
- ZEMAIRA
- ARALAST NP
- PROLASTIN-C

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patients must have clinically evident emphysema. Patients must have a pretreatment serum alpha1-proteinase inhibitor level less than 11 micromoles/L (80 mg/dl). Patients must have a pretreatment post-bronchodilation FEV1 greater than, or equal to, 25 percent and less than, or equal to, 80 percent of predicted.

AGE RESTRICTION
18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
AMPYRA

PRODUCT(s) AFFECTED
AMPYRA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Member is receiving treatment with a disease modifying medication for multiple sclerosis (e.g., dimethyl fumarate, fingolimod, glatiramer, interferon beta, natalizumab, teriflunomide). Prior to initiating therapy, member must demonstrate sustained walking impairment and the ability to walk 25 feet (with or without assistance). For new starts, member will be assessed for continuation of therapy after 3 weeks of initial treatment. For continuation of therapy, member must have experienced an improvement in walking speed or other objective measure of walking ability since starting Ampyra. Coverage not recommended for patients with CrCl less than or equal to 50 ml/min or patients with a history of seizure disorder.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
MS. If prescribed by, or in consultation with, a neurologist or MS specialist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For initial approval for MS, authorize for 1 month. After up to 1 month of dalfampridine extended-release
therapy, if MS patient has had a response to therapy as determined by prescribing physician (eg, increased walking distance, improved leg/limb strength, improvement in activities of daily living), then an additional authorization is allowed.
## 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. AIDS-wasting or cachexia due to chronic disease. Turner's syndrome.

### EXCLUSION CRITERIA
Pregnancy. Known or suspected carcinoma of the prostate or breast in male patients. Carcinoma of the breast in females with hypercalcemia. Nephrosis, the nephrotic phase of nephritis. Hypercalcemia.

### REQUIRED MEDICAL INFORMATION
Patient will be monitored for peliosis hepatis, liver cell tumors and blood lipid changes.

### AGE RESTRICTION
N/A

### PRESCRIBER RESTRICTION
N/A

### COVERAGE DURATION
6 months

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

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

EXCLUSION CRITERIA
Concomitant treatment with a serotonin 5HT3 antagonist (e.g. ondansetron, granisetron, dolasetron, palonosetron, and alosetron).

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

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 10 MCG/0.4ML
- ARANESP (ALBUMIN FREE) SOLUTION 200 MCG/ML
- ARANESP (ALBUMIN FREE) SOLUTION 300 MCG/ML
- ARANESP (ALBUMIN FREE) SOLUTION 60 MCG/ML

### COVERED USES

All medically accepted indications not otherwise excluded from Part D.

### EXCLUSION CRITERIA

N/A

### REQUIRED MEDICAL INFORMATION

Confirmation of adequate iron stores (e.g., prescribing information recommends supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%). Anemia w/CRF on dialysis. A hemoglobin (Hb) of less than 10.0 g/dL required for start, Hb has to be less than or equal 11.0 g/dL if previously receiving epoetin alfa (EA) or Aranesp. CRF anemia in patients not on dialysis. Hemoglobin (Hb) of less than 10.0 g/dL. Anemia due to myelosuppressive chemotx, Hb is 10.0
g/dL or less to start. Hb less than or equal to 12.0 g/dL if previously on epoetin alfa EA. MDS, approve tx if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. If the pt has previously been receiving Aranesp or EA, approve only if Hb is 12.0 g/dL or less. Anemia due to ribavirin for Hep C, Hb is 10.0 g/dL or less at tx start. Previously on EA approve if Hb is 12.0 g/dL or less. All conditions, deny if Hb exceeds 12.0 g/dL.

AGE RESTRICTION
MDS anemia= 18 years of age and older.

PRESCRIBER RESTRICTION
MDS anemia, prescribed by or in consultation with, a hematologist or oncologist.

COVERAGE DURATION
Anemia w/myelosuppressive = 4 mos, Other=6 mos.

OTHER CRITERIA
Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.
ARCALYST

PRODUCT(s) AFFECTED
ARCALYST

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
12 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
BETASERON

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Have a relapsing form of MS (eg, relapsing-remitting MS, progressive-relapsing MS, or secondary progressive MS with relapses) OR first clinical episode of MS with MRI scan that demonstrated features consistent with a diagnosis of MS (ie, multifocal white matter disease).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
BOSULIF

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL).

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of CML or Ph+ ALL was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML, patient meets any of the following: 1) patient has accelerated or blast phase CML, OR 2) patient experienced resistance, intolerance or toxicity to alternative tyrosine kinase inhibitor (imatinib, dasatinib, nilotinib, ponatinib), OR 3) patient received a hematopoietic stem cell transplant. For Ph+ ALL, ALL is relapsed or refractory to prior therapy.

AGE RESTRICTION
18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
- BUPRENORPHINE HCL SL TAB 2 MG
- BUPRENORPHINE HCL SL TAB 8 MG

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1) The prescriber agrees not to prescribe other opioids while the patient is taking buprenorphine AND 2) If the patient is a pregnant female and being prescribed buprenorphine for induction therapy and subsequent maintenance therapy for transition from opioid use to opioid dependence treatment OR 3) if buprenorphine is being prescribed for induction therapy for transition from opioid use to opioid dependence treatment OR 4) if buprenorphine is being prescribed for maintenance therapy for opioid dependence treatment in a patient who is intolerant to naloxone.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Induction 3 months, Maintenance Plan Year, Pregnancy 10 months

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
BUPRENORPHINE HCL-NALOXONE HCL

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
The prescriber agrees not to prescribe other opioids while the patient is taking the requested drug for opioid dependence treatment.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
CAPRELSA

PRODUCT(s) AFFECTED
CAPRELSA

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Differentiated thyroid cancer subtypes: papillary, follicular, Hurthle cell.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For medullary thyroid cancer: 1) disease is symptomatic or progressive AND 2) patient has unresectable locoregional or metastatic disease. For differentiated thyroid cancer: 1) histologic subtype is papillary, follicular, or Hurthle cell AND 2) disease is symptomatic or progressive AND 3) disease is iodine-refractory AND 4) patient has unresectable locoregional or metastatic disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
CARBAGLU

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Methylmalonic acidemia, propionic acidemia.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of NAGS deficiency was confirmed by enzymatic or genetic testing.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

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

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

**EXCLUSION CRITERIA**
CYP2D6 extensive metabolizers and intermediate metabolizers taking a strong or moderate CYP2D6 inhibitor (e.g., paroxetine, terbinafine) concomitantly with a strong or moderate CYP3A inhibitor (e.g., ketoconazole, fluconazole). CYP2D6 intermediate metabolizers and poor metabolizers taking a strong CYP3A inhibitor (e.g., ketoconazole). CYP2D6 indeterminate metabolizers (i.e., CYP2D6 genotype cannot be determined). CYP2D6 ultra-rapid metabolizers.

**REQUIRED MEDICAL INFORMATION**
Diagnosis of Gaucher disease was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by DNA testing. The patient's CYP2D6 metabolizer status has been established using an FDA-cleared test. Patient is a CYP2D6 extensive metabolizer, an intermediate metabolizer, or a poor metabolizer.

**AGE RESTRICTION**
18 years of age or older.

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
N/A
PRODUCT(s) AFFECTED
CEREZYME RECON SOLN 400 UNIT

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Type 3 Gaucher disease.

EXCLUSION CRITERIA
Concomitant therapy with miglustat (Zavesca).

REQUIRED MEDICAL INFORMATION
Diagnosis of Gaucher disease was confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by DNA testing. For Type 1 Gaucher disease, patient has one or more of the following disease complications: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly. For Type 3 Gaucher disease, patient has one or more of the following disease complications: anemia, thrombocytopenia, bone disease, hepatomegaly, splenomegaly, developmental delay, or ophthalmoplegia (gaze palsy).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
**PRODUCT(s) AFFECTED**
- CIALIS TAB 2.5 MG  
- CIALIS TAB 5 MG

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

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Indication for which tadalafil is being prescribed.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED) and after a trial of an alpha-1 blocker (eg, doxazosin [Cardura XL], terazosin, tamsulosin [Flomax], alfuzosin extended-release [UroXatral]) or 5 alpha reductase inhibitor (eg, finasteride, dutasteride [Avodart]).
CIMZIA

PRODUCT(s) AFFECTED
- CIMZIA
- CIMZIA STARTER KIT
- CIMZIA PREFILLED

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Latent TB screening with either a TB skin test or an interferon gamma release assay (eg, QFT-GIT, T-SPOT.TB) prior to initiating Cimzia (or other biologic). For moderately to severely active Crohn's disease (new starts only): Member meets ANY of the following: 1) Inadequate response to at least one conventional therapy (eg, corticosteroids, SSZ, azathioprine, mesalamine), 2) Intolerance or contraindication to conventional therapy. For moderately to severely active RA (new starts only): Member meets ANY of the following: 1) Inadequate response to at least a 3-month trial of methotrexate (MTX) despite adequate dosing (ie, titrated to 25-30 mg/week), 2) Intolerance or contraindication to MTX. For active psoriatic arthritis (PsA) (new starts only): Member meets ANY of the following: 1) Inadequate response to at least a 3-month trial of MTX, sulfasalazine, or leflunomide 2) Intolerance or contraindication to MTX, sulfasalazine, or leflunomide, 3) Inadequate response to at least a 3-month trial of a prior biologic DMARD, 4) Intolerance to a prior biologic DMARD, 5) Severely active PsA as evidenced by ANY of the following: a) multiple swollen joints, b) structural damage in the presence of inflammation, or c) clinically relevant extra-articular manifestations (eg, extensive skin, bowel, ocular, cardiovascular, urogenital, or pulmonary involvement), 6) Active enthesitis and/or dactylitis (i.e., sausage finger) 7) Predominant axial disease (i.e. extensive spinal involvement).

AGE RESTRICTION
N/A
PREScriber restriction
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For active ankylosing spondylitis and axial spondyloarthritis (new starts only): 1) Inadequate response to at least a 4-week NSAID trial at maximum recommended or tolerated dose OR intolerance and/or contraindication to NSAIDs, AND 2) Member has at least ONE of the following: a) predominant axial disease (i.e. extensive spinal involvement), b) inadequate response to a synthetic DMARD (eg, sulfasalazine), c) intolerance or contraindication to a synthetic DMARD, d) inadequate response to at least a 3-month trial of a prior biologic DMARD, or e) intolerance to a prior biologic DMARD.
PRODUCT(s) AFFECTED
CINRYZE

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Plus for the acute treatment of Hereditary Angioedema (HAE).

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of HAE confirmed by laboratory tests (eg, C4, C1 inhibitor functional, and C1 inhibitor antigenic protein levels).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Must be prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
- COMETRIQ (100 MG DAILY DOSE)  - COMETRIQ (140 MG DAILY DOSE)
- COMETRIQ (60 MG DAILY DOSE)

COVERED USES
All FDA-approved indications not otherwise excluded from Part D, NSCLC with RET rearrangements.

EXCLUSION CRITERIA
Severe hemorrhage.

REQUIRED MEDICAL INFORMATION
Medullary thyroid cancer is symptomatic, progressive, or metastatic. Non-small cell lung cancer is with RET gene rearrangements.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Therapy will be discontinued if gastrointestinal perforation or fistula formation occurs.
COPAXONE

PRODUCT(s) AFFECTED
COPAXONE

COVERED USES
All FDA-approved indications not otherwise excluded from Part D, first clinical episode of MS.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Have a relapsing form of MS (eg, relapsing-remitting MS, progressive-relapsing MS, or secondary progressive MS with relapses) OR first clinical episode of MS with MRI scan that demonstrated features consistent with a diagnosis of MS (ie, multifocal white matter disease).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

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

**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
CYSTAGON

PRODUCT(s) AFFECTED
CYSTAGON

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

EXCLUSION CRITERIA
Documented history of hypersensitivity to penicillamine.

REQUIRED MEDICAL INFORMATION
Diagnosis of nephropathic cystinosis was confirmed by the presence of increased cysteine concentration in leukocytes or by DNA testing.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
DAKLINZA

PRODUCT(s) AFFECTED
DAKLINZA

COVERED USES
All FDA-approved indications not otherwise excluded from Part D, chronic hepatitis C genotype 2 or 4 infection.

EXCLUSION CRITERIA
Use with a strong inducer of CYP3A, including phenytoin, carbamazepine, rifampin and St. John's wort.

REQUIRED MEDICAL INFORMATION
Chronic hepatitis C infection confirmed by presence of HCV RNA in serum prior to starting treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated variants (eg, NS3 Q80K polymorphism) where applicable, liver transplantation status if applicable. Coverage conditions and specific durations of approval will be based on current AASLD treatment guidelines.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Criteria will be applied consistent with current AASLD-IDSA guidance.

OTHER CRITERIA
For HCV/HIV coinfection, patient meets criteria for requested regimen.
DALIRESP

PRODUCT(s) AFFECTED
DALIRESP

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Clinical measures of liver disease including total bilirubin, serum albumin, PT INR, degree of ascites, and grade of hepatic encephalopathy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Pulmonologist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For patients with history of depression and/or suicidal thoughts, assessment has been made of risk versus benefit in patients with history of depression and/or suicidal thoughts and physician determines benefit outweighs the risks. Not recommended in patients with moderate to severe hepatic impairment (Child-Pugh Class B or C).
PRODUCT(s) AFFECTED
EGRIFTA

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
PRODUCT(s) AFFECTED
ELELYSO

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Type 1 Gaucher's disease

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, a physician who specializes in the treatment of inherited metabolic disorders.

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
N/A

REQUIRED MEDICAL INFORMATION
Latent TB screening with either a TB skin test or an interferon gamma release assay (eg, QFT-GIT, T-SPOT.TB) prior to initiating Enbrel (or other biologic). For moderately to severely active rheumatoid arthritis (new starts only): 1) Inadequate response, intolerance, or contraindication to MTX, OR 2) Inadequate response or intolerance to a prior biologic DMARD, OR 3) Enbrel will be used as first-line therapy for severely active RA. For moderately to severely active juvenile idiopathic arthritis (new starts only): 1) Inadequate response to MTX, OR 2) Intolerance or contraindication to MTX. For active ankylosing spondylitis (new starts only): Inadequate response, contraindication or intolerance to at least 2 NSAIDs. For chronic moderate to severe plaque psoriasis (new starts only): 1) At least 5% of BSA is affected or crucial body areas (eg, feet, hands, face, neck and/or groin) are affected, AND 2) Inadequate response to either phototherapy (eg, UVB, PUVA) or a traditional systemic agent (eg, methotrexate, cyclosporine, acitretin), unless contraindicated or intolerant to such therapies.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year
OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
- EPOGEN
- PROCRIT

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Anemia due to myelodysplastic syndromes (MDS), anemia in congestive heart failure (CHF), anemia in rheumatoid arthritis (RA), anemia due to hepatitis C treatment (ribavirin in combination with either interferon alfa or peginterferon alfa).

EXCLUSION CRITERIA
Patients receiving chemotherapy with curative intent. Patients with myeloid cancer. Use to facilitate preoperative autologous blood donation.

REQUIRED MEDICAL INFORMATION
For all uses except surgery: 1) Pretreatment (no erythropoietin treatment in previous month) Hgb is less than 10 g/dL (less than 9 g/dL for anemia in CHF only) AND 2) For reauthorizations (patient received erythropoietin in previous month), an increase in Hgb of at least 1 g/dL after at least 12 weeks of therapy. Additional requirements for anemia due to myelosuppressive cancer chemotherapy: 1) For initial therapy, at least 2 more months of chemotherapy is expected, AND 2) For reauthorizations, current Hgb is less than 11 g/dL. Additional requirements for CKD not on dialysis reauthorization: 1) Current Hgb is less than or equal to 10 g/dL OR Hgb is greater than 10 but less than or equal to 12 g/dL AND prescriber will reduce or interrupt dose. Additional requirements for MDS: 1) Patient has symptomatic anemia, AND 2) Pretreatment serum erythropoietin level is less than or equal to 500 mU/mL, AND 3) For reauthorizations, current Hgb is less than or equal to 11 g/dL OR Hgb is greater than 11 but less than or equal to 12 g/dL AND prescriber will reduce or interrupt dose. Additional requirements for HIV: 1) Concomitant use of zidovudine at a maximum dose of 4200 mg per week, AND 2) For initial therapy, pretreatment serum erythropoietin level is less than or equal to 500 mU/mL, AND 3) For reauthorizations, current Hgb is less than or equal to 11 g/dL OR Hgb is greater than 11 but less than or equal to 12 g/dL AND prescriber will reduce or interrupt dose. Additional requirements for anemia due to CHF, RA, hepatitis C treatment, or patients whose religious beliefs forbid blood transfusions: 1) For reauthorizations, current Hgb is less than or equal to 11 g/dL OR Hgb is greater than 11 but less than or equal to 12 g/dL AND prescriber will reduce or interrupt dose. For surgery: 1) Patient is scheduled for elective, noncardiac, nonvascular surgery, AND 2) Pretreatment Hgb is
greater than 10 but not more than 13 g/dL.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12 weeks

OTHER CRITERIA
Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual (eg, used for treatment of anemia for a patient with chronic renal failure who is undergoing dialysis, or furnished from physician's supply incident to a physician service). Coverage includes use in anemia in patients whose religious beliefs forbid blood transfusions. Requirements regarding Hgb values exclude values due to a recent transfusion.
PRODUCT(s) AFFECTED
ERIVEDGE

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 distant metastatic basal cell carcinoma (BCC), OR 2) patient has undergone surgery and/or radiation therapy for BCC and has residual or recurrent disease following surgery and/or radiation, OR 3) both surgery and radiation are contraindicated or not appropriate for the patient.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
ESBRIET

PRODUCT(s) AFFECTED
ESBRIET

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

EXCLUSION CRITERIA
Use in patients with more severe disease (FVC less than 50% of the predicted value) or with an acute exacerbation.

REQUIRED MEDICAL INFORMATION
ALT, AST, and bilirubin

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Pulmonologist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Prescriber agrees to monitor liver function before and during treatment per package labeling. Temporary dosage reductions or discontinuations may be required per package labeling.
**EXJADE**

**PRODUCT(s) AFFECTED**
EXJADE

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

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
For chronic iron overload due to blood transfusions: pretreatment serum ferritin level is greater than 1000 mcg/L. For chronic iron overload in patients with non-transfusion dependent thalassemia (NTDT) syndromes: a) for initiation of the deferasirox therapy, pretreatment liver iron concentration (LIC), measured by liver biopsy or by an FDA-cleared or approved method, is at least 5 mg of iron per gram of liver dry weight (mg Fe/g dw) AND pretreatment serum ferritin levels are greater than 300 mcg/L on 2 consecutive measurements 1 month apart, b) for continuation of the deferasirox therapy: current LIC is greater than 3 mg Fe/g dw or the deferasirox therapy will be withheld until the LIC reaches above 5 mg Fe/g dw.

**AGE RESTRICTION**
2 years of age or older

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**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 of Fabry disease is confirmed by an enzyme assay showing deficiency of alpha-galactosidase enzyme activity or by DNA testing. Patient has clinical signs and symptoms of Fabry disease.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
FARYDAK

PRODUCT(s) AFFECTED
FARYDAK

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
Oncologist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
FIRAZYR

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of HAE confirmed by laboratory tests (eg, C4, C1 inhibitor functional, and C1 inhibitor antigenic protein levels).

AGE RESTRICTION
Adults

PRESCRIBER RESTRICTION
Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
FLECTOR

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Adults.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Authorization may be given if the patient has tried two unique generic prescription strength non-steroidal anti-inflammatory drugs (NSAIDs). Authorization may be given for patients with difficulty swallowing or cannot swallow.
PRODUCT(s) AFFECTED
FORTEO

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

EXCLUSION CRITERIA
Paget's disease of bone, unexplained elevations of alkaline phosphatase, open epiphyses (ie, pediatric or young adult patient), prior radiation therapy involving the skeleton, history of a skeletal malignancy, bone metastases, pre-existing hypercalcemia, metabolic bone disease other than osteoporosis.

REQUIRED MEDICAL INFORMATION
For all indications, patient has had an oral bisphosphonate trial of at least 1-year duration unless contraindicated or intolerant to an oral bisphosphonate. For primary or hypogonadal osteoporosis and postmenopausal osteoporosis: Patient has a) a history of an osteoporotic vertebral or hip fracture OR b) a pre-treatment T-score of less than or equal to -2.5 OR c) a pre-treatment T-score of less than or equal to -1 but greater than -2.5 AND a pre-treatment FRAX score of greater than or equal to 20 percent for any major osteoporotic fracture. For glucocorticoid-induced osteoporosis in postmenopausal women and men 50 years of age or older: 1) patient is currently receiving or will be initiating glucocorticoid therapy, AND 2) patient has a) a history of fragility fracture OR b) a pre-treatment T-score of less than or equal to -2.5 OR c) a pre-treatment FRAX score of greater than or equal to 20 percent for any major osteoporotic fracture. For glucocorticoid-induced osteoporosis in premenopausal women and men less than 50 years of age: 1) patient is currently receiving or will be initiating glucocorticoid therapy AND, 2) the anticipated glucocorticoid length of therapy is at least 3 months, AND 3) patient has a history of a fragility fracture.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A
COVERAGE DURATION
24 months (lifetime)

OTHER CRITERIA
N/A
GILENYA

PRODUCT(s) AFFECTED
GILENYA

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

EXCLUSION CRITERIA
Recent occurrence (within the last 6 months) of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, class III or IV heart failure. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker. Baseline QTc interval equal to or greater than 500ms. Treatment with Class Ia or Class III anti-arrhythmic drugs.

REQUIRED MEDICAL INFORMATION
Have a relapsing form of MS (e.g. relapsing-remitting MS, progressive-relapsing MS, or secondary progressive MS with relapses).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For patients previously treated with Tysabri: a minimum 3 month washout period is required after discontinuation of Tysabri.
**GILOTTRIF**

**PRODUCT(s) AFFECTED**
GILOTTRIF

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

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Patient has metastatic non-small cell lung cancer. Patient had EGFR mutation testing and is positive for EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
N/A
PRODUCT(s) AFFECTED
- GLEEVEC - IMATINIB MESYLATE

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Desmoid tumors, pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT), chordoma, and melanoma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of CML or Ph+ ALL was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML, patient did not fail (excluding failure due to intolerance) prior therapy with a tyrosine kinase inhibitor (dasatinib, nilotinib, bosutinib, ponatinib). For myelodysplastic/ myeloproliferative disease, disease is associated with PDGFR gene re-arrangements. For aggressive systemic mastocytosis, D816V c-Kit mutation is negative or unknown. For melanoma, c-Kit mutation is positive. Patient has one of the following diagnoses: gastrointestinal stromal tumor, hypereosinophilic syndrome, chronic eosinophilic leukemia, desmoid tumor, dermatofibrosarcoma protuberans, PVNS/TGCT, or chordoma.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
GLUCAGON-LIKE PEPTIDE-1 AGONISTS

PRODUCT(s) AFFECTED
- BYDUREON
- BYETTA 10 MCG PEN
- BYETTA 5 MCG PEN
- TRULICITY
- VICTOZA

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
PRODUCT(s) AFFECTED
- GENOTROPIN
- HUMATROPE
- NORDITROPIN NORDIFLEX PEN SOLUTION 15 MG/1.5ML
- NORDITROPIN NORDIFLEX PEN SOLUTION 5 MG/1.5ML
- NUTROPIN AQ NUSPIN 20
- NUTROPIN AQ PEN
- SAIZEN
- SEROSTIM
- GENOTROPIN MINIQUICK
- NORDITROPIN FLEXPRO
- NORDITROPIN NORDIFLEX PEN SOLUTION 30 MG/3ML
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 5
- OMNITROPE
- SAIZEN CLICK,EASY
- ZORBTIVE

COVERED USES
All FDA-approved indications not otherwise excluded from Part D including pediatric growth hormone deficiency (GHD), Turner syndrome (TS), Noonan syndrome (NS), chronic kidney disease (CKD), small for gestational age (SGA), Prader-Willi syndrome (PWS), idiopathic short stature (ISS), short stature homeobox-containing gene deficiency (SHOXD), adult GHD, HIV-associated wasting/cachexia, short bowel syndrome (SBS).

EXCLUSION CRITERIA
Active malignancy. Closed epiphyses (except PWS, adult GHD, HIV wasting/cachexia and SBS).

REQUIRED MEDICAL INFORMATION
Pediatric GHD, TS, CKD, SHOXD, NS: 1) younger than 2.5 yrs old, when applicable: pre-tx height (ht) more than 2 SD below mean and slow growth velocity, 2) 2.5 yrs old or older: pre-tx 1-yr ht velocity more than 2 SD below mean, OR pre-tx ht more than 2 SD below mean and 1-yr ht velocity more than 1 SD below mean. Pediatric GHD: 1) failed 2 pre-tx stimulation tests (peak below 10 ng/mL) OR 2) pituitary/CNS disorder and pre-tx IGF-1 more than 2 SD below mean OR 3) patient is a neonate. TS: confirmed by karyotyping. CKD: not post-kidney transplant. SGA: 1) birth wt below 2500g at gestational age (GA) more than 37 wks OR 2) birth wt or length below 3rd percentile or at least 2 SD below mean for
GA, AND 3) did not manifest catch-up growth by age 2. PWS: confirmed by 1) deletion in the chromosomal 15q11.2-q13 region OR 2) maternal uniparental disomy in chromosome 15 OR 3) imprinting defects or translocations involving chromosome 15. SHOXD: confirmed by molecular or genetic testing. ISS: 1) pediatric GHD ruled out with appropriate provocative test more than 10 ng/mL, and 2) pre-tx ht more than 2.25 SD below mean, and 3) adult ht prediction below 63 inches for boys, 59 inches for girls. Adult GHD: 1) failed 2 pre-tx stimulation tests (peak below 5 ng/mL), OR 2) structural abnormality of hypothalamus/pituitary AND 3 or more pituitary hormone deficiencies, OR 3) childhood-onset GHD with congenital (genetic/structural) abnormality of hypothalamus/pituitary/CNS, OR 4) low pre-tx IGF-1 and failed 1 pre-tx stimulation test (peak below 5 ng/mL). HIV wasting/cachexia: 1) on antiretroviral tx AND 2) suboptimal response to at least 1 other therapy for wasting/cachexia (eg, megestrol, dronabinol, cyproheptadine, or testosterone if hypogonadal) OR contraindication/intolerance to alternative therapies, AND 3) pre-tx BMI less than 18.5 kg/m2 AND unintentional wt loss greater than 5% body weight in the past 6 mos. SBS: used with optimal management of SBS.

AGE RESTRICTION
SGA: 2 years of age or older. NS and SHOXD: 3 years of age or older.

PRESCRIBER RESTRICTION
Endocrinologist, pediatric nephrologist, infectious disease specialist, gastroenterologist, nutritional support specialist.

COVERAGE DURATION
SBS = Up to 8 wks total lifetime. HIV wasting = 12 wks. All other indications = Plan Year.

OTHER CRITERIA
Renewal for pediatric GHD, TS, NS, CKD, SGA, PWS patients with open epiphyses, ISS, or SHOXD: patient is growing more than 2 cm/year. Also for renewal for PWS only: body composition and psychomotor function have improved. Renewal for PWS patients with closed epiphyses and adult GHD patients: current IGF-1 level is normal for age and gender. Renewal for HIV-associated wasting: demonstrated response to GH therapy (ie, BMI has improved or stabilized) and BMI is less than 27 kg/m2.
PRODUCT(s) AFFECTED
HARVONI

COVERED USES
All FDA-approved indications not otherwise excluded from Part D, chronic hepatitis C genotype 4, 5, or 6 infection.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Chronic hepatitis C infection confirmed by presence of HCV RNA in the serum prior to starting tx. For G1 infection, monotherapy: 1)Total 12 wks for tx-naive pts with or without cirrhosis. Tx for 8 wks can be considered in tx-naive pts without cirrhosis who have pre-tx HCV RNA below 6 million IU/mL, 2)For pts who failed prior tx with PEG-IFN and RBV with or without HCV PI: a) total 12 wks if no cirrhosis, b) total 24 wks for cirrhosis. For G4 infection, monotherapy: Total 12 wks for pts who are tx-naive or failed prior tx with PEG-IFN and RBV. For G5 infection, monotherapy: Total 12 wks for pts who are tx-naive or failed prior tx with PEG-IFN and RBV. For G6 infection, monotherapy: Total 12 wks for pts who are tx-naive or failed prior tx with PEG-IFN and RBV. For recurrent HCV infection post liver txp, monotherapy: Total 24 wks for tx-naive pts with G1 or 4 infection and documented anemia or RBV ineligibility. For G1 infection, tx with RBV: 1)Total 12 wks for pts with cirrhosis who failed prior tx with PEG-IFN and RBV with or without an HCV PI, 2)Total 12 wks for pts without cirrhosis who failed prior tx with a SOF-containing regimen, 3)Total 24 wks for pts with cirrhosis who failed prior tx with a SOF-containing regimen. For decompensated cirrhosis (CTP class B or C), tx with RBV: 1)Total 12 wks for pts with G1 or 4 infection, 2)Total 24 wks for pts with G1 or 4 infection who failed prior tx with a SOF-containing regimen, 3)Total 12 wks for pts with recurrent G1 or 4 infection post liver txp. For recurrent HCV infection post liver txp, tx with RBV: Total 12 wks for pts with G1 or 4 infection. For HCV/HIV coinfection, pt meets all of the following: 1)Pt meets the criteria for requested regimen above, 2)Will not receive tx with cobicistat given with tenofovir, 3)Will not receive tx with tipranavir.
AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
12-24 wks depending on baseline host/viral factors with reminder for 8 wk option when appropriate

OTHER CRITERIA
Harvoni will not be used with other drugs containing sofosbuvir, including Sovaldi. Anemia defined as baseline hemoglobin below 10g/dL, RBV ineligibility defined as intolerance to RBV, pregnant female or male whose female partner is pregnant, hemoglobinopathy, or coadministration with didanosine. tx=treatment, G=genotype, pt=patient, PEG-IFN=peginterferon alfa, RBV=ribavirin, PI=protease inhibitor, SOF=sofosbuvir, CTP=Child Turcotte Pugh, txp=transplantation, ART=antiretroviral therapy.
HIGH RISK MEDICATIONS - ANTIPSYCHOTICS

PRODUCT(s) AFFECTED
- THIORIDAZINE HCL TAB 10 MG
- THIORIDAZINE HCL TAB 25 MG
- THIORIDAZINE HCL TAB 100 MG
- THIORIDAZINE HCL TAB 50 MG

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
PA is only required for 65 years of age or older. For patients less than 65 years of age, this will be approved without PA.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
In most patients 65 years of age or older, the prescribed medication is considered a "high risk medication" that poses an unnecessarily high risk when safer alternative therapy may be available. See American Geriatrics Society 2012 Beers Criteria Update Expert Panel, American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults, J Am Geriatr Soc, 2012, 60(4). 616-31. 1) A non-HRM alternative formulary drug (olanzapine, quetiapine, risperidone, ziprasidone) has not been tried AND 2) A non-HRM alternative formulary drug (olanzapine, quetiapine, risperidone,
ziprasidone) is not clinically appropriate AND 3) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older OR 4) A non-HRM alternative formulary drug (olanzapine, quetiapine, risperidone, ziprasidone) has been tried AND 5) The patient experienced an inadequate treatment response OR intolerance to a non-HRM alternative formulary drug (olanzapine, quetiapine, risperidone, ziprasidone) AND 6) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older.
HIGH RISK MEDICATIONS - BARBITURATES

PRODUCT(s) AFFECTED
- PHENOBARBITAL ELIXIR 20 MG/5ML
- PHENOBARBITAL TAB 100 MG
- PHENOBARBITAL TAB 16.2 MG
- PHENOBARBITAL TAB 32.4 MG
- PHENOBARBITAL TAB 64.8 MG
- PHENOBARBITAL SOLUTION 20 MG/5ML
- PHENOBARBITAL TAB 15 MG
- PHENOBARBITAL TAB 30 MG
- PHENOBARBITAL TAB 60 MG
- PHENOBARBITAL TAB 97.2 MG

COVERED USES
All medically accepted 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
This Prior Authorization requirement only applies to patients 65 years of age or older. In most patients 65 years of age or older, the prescribed medication is considered a high risk medication that poses an unnecessarily high risk when safer alternative therapy may be available. 1) A non-HRM alternative
formulary drug (carbamazepine, lamotrigine, topiramate) has not been tried AND 2) A non-HRM alternative
formulary drug (carbamazepine, lamotrigine, topiramate) is not clinically appropriate AND 3) Prescriber
must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older
OR 4) A non-HRM alternative formulary drug (carbamazepine, lamotrigine, topiramate) has been tried
AND 5) The patient experienced an inadequate treatment response OR intolerance to a non-HRM alternative
formulary drug (carbamazepine, lamotrigine, topiramate) AND 6) Prescriber must acknowledge that
medication benefits outweigh potential risks in the patient 65 years of age or older.
**HIGH RISK MEDICATIONS - CLOMIPRAMINE**

**PRODUCT(s) AFFECTED**
- CLOMIPRAMINE HCL CAP 25 MG  
- CLOMIPRAMINE HCL CAP 50 MG  
- CLOMIPRAMINE HCL CAP 75 MG

**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**
This Prior Authorization requirement only applies to patients 65 years of age or older. In most patients 65 years of age or older, the prescribed medication is considered a high risk medication that poses an unnecessarily high risk when safer alternative therapy may be available. 1) A non-HRM alternative formulary drug (fluoxetine, fluvoxamine) has not been tried AND 2) A non-HRM alternative formulary drug (fluoxetine, fluvoxamine) is not clinically appropriate AND 3) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older OR 4) A non-HRM alternative formulary drug (fluoxetine, fluvoxamine) has been tried AND 5) The patient experienced an inadequate
treatment response OR intolerance to a non-HRM alternative formulary drug (fluoxetine, fluvoxamine)
AND 6) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older.
HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

PRODUCT(s) AFFECTED
- CYCLOBENZAPRINE HCL 5 MG
- CYCLOBENZAPRINE HCL TAB 10 MG
- CYCLOBENZAPRINE HCL TAB 5 MG
- CYCLOBENZAPRINE HCL TAB 7.5 MG

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis

AGE RESTRICTION
PA is only required for 65 years of age or older. For patients less than 65 years of age, this will be approved without PA.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
In most patients 65 years of age or older, the prescribed medication is considered a "high risk medication" that poses an unnecessarily high risk when safer alternative therapy may be available. See American Geriatrics Society 2012 Beers Criteria Update Expert Panel, American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults, J Am Geriatr Soc, 2012, 60(4). 616-31. Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older.
HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

PRODUCT(s) AFFECTED
- PROMETHAZINE HCL SOLUTION 6.25 MG/5ML
- PROMETHAZINE HCL TAB 12.5 MG
- PROMETHAZINE HCL TAB 50 MG
- PROMETHAZINE VC PLAIN
- PROMETHAZINE VC
- PROMETHAZINE-PHENYLEPHRINE

COVEREDUSES
All FDA-approved indications not otherwise excluded from Part D.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
In most patients 65 years of age or older, the prescribed medication is considered a "high risk medication" that poses an unnecessarily high risk when safer alternative therapy may be available. See American Geriatrics Society 2012 Beers Criteria Update Expert Panel, American Geriatrics Society Updated Beers
Criteria for Potentially Inappropriate Medication Use in Older Adults, J Am Geriatr Soc, 2012, 60(4). 616-31. For nausea/vomiting 1) A non-HRM alternative formulary drug (ondansetron) has not been tried AND 2) A non-HRM alternative formulary drug (ondansetron) is not clinically appropriate AND 3) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older OR 4) A non-HRM alternative formulary drug (ondansetron) has been tried AND 5) The patient experienced an inadequate treatment response OR intolerance to a non-HRM alternative formulary drug (ondansetron) AND 6) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older. For allergic rhinitis, 1) A non-HRM alternative formulary drug (levocetirizine, azelastine nasal, fluticasone nasal) has not been tried AND 2) A non-HRM alternative formulary drug (levocetirizine, azelastine nasal, fluticasone nasal) is not clinically appropriate AND 3) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older OR 4) A non-HRM alternative formulary drug (levocetirizine, azelastine nasal, fluticasone nasal) has been tried AND 5) The patient experienced an inadequate treatment response OR intolerance to a non-HRM alternative formulary drug (levocetirizine, azelastine nasal, fluticasone nasal) AND 6) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older. For urticaria 1) A non-HRM alternative formulary drug (levocetirizine) has not been tried AND 2) A non-HRM alternative formulary drug (levocetirizine) is not clinically appropriate AND 3) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older. OR 4) A non-HRM alternative formulary drug (levocetirizine) has been tried AND 5) The patient experienced an inadequate treatment response OR intolerance to a non-HRM alternative formulary drug (levocetirizine) AND 6) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older.
HIGH RISK MEDICATIONS - HIGH DOSE DIGOXIN

PRODUCT(s) AFFECTED
DIGOXIN TAB 250 MCG

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Digoxin level

AGE RESTRICTION
PA is only required for 65 years of age or older. For patients less than 65 years of age, this will be approved without PA.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
In most patients 65 years of age or older, digoxin 0.25 mg is considered a "high risk medication" that poses an unnecessarily high risk when safer alternative therapy may be available, especially for heart failure patients greater than 70 years of age. See American Geriatrics Society 2012 Beers Criteria Update Expert Panel, American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults, J Am Geriatr Soc, 2012, 60(4). 616-31. See also 2013 ACCF/AHA Guideline for the Management of Heart Failure. A Report of the American College of Cardiology Foundation/American Heart
Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013.62(16). e147-e239. In heart failure, doses of 0.125 mg daily or every other day should be used initially if the patient is greater than 70 years of age, has impaired renal function, or has a low lean body mass. 1) Patient has persistent or permanent atrial fibrillation, and beta-blocker, verapamil, or diltiazem not adequate for rate control. 2) Prescriber must document that digoxin 0.125 mg is not an acceptable alternative for digoxin 0.25 mg. AND 3) The patient experienced an inadequate treatment response to digoxin 0.125 mg and for heart failure, the digoxin level is less than or equal to 0.9 ng/ml (See within heart failure citation above, section 7.3.2.7.2) AND 4) Prescriber must acknowledge that medication dosing benefits outweigh potential risks in the patient 65 years of age or older.
HIGH RISK MEDICATIONS - MEGESTROL

PRODUCT(s) AFFECTED
- MEGESTROL ACETATE SUSPENSION 40 MG/ML
- MEGESTROL ACETATE TAB 20 MG
- MEGESTROL ACETATE SUSPENSION 400 MG/10ML
- MEGESTROL ACETATE TAB 40 MG

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
PA is only required for 65 years of age or older. For patients less than 65 years of age, this will be approved without PA.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
In most patients 65 years of age or older, the prescribed medication is considered a "high risk medication" that poses an unnecessarily high risk when safer alternative therapy may be available. See American Geriatrics Society 2012 Beers Criteria Update Expert Panel, American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults, J Am Geriatr Soc, 2012, 60(4), 616-31. Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older.
age or older.
PRODUCT(s) AFFECTED
- NITROFURANTOIN
- NITROFURANTOIN MACROCRYSTAL CAP 100 MG
- NITROFURANTOIN MACROCRYSTAL CAP 25 MG
- NITROFURANTOIN MONOHYD MACRO

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
PA is only required for 65 years of age or older. For patients less than 65 years of age, this will be approved without PA.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
In most patients 65 years of age or older, the prescribed medication is considered a "high risk medication" that poses an unnecessarily high risk when safer alternative therapy may be available. See American Geriatrics Society 2012 Beers Criteria Update Expert Panel, American Geriatrics Society Updated Beers Criteria.
Criteria for Potentially Inappropriate Medication Use in Older Adults, J Am Geriatr Soc, 2012, 60(4), 616-31. 1) A non-HRM alternative formulary drug (cephalexin, ciprofloxacin, levofloxacin, sulfamethoxazole/trimethoprim, trimethoprim) has not been tried AND 2) A non-HRM alternative formulary drug (cephalexin, ciprofloxacin, levofloxacin, sulfamethoxazole/trimethoprim, trimethoprim) is not clinically appropriate AND 3) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older OR 4) A non-HRM alternative formulary drug (cephalexin, ciprofloxacin, levofloxacin, sulfamethoxazole/trimethoprim, trimethoprim) has been tried AND 5) The patient experienced an inadequate treatment response OR intolerance to a non-HRM alternative formulary drug (cephalexin, ciprofloxacin, levofloxacin, sulfamethoxazole/trimethoprim, trimethoprim) AND 6) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older. APPLIES TO GREATER THAN CUMULATIVE 90 DAYS OF THERAPY PER YEAR.
HIGH RISK MEDICATIONS - ORAL ESTROGENS AND TOPICAL

ESTROGEN PATCH PRODUCTS

PRODUCT(s) AFFECTED
- ANGELIQ TAB 0.5-1 MG
- COMBIPATCH
- ESTRADIOL PATCH WK 0.0375 MG/24HR
- ESTRADIOL PATCH WK 0.06 MG/24HR
- ESTRADIOL PATCH WK 0.1 MG/24HR
- ESTRADIOL TAB 1 MG
- ESTRADIOL-NORETHINDRONE ACET
- ESTROPIPATE TAB 0.75 MG
- ESTROPIPATE TAB 3 MG
- NORETHINDRONE-ETH ESTRADIOL
- PREMARIN TAB 0.3 MG
- PREMARIN TAB 0.625 MG
- PREMARIN TAB 1.25 MG
- VIVELLE-DOT
- CLIMARA PRO
- ESTRADIOL PATCH WK 0.025 MG/24HR
- ESTRADIOL PATCH WK 0.05 MG/24HR
- ESTRADIOL PATCH WK 0.075 MG/24HR
- ESTRADIOL TAB 0.5 MG
- ESTRADIOL TAB 2 MG
- ESTROPIPATE 1.5 MG
- ESTROPIPATE TAB 1.5 MG
- MENEST
- PREFEST
- PREMARIN TAB 0.45 MG
- PREMARIN TAB 0.9 MG
- PREMPRO

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
PA is only required for 65 years of age or older. For patients less than 65 years of age, this will be approved
without PA.

**PRESCRIBER RESTRICTION**

N/A

**COVERAGE DURATION**

Plan Year

**OTHER CRITERIA**

In most patients 65 years of age or older, the prescribed medication is considered a "high risk medication" that poses an unnecessarily high risk when safer alternative therapy may be available. See American Geriatrics Society 2012 Beers Criteria Update Expert Panel, American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults, J Am Geriatr Soc, 2012, 60(4). 616-31. In addition, the prescribed medication is not recommended for postmenopausal women for the primary prevention of chronic medical conditions. See Ann Intern Med. 2013, 158. 47-54. 1) Prescriber must document that a non-HRM formulary drug is not an acceptable alternative for the drug being prescribed. For example, non-HRM alternative medications for hot flashes include SSRIs, gabapentin, and venlafaxine. Alternatives for bone density include alendronate and raloxifene. Alternatives for vaginal symptoms include vaginal estrogen cream. OR 2) The prescriber documents that the patient experienced an inadequate treatment response or intolerance to a non-HRM formulary drug or non-HRM formulary drugs are contraindicated. 3) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older.
HIGH RISK MEDICATIONS - SEDATIVE/HYPNOTICS

PRODUCT(s) AFFECTED
- ZOLPIDEM TARTRATE 10 MG
- ZOLPIDEM TARTRATE ER
- ZOLPIDEM TARTRATE TAB 5 MG
- ZOLPIDEM TARTRATE 5 MG
- ZOLPIDEM TARTRATE TAB 10 MG

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
In the elderly, not recommended for chronic use. See American Geriatrics Society 2012 Beers Criteria Update Expert Panel, American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults, J Am Geriatr Soc, 2012, 60(4). 616-31. 1) A non-HRM alternative formulary drug (Rozerem, Silenor 3mg, Silenor 6mg, trazodone) has not been tried AND 2) A non-HRM alternative formulary drug (Rozerem, Silenor 3mg, Silenor 6mg, trazodone) is not clinically appropriate AND 3) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65
years of age or older OR 4) A non-HRM alternative formulary drug (Rozerem, Silenor 3mg, Silenor 6mg, trazodone) has been tried AND 5) The patient experienced an inadequate treatment response OR intolerance to a non-HRM alternative formulary drug (Rozerem, Silenor 3mg, Silenor 6mg, trazodone) AND 6) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older. APPLIES TO GREATER THAN CUMULATIVE 90 DAYS OF THERAPY PER YEAR.
HIGH RISK MEDICATIONS - TRICYCLIC ANTIDEPRESSANTS

PRODUCT(s) AFFECTED
- AMITRIPTYLINE HCL 150 MG
- AMITRIPTYLINE HCL TAB 10 MG
- AMITRIPTYLINE HCL TAB 150 MG
- AMITRIPTYLINE HCL TAB 50 MG
- DOXEPIN HCL CAP 10 MG
- DOXEPIN HCL CAP 150 MG
- DOXEPIN HCL CAP 50 MG
- DOXEPIN HCL CONC 10 MG/ML
- IMIPRAMINE HCL TAB 25 MG
- IMIPRAMINE PAMOATE
- TRIMIPRAMINE MALEATE CAP 100 MG
- TRIMIPRAMINE MALEATE CAP 50 MG
- AMITRIPTYLINE HCL 25 MG
- AMITRIPTYLINE HCL TAB 100 MG
- AMITRIPTYLINE HCL TAB 25 MG
- AMITRIPTYLINE HCL TAB 75 MG
- DOXEPIN HCL CAP 100 MG
- DOXEPIN HCL CAP 25 MG
- DOXEPIN HCL CAP 75 MG
- IMIPRAMINE HCL TAB 10 MG
- IMIPRAMINE HCL TAB 50 MG
- SURMONTIL
- TRIMIPRAMINE MALEATE CAP 25 MG

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
PA is only required for 65 years of age or older. For patients less than 65 years of age, this will be approved without PA.

PRESCRIBER RESTRICTION
OTHER CRITERIA
In most patients 65 years of age or older, tertiary amine tricyclic antidepressants are considered "high risk medications" that poses an unnecessarily high risk when safer alternative therapy may be available. See American Geriatrics Society 2012 Beers Criteria Update Expert Panel, American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults, J Am Geriatr Soc, 2012, 60(4). 616-31. 1) A non-HRM alternative formulary drug (citalopram, desipramine, duloxetine, escitalopram, fluoxetine, nortriptyline, sertraline, venlafaxine, venlafaxine ER) has not been tried AND 2) A non-HRM alternative formulary drug (citalopram, desipramine, duloxetine, escitalopram, fluoxetine, nortriptyline, sertraline, venlafaxine, venlafaxine ER) is not clinically appropriate AND 3) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older OR 4) A non-HRM alternative formulary drug (citalopram, desipramine, duloxetine, escitalopram, fluoxetine, nortriptyline, sertraline, venlafaxine, venlafaxine ER) has been tried AND 5) The patient experienced an inadequate treatment response OR intolerance to a non-HRM alternative formulary drug (citalopram, desipramine, duloxetine, escitalopram, fluoxetine, nortriptyline, sertraline, venlafaxine, venlafaxine ER) AND 6) Prescriber must acknowledge that medication benefits outweigh potential risks in the patient 65 years of age or older.
PRODUCT(s) AFFECTED
- HUMIRA
- HUMIRA PEN
- HUMIRA PEN-PSORIASIS STARTER

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Latent TB screening with either a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB) prior to initiating Humira (or other biologic). For moderately to severely active rheumatoid arthritis (new starts only): 1) Inadequate response to at least a 3-month trial of methotrexate despite adequate dosing (i.e., titrated to 25-30 mg/week) OR 2) intolerance or contraindication to MTX OR 3) Inadequate response to at least a 3-month trial of a prior biologic DMARD or a targeted synthetic DMARD (e.g., Xeljanz) OR 4) Intolerance to a prior biologic DMARD or a targeted synthetic DMARD OR 5) Severely active RA. For moderately to severely active polyarticular juvenile idiopathic arthritis (new starts only): 1) Inadequate response to at least a 3-month trial of MTX OR 2) Intolerance or contraindication to MTX OR 3) Inadequate response to at least a 3-month trial of a prior biologic DMARD OR 4) Intolerance to a prior biologic DMARD. For active ankylosing spondylitis (new starts only): 1) Inadequate response to at least a 4-week NSAID trial at maximum recommended or tolerated dose OR intolerance and/or contraindication to NSAIDs AND 2) Member has at least ONE of the following: a) Predominant axial disease (i.e., extensive spinal involvement), b) Inadequate response to a synthetic DMARD (e.g., sulfasalazine), c) Intolerance or contraindication to a synthetic DMARD, d) Inadequate response to at least a 3-month trial of a prior biologic DMARD, e) Intolerance to a prior biologic DMARD. For moderate to severe chronic plaque psoriasis (new starts only): 1) At least 5% of BSA is affected or crucial body areas (e.g., feet, hands, face, neck and/or groin) are affected AND 2) Inadequate response to either phototherapy (e.g., UVB, PUVA) or a traditional systemic agent (e.g., methotrexate, cyclosporine, acitretin), unless contraindicated or intolerant to such therapies.
AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For moderately to severely active Crohn's disease (new starts only): 1) Inadequate response to at least one conventional therapy (e.g., corticosteroids, sulfasalazine, azathioprine, mesalamine) OR 2) Intolerance or contraindication to conventional therapy. For moderately to severely active ulcerative colitis (new starts only): 1) Inadequate response to immunosuppressant therapy (e.g., corticosteroids, azathioprine, mercaptopurine) or intolerance or contraindication to immunosuppressant therapy AND 2) Patient is naive to TNF inhibitor therapy or patient lost response to previous TNF inhibitor therapy due to antibody formation. For active psoriatic arthritis (PsA) (new starts only): Member meets ANY of the following: 1) Inadequate response to at least a 3-month trial of MTX, sulfasalazine, or leflunomide, 2) Intolerance or contraindication to MTX, sulfasalazine, or leflunomide, 3) Inadequate response to at least a 3-month trial of a prior biologic DMARD, 4) Intolerance to a prior biologic DMARD, 5) Severely active PsA as evidenced by ANY of the following: a) multiple swollen joints, b) structural damage in the presence of inflammation, or c) clinically relevant extra-articular manifestations (eg, extensive skin, bowel, ocular, cardiovascular, urogenital, or pulmonary involvement), 6) Active enthesitis and/or dactylitis (i.e., sausage finger) 7) Predominant axial disease (ie, extensive spinal involvement).
IBRANCE

PRODUCT(s) AFFECTED
IBRANCE

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
Oncologist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
ICLUSIG

PRODUCT(s) AFFECTED
ICLUSIG

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of CML or Ph+ ALL was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Oncologist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Prescriber must confirm monitoring for evidence of thromboembolism and vascular occlusion. Prescriber must confirm monitoring for cardiac function and hepatic function.
**PRODUCT(s) AFFECTED**
ILARIS

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

**EXCLUSION CRITERIA**
When used in combination with tumor necrosis factor (TNF) blocking agents (e.g., etanercept, adalimumab, certolizumab pegol, golimumab, infliximab), anakinra, or rilonacept.

**REQUIRED MEDICAL INFORMATION**
N/A

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
Prescribed by or in consultation with a rheumatologist, geneticist, or dermatologist.

**COVERAGE DURATION**
Initial approval for MWS or FCAS, one dose, subsequent auth 12 mo if response. SJIA, 12 mos.

**OTHER CRITERIA**
For initial approval for MWS or FCAS, authorize one dose. After up to 8 weeks of therapy if the patient has had a response to therapy as determined by prescribing physician an additional 12 months authorization is allowed. For treatment of SJIA, approve.
PRODUCT(s) AFFECTED
IMBRUVICA

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Small lymphocytic lymphoma, lymphoplasmacytic lymphoma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For small lymphocytic lymphoma (SLL): patient has SLL with 17p deletion OR has received at least one prior therapy. For Waldenstrom's macroglobulinemia and lymphoplasmacytic lymphoma (WM/LPL): Imbruvica is used as a single agent.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

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
Closed epiphyses.

REQUIRED MEDICAL INFORMATION
Must meet all of the following prior to beginning Increlex therapy (new starts only): 1) height 3 or more standard deviations below the mean for children of the same age and gender AND 2) basal IGF-1 level 3 or more standard deviations below the mean for children of the same age and gender AND 3) stimulation test showing a normal or elevated growth hormone level. For renewal, patient is growing more than 2 cm/year AND the current IGF-1 level is normal for age and gender.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Endocrinologist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
INLYTA

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Papillary, Hurthle cell, or follicular thyroid carcinoma

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For renal cell carcinoma, the disease is relapsed or medically unresectable. The medication will be used as a single agent. The tumor expresses predominantly clear cell or non-clear cell histology. If clear cell, the patient has previous tried and failed, or had an intolerance or contraindication to, Votrient (pazopanib) or Sutent (sunitinib). For thyroid carcinoma, the disease has papillary, Hurthle cell, or follicular histology. Nexavar is not an appropriate option for the patient. The disease is unresectable or metastatic. The disease is radioiodine refractory. The disease is progressive or symptomatic.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
IRESSA

PRODUCT(s) AFFECTED
IRESSA

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
**IVIG**

**PRODUCT(s) AFFECTED**
- BIVIGAM
- FLEBOGAMMA DIF SOLUTION 10 GM/100ML
- FLEBOGAMMA DIF SOLUTION 5 GM/50ML
- GAMMAGARD S/D
- GAMMAPLEX
- GAMUNEX-C

**COVERED USES**
All FDA-approved indications not otherwise excluded from Part D, chronic inflammatory demyelinating polyneuropathy, multifocal motor neuropathy, dermatomyositis, polymyositis, Guillain-Barre syndrome (GBS), relapsing-remitting multiple sclerosis (RRMS), myasthenia gravis, Lambert-Eaton myasthenic syndrome, Kawasaki syndrome, idiopathic thrombocytopenic purpura, pure red cell aplasia (PRCA), fetal/neonatal alloimmune thrombocytopenia, and prophylaxis of bacterial infections in B-cell chronic lymphocytic leukemia (CLL), bone marrow/hematopoietic stem cell transplant (BMT/HSCT) recipients, and pediatric HIV infection.

**EXCLUSION CRITERIA**
IgA deficiency with antibodies to IgA and a history of hypersensitivity. History of anaphylaxis or severe systemic reaction to human immune globulin or product components.

**REQUIRED MEDICAL INFORMATION**
For dermatomyositis and polymyositis: standard 1st line treatments (corticosteroids or immunosuppressants) have been tried but were unsuccessful or not tolerated OR patient is unable to receive standard therapy because of a contraindication or other clinical reason. For GBS: physical mobility must be severely affected such that the patient requires an aid to walk AND IVIG therapy must be initiated within 2 weeks of symptom onset. For RRMS: standard 1st line treatments (interferon or glatiramer) have been tried but were unsuccessful or not tolerated OR patient is unable to receive standard therapy because of a contraindication or other clinical reason. For CLL: serum IgG less than 500 mg/dL OR a history of recurrent bacterial infections. For BMT/HSCT: serum IgG less than 400 mg/dL. For pediatric HIV infection: serum IgG less
than 400 mg/dL OR a history of recurrent bacterial infections. PRCA is secondary to parvovirus B19 infection. For all indications: patients with any of the following risk factors for renal dysfunction must receive the minimum dose or concentration available of IVIG and the minimum infusion rate practicable: pre-existing renal insufficiency, diabetes mellitus, age over 65 years, volume depletion, sepsis, paraproteinemia, or receiving concomitant nephrotoxic drugs. For all indications: patients with any of the following risk factors for thrombosis must receive the minimum dose or concentration available of IVIG and the minimum infusion rate practicable: age 45 years or older, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, or cardiovascular risk factors.

AGE RESTRICTION
For pediatric HIV infection: age 12 years or younger.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
JAKAFI

PRODUCT(s) AFFECTED
JAKAFI

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For polycythemia vera, patient has had an inadequate response to or is intolerant of hydroxyurea.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
KALYDECO

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

EXCLUSION CRITERIA
Patients with CF who are homozygous for the F508del mutation in the CFTR gene.

REQUIRED MEDICAL INFORMATION
Documentation of one of the following mutations in the CFTR gene - G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R or R117H.

AGE RESTRICTION
For Kalydeco granules, patient must be 2 years old to less than 6 years old. For Kalydeco tablets, patient must be 6 years old or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Prescriber agrees to monitor liver function per package labeling.
KORLYM

PRODUCT(s) AFFECTED
KORLYM

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

EXCLUSION CRITERIA
Medical termination of intrauterine pregnancy.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or after consultation with an endocrinologist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
KUVAN

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Kuvan will be used in conjunction with a phenylalanine-restricted diet. For patients who have not yet received a therapeutic trial of Kuvan: a) patients less than or equal to 12 years of age have a baseline blood Phe level greater than 6 mg/dL OR b) patients greater than 12 years of age have a baseline blood Phe level greater than 10 mg/dL. For patients for whom this is the first treatment after a therapeutic trial of Kuvan: a) patient must have experienced a reduction in blood Phe level of greater than or equal to 30 percent from baseline OR b) patient has demonstrated an improvement in neuropsychiatric symptoms.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Initial: 1 month. Continuation of treatment: Plan Year.

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
KYNAMRO

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
Initial authorization will be for 6 months. Approve for another 6 months per other criteria

OTHER CRITERIA
Use must be in accordance with the Risk Evaluation and Mitigation Strategy (REMS) program for mipomersen.
LAZANDA

PRODUCT(s) AFFECTED
LAZANDA

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

EXCLUSION CRITERIA
Significant respiratory depression. Known or suspected paralytic ileus.

REQUIRED MEDICAL INFORMATION
1) The drug is being prescribed for the management of breakthrough pain in a cancer patient who is already receiving around-the-clock opioid therapy for underlying cancer pain AND 2) The patient can safely take the requested dose based on their current opioid use history. [Note: Lazanda is indicated for opioid-tolerant patients. Patients considered opioid tolerant are those who are taking at least: 60 mg of oral morphine/day, 25 mcg of transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for a week or longer.]

AGE RESTRICTION
Adults.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year.

OTHER CRITERIA
N/A
LENVIMA

PRODUCT(s) AFFECTED
- LENVIMA 10 MG DAILY DOSE
- LENVIMA 20 MG DAILY DOSE
- LENVIMA 8 MG DAILY DOSE
- LENVIMA 14 MG DAILY DOSE
- LENVIMA 24 MG DAILY DOSE

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
Oncologist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
LETAIRIS

PRODUCT(s) AFFECTED
LETAIRIS

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
NYHA Functional Class II or III symptoms. PAH (WHO Group 1) was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) pretreatment pulmonary vascular resistance is greater than 3 Wood units.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
LEUKINE

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

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Chemotherapy-induced febrile neutropenia (FN), following chemotherapy for acute lymphocytic leukemia (ALL) or acute myeloid leukemia (AML), myelodysplastic syndromes (MDS), agranulocytosis, aplastic anemia, HIV-related neutropenia.

EXCLUSION CRITERIA
Use of Leukine within 24 hours preceding or following chemotherapy or radiotherapy. For treatment of chemotherapy-induced FN, patient received prophylactic pegylated G-CSF (eg, Neulasta) during the current chemotherapy cycle.

REQUIRED MEDICAL INFORMATION
For prophylaxis of myelosuppressive chemotherapy-induced FN: 1) Patient has a non-myeloid cancer AND 2) Patient is currently receiving or will be receiving treatment with myelosuppressive anti-cancer therapy.
For treatment of myelosuppressive chemotherapy-induced FN: 1) Patient has a non-myeloid cancer AND 2) Patient is currently receiving or has received treatment with myelosuppressive anti-cancer therapy. For MDS: Patient has neutropenia and recurrent or resistant infections.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 Months
OTHER CRITERIA
N/A
LIDOCAINE TRANSDERMAL PATCH

PRODUCT(s) AFFECTED
LIDOCAINE PATCH 5 %

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Adults.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year.

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
LONSURF

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For metastatic colorectal cancer, KRAS (with or without NRAS) mutation testing is performed on either the primary tumor or metastases to confirm RAS mutation status. The patient must have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS or NRAS wild type, an anti-EGFR therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
LUMIZYME

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of Pompe disease was confirmed by an enzyme assay demonstrating a deficiency of GAA enzyme activity or by DNA testing that identifies mutations in the GAA gene.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
LYNPARZA

PRODUCT(s) AFFECTED
LYNPARZA

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
MEGACE-ES

PRODUCT(s) AFFECTED
- MEGACE ES
- MEGESTROL ACETATE SUSPENSION 625 MG/5ML

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

EXCLUSION CRITERIA
Pregnancy

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
MEKINIST

PRODUCT(s) AFFECTED
MEKINIST

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

EXCLUSION CRITERIA
As a single agent for the treatment of patients who have received prior BRAF-inhibitor therapy (eg, Zelboraf, Tafinlar)

REQUIRED MEDICAL INFORMATION
Patient has a diagnosis of unresectable or metastatic melanoma AND the tumor is positive for either BRAF V600E or V600K mutation AND patient will use Mekinist as either a single agent or in combination with Tafinlar.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
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
N/A
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 of Pompe disease was confirmed by an enzyme assay demonstrating a deficiency of GAA enzyme activity or by DNA testing that identifies mutations in the GAA gene.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
**NAGLAZYME**

**PRODUCT(s) AFFECTED**
NAGLAZYME

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

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Diagnosis of mucopolysaccharidosis VI (MPS VI) was confirmed by an enzyme assay demonstrating a deficiency in N-acetylgalactosamine 4-sulfatase (arylsulfatase B) enzyme activity or by DNA testing.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
N/A
NEXAVAR

PRODUCT(s) AFFECTED
NEXAVAR

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Osteosarcoma, angiosarcoma, desmoid tumors (aggressive fibromatosis), progressive gastrointestinal stromal tumor (GIST), medullary thyroid carcinoma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For renal cell carcinoma, patient has relapsed or medically unresectable disease and Nexavar will be used as a single agent. If clear cell histology, the patient has previous tried and failed, or had an intolerance or contraindication to, Votrient (pazopanib) or Sutent (sunitinib). For hepatocellular carcinoma, patient has unresectable disease and Nexavar will be used as a single agent. For osteosarcoma, Nexavar will be used as a single agent. For GIST, disease progressed after failure of imatinib, sunitinib, or regorafenib. For follicular, Hurthle cell, and papillary thyroid carcinoma, the disease is unresectable or metastatic. The disease is radio-iodine refractory. The disease is progressive or symptomatic. For medullary thyroid carcinoma, after progression on vandetanib or cabozantinib OR vandetanib or cabozantinib are not appropriate options.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year
OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
NINLARO

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
**NUEDEXTA**

**PRODUCT(s) AFFECTED**
NUEDEXTA

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

**EXCLUSION CRITERIA**
Patient is currently using quinidine, quinine, mefloquine, monoamine oxidase inhibitors (MAOIs), or drugs that both prolong the QT interval and are metabolized by CYP2D6 (examples: thioridazine and pimozide). Patient has a prolonged QT interval or congenital long QT syndrome (LQTS), or heart failure or a history suggestive of torsades de pointes (TdP). Patient has complete atrioventricular (AV) block without an implanted pacemaker or is at high risk of complete AV block.

**REQUIRED MEDICAL INFORMATION**
Nuedexta is being requested for the treatment of pseudobulbar affect (PBA).

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

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

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1) Diagnosis is narcolepsy confirmed by sleep lab evaluation OR 2) Diagnosis is obstructive sleep apnea (OSA) confirmed by polysomnography OR 3) Diagnosis is Shift Work Disorder (SWD).

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 indication not otherwise covered under Part D. Poorly differentiated (high-grade) neuroendocrine tumor (NET)/large or small cell, pancreatic endocrine tumors (Islet cell tumors), carcinoid tumors, lung NET, unresectable and recurrent meningiomas, thymic carcinomas.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Acromegaly, must meet all of the following: 1) Clinical evidence of acromegaly, AND 2) Pre-treatment high IGF-1 level for age/gender, AND 3) Patient had an inadequate or partial response to surgery and/or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For acromegaly continuation of therapy: the IGF-1 level decreased or normalized.
PRODUCT(s) AFFECTED
ODOMZO

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

EXCLUSION CRITERIA
Pregnancy

REQUIRED MEDICAL INFORMATION
Member has a diagnosis of locally advanced basal cell carcinoma (BCC). Member experienced disease recurrence following surgery or radiation therapy OR member is not a candidate for surgery or radiation therapy. For females of reproductive potential, pregnancy has been ruled out with a negative pregnancy test result.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
OFEV

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

EXCLUSION CRITERIA
Use in patients with more severe disease (FVC less than 50% of the predicted value) or with an acute exacerbation.

REQUIRED MEDICAL INFORMATION
ALT, AST, and bilirubin

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Pulmonologist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Prescriber agrees to monitor ALT, AST, and bilirubin before and during treatment per package labeling. Temporary dosage reductions or discontinuations may be required per package labeling.
OPSUMIT

PRODUCT(s) AFFECTED
OPSUMIT

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
NYHA Functional Class II or III symptoms. PAH (WHO Group 1) was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) pretreatment pulmonary vascular resistance is greater than 3 Wood units.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Cardiologist or pulmonologist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
- ABSTRAL
- FENTANYL CITRATE 1600 MCG
- FENTANYL CITRATE 400 MCG
- FENTANYL CITRATE 800 MCG
- FENTANYL CITRATE LOZ HANDLE 1600 MCG
- FENTANYL CITRATE LOZ HANDLE 400 MCG
- FENTANYL CITRATE LOZ HANDLE 800 MCG
- FENTORA TAB 200 MCG
- FENTORA TAB 600 MCG
- SUBSYS

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

EXCLUSION CRITERIA
Significant respiratory depression. Known or suspected paralytic ileus.

REQUIRED MEDICAL INFORMATION
1) The drug is being prescribed for the management of breakthrough pain in a cancer patient who is already receiving around-the-clock opioid therapy for underlying cancer pain AND 2) The patient can safely take the requested dose based on their current opioid use history. [Note: The TIRF (Transmucosal Immediate-Release Fentanyl) products (Abstral, Actiq, Fentora, Lazanda, and Subsys) are indicated for opioid-tolerant patients. Patients considered opioid tolerant are those who are taking at least: 60 mg of oral morphine/day, 25 mcg of transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for a week or longer.]
AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
6 Months

OTHER CRITERIA
N/A
ORENITRAM

PRODUCT(s) AFFECTED
ORENITRAM

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis was confirmed by right heart catheterization. Child-Pugh score determination - bilirubin, albumin, INR, presence of ascites, presence of encephalopathy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Cardiologist or pulmonologist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Contraindicated for Child-Pugh Class C
ORKAMBI

PRODUCT(s) AFFECTED
ORKAMBI TAB 200-125 MG

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

EXCLUSION CRITERIA
Use in combination with Kalydeco

REQUIRED MEDICAL INFORMATION
The patient is positive for the F508del mutation on both alleles of the CFTR gene.

AGE RESTRICTION
12 years of age or older

PRESCRIBER RESTRICTION
N/A

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>
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<tr>
<td>ACETYLICYSTEINE SOLUTION 10 %</td>
<td>ACETYLICYSTEINE SOLUTION 20 %</td>
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<tr>
<td>ACYCLOVIR SODIUM RECON SOLN 500 MG</td>
<td>ACYCLOVIR SODIUM SOLUTION 50 MG/ML</td>
</tr>
<tr>
<td>ADRUCIL</td>
<td>AKYNZEO</td>
</tr>
<tr>
<td>ALBUTEROL SULFATE NEBU SOLN (2.5 MG/3ML) 0.083%</td>
<td>ALBUTEROL SULFATE NEBU SOLN (5 MG/ML) 0.5%</td>
</tr>
<tr>
<td>ALBUTEROL SULFATE NEBU SOLN 0.63 MG/3ML</td>
<td>ALBUTEROL SULFATE NEBU SOLN 1.25 MG/3ML</td>
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<tr>
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<tr>
<td>AMINOSYN II</td>
<td>AMINOSYN II/ELECTROLYTES</td>
</tr>
<tr>
<td>AMINOSYN M</td>
<td>AMINOSYN-HBC</td>
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<td>AMINOSYN-PF</td>
<td>AMINOSYN-RF</td>
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<td>AMINOSYN/ELECTROLYTES</td>
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<td>ARRANON</td>
<td>ARZERRA CONC 100 MG/5ML</td>
</tr>
<tr>
<td>ASTAGRAF XL</td>
<td>AVASTIN</td>
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<td>AZACITIDINE</td>
<td>AZATHIOPRINE SODIUM</td>
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<tr>
<td>BLEOMYCIN SULFATE</td>
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<td>BUDESONIDE SUSPENSION 0.25 MG/2ML</td>
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</tr>
<tr>
<td>CARBOPLATIN SOLUTION 600 MG/60ML</td>
<td>CISPLATIN SOLUTION 100 MG/100ML</td>
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</table>
- CISPLATIN SOLUTION 200 MG/200ML
- CALCITRIOL CAP 0.25 MCG
- CALCITRIOL SOLUTION 1 MCG/ML
- CELLCEPT RECON SUSP 200 MG/ML
- CLADRIBINE
- CROMOLYN SODIUM NEBU SOLN 20 MG/2ML
- CYCLOSPORINE 100 MG
- CYCLOSPORINE CAP 25 MG
- CYCLOSPORINE SOLUTION 50 MG/ML
- CYCLOPHOSPHAMIDE CAP 50 MG
- CYTARABINE (PF)
- CYTARABINE RECON SOLN 100 MG
- CYTARABINE SOLUTION 20 MG/ML
- DOCETAXEL CONC 140 MG/7ML
- DOCETAXEL CONC 20 MG/ML
- DOCETAXEL SOLUTION 160 MG/16ML
- DOCETAXEL SOLUTION 200 MG/20ML
- DOXORUBICIN HCL
- DACARBAZINE RECON SOLN 200 MG
- DEPO-PROVERA SUSPENSION 400 MG/ML
- DIPHTHERIA-TETANUS TOXOIDS DT
- DRONABINOL
- ELITEK RECON SOLN 1.5 MG
- EMEND CAP 40 MG
- EMEND CAP 80 MG
- EMPLICITI
- ENVARSUS XR
- CISPLATIN SOLUTION 50 MG/50ML
- CALCITRIOL CAP 0.5 MCG
- CELLCEPT INTRAVENOUS
- CESAMET
- CLOLAR
- CUBICIN
- CYCLOSPORINE CAP 100 MG
- CYCLOSPORINE MODIFIED
- CYCLOSPORINE CAP 25 MG
- CYCLOSPORINE SOLUTION 50 MG/ML
- CYRAMZA
- CYTARABINE RECON SOLN 1 GM
- CYTARABINE RECON SOLN 2 GM
- DAUNORUBICIN HCL
- DOCEFREZ RECON SOLN 20 MG
- DARZALEX SOLUTION 100 MG/5ML
- DEXRAZOXANE
- DOCEFREZ RECON SOLN 20 MG
- EMEND CAP 125 MG
- EMEND CAP 80 & 125 MG
- EMEND RECON SOLN 150 MG
- ENGERIX-B
- EPIRUBICIN HCL SOLUTION 200 MG/100ML
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.
PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

PRODUCT(s) AFFECTED
ADCIRCA

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

EXCLUSION CRITERIA
Patient requires nitrate therapy on a regular or intermittent basis.

REQUIRED MEDICAL INFORMATION
NYHA Functional Class II or III symptoms. PAH (WHO Group 1) was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) pretreatment pulmonary vascular resistance is greater than 3 Wood units.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For approval of sildenafil injection, patient must be unable to take an oral PDE-5 inhibitor.
PHOSPHODIESTERASE-5 INHIBITORS FOR PAH- NSO

PRODUCT(s) AFFECTED
- REVATIO RECON SUSP 10 MG/ML
- SILDENAFIL CITRATE SOLUTION 10 MG/12.5ML
- REVATIO SOLUTION 10 MG/12.5ML
- SILDENAFIL CITRATE TAB 20 MG

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

EXCLUSION CRITERIA
Patient requires nitrate therapy on a regular or intermittent basis.

REQUIRED MEDICAL INFORMATION
NYHA Functional Class II or III symptoms. PAH (WHO Group 1) was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) pretreatment pulmonary vascular resistance is greater than 3 Wood units.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For approval of sildenafil injection, patient must be unable to take an oral PDE-5 inhibitor.
PLEGRIDY

PRODUCT(s) AFFECTED
- PLEGRIDY
- PLEGRIDY STARTER PACK

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Member must have a relapsing form of multiple sclerosis (MS) (eg, relapsing-remitting MS, progressive-relapsing MS, or secondary progressive MS with relapses).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
POMALYST

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Systemic light chain amyloidosis.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For multiple myeloma, the patient has been previously treated with bortezomib. The patient has been previously treated with lenalidomide or thalidomide. The disease progressed during the previous treatment or within 60 days of completion of the previous therapy. Pomalyst will be used as a single agent or in combination with dexamethasone. For amyloidosis, Pomalyst will be given in combination with dexamethasone.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

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

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

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Member must have one of the following conditions (new starts and continuation): 1) Prior clinical atherosclerotic cardiovascular disease (ASCVD) or cardiovascular event (see Other Criteria), or 2) Heterozygous familial hypercholesterolemia (HeFH): Definite diagnosis of FH (See Other Criteria). For new starts: For members with prior clinical ASCVD or cardiovascular event, at least one of the following requirements is met: 1) Current LDL-C level 70 mg/dL or greater after treatment with a high-intensity statin (eg, atorvastatin, rosuvastatin), 2) Current LDL-C level 70 mg/dL or greater with intolerance to a high-intensity statin AND is taking a maximally tolerated dose of any statin, 3) Current LDL-C level 70 mg/dL or greater with contraindication to statin (see Other Criteria) OR intolerance to any dose of two statins, or 4) Recent treatment (ie, within the last 120 days) with another PCSK9 inhibitor. For members with HeFH, at least one of the following requirements is met: 1) With ASCVD: See requirements for members with prior ASCVD above, 2) Current LDL-C level 100 mg/dL or greater after treatment with a high-intensity statin (eg, atorvastatin, rosuvastatin), 3) Current LDL-C level 100 mg/dL or greater with intolerance to a high-intensity statin AND is taking a maximally tolerated dose of any statin, 4) Current LDL-C level 100 mg/dL or greater with contraindication to statin (see Other Criteria) OR intolerance to any dose of two statins, or 5) Recent treatment (ie, within the last 120 days) with another PCSK9 inhibitor. For continuation: Response to therapy as demonstrated by a reduction in LDL-C.

**AGE RESTRICTION**
18 years of age or older
OTHER CRITERIA
Clinical ASCVD or cardiovascular event defined as acute coronary syndromes, myocardial infarction, stable or unstable angina, coronary or other arterial revascularization procedure [eg, PTCA, CABG], stroke of presumed atherosclerotic origin, transient ischemic attack, peripheral arterial disease of presumed atherosclerotic origin, findings from CT angiogram or catheterization consistent with clinical ASCVD). Diagnosis of FH must be confirmed by one of the following: 1) Genetic confirmation: An LDL-receptor mutation, familial defective apo B-100, or a PCSK9 gain-of-function mutation, 2) Simon-Broome Diagnostic Criteria for definite FH: Total cholesterol greater than 290 mg/dL or LDL-C greater than 190 mg/dL, plus tendon xanthoma in patient, first-degree (parent, sibling or child) or second-degree relative (grandparent, uncle or aunt), or 3) Dutch Lipid Clinic Network Criteria for definite FH: Total score greater than 8 points. Contraindication to statin must be due to one of the following: 1) Active liver disease, including unexplained persistent elevations in hepatic transaminase levels (eg, ALT level at least 3 times ULN), 2) Women who are pregnant or may become pregnant, or 3) Nursing mothers.
PRODUCT(s) AFFECTED
PRIVIGEN

COVERED USES
All FDA-approved indications not otherwise excluded from Part D, chronic inflammatory demyelinating polyneuropathy, multifocal motor neuropathy, dermatomyositis, polymyositis, Guillain-Barre syndrome (GBS), relapsing-remitting multiple sclerosis (RRMS), myasthenia gravis, Lambert-Eaton myasthenic syndrome, Kawasaki syndrome, pure red cell aplasia (PRCA), fetal/neonatal alloimmune thrombocytopenia, and prophylaxis of bacterial infections in B-cell chronic lymphocytic leukemia (CLL), bone marrow/hematopoietic stem cell transplant (BMT/HSCT) recipients, and pediatric HIV infection.

EXCLUSION CRITERIA
IgA deficiency with antibodies to IgA and a history of hypersensitivity. History of anaphylaxis or severe systemic reaction to human immune globulin or product components. Hyperprolinemia.

REQUIRED MEDICAL INFORMATION
For dermatomyositis and polymyositis: standard 1st line treatments (corticosteroids or immunosuppressants) have been tried but were unsuccessful or not tolerated OR patient is unable to receive standard therapy because of a contraindication or other clinical reason. For GBS: physical mobility must be severely affected such that the patient requires an aid to walk AND IVIG therapy must be initiated within 2 weeks of symptom onset. For RRMS: standard 1st line treatments (interferon or glatiramer) have been tried but were unsuccessful or not tolerated OR patient is unable to receive standard therapy because of a contraindication or other clinical reason. For CLL: serum IgG less than 500 mg/dL OR a history of recurrent bacterial infections. For BMT/HSCT: serum IgG less than 400 mg/dL. For pediatric HIV infection: serum IgG less than 400 mg/dL OR a history of recurrent bacterial infections. PRCA is secondary to parvovirus B19 infection. For all indications: patients with any of the following risk factors for renal dysfunction must receive the minimum dose or concentration available of IVIG and the minimum infusion rate practicable: pre-existing renal insufficiency, diabetes mellitus, age over 65 years, volume depletion, sepsis, paraproteinemia, or receiving concomitant nephrotoxic drugs. For all indications: patients with any of the following risk factors for thrombosis must receive the minimum dose or concentration available of IVIG and...
the minimum infusion rate practicable: age 45 years or older, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, or cardiovascular risk factors.

AGE RESTRICTION
For pediatric HIV infection: age 12 years or younger.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
PRODUCT(s) AFFECTED
PROMACTA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For chronic or persistent immune thrombocytopenia (ITP): 1) For new starts: a) Patient has had an inadequate response or is intolerant to corticosteroids, immunoglobulins or splenectomy, AND b) Untransfused platelet count at time of diagnosis is less than 30,000/mcL OR 30,000-50,000/mcL with symptomatic bleeding or risk factor(s) for bleeding. 2) For continuation of therapy, platelet (plt) count response to Promacta: a) Current plt count is 50,000-200,000/mcL OR b) Current plt count is less than 50,000/mcL and sufficient to avoid clinically important bleeding OR c) Current plt count is less than 50,000/mcL and patient has not received a maximal dose of Promacta for at least 4 weeks OR d) Current plt count is greater than 200,000/mcL and dosing will be adjusted to a plt count sufficient to avoid clinically important bleeding. For thrombocytopenia associated with chronic hepatitis C: 1) For new starts: a) Promacta is used for initiation and maintenance of interferon-based therapy, AND b) Untransfused platelet count at time of diagnosis is less than 75,000/mcL. 2) For continuation of therapy: patient is receiving interferon-based therapy. For severe aplastic anemia (AA): 1) For new starts: a) Patient has had an inadequate response to immunosuppressive therapy, AND b) Untransfused platelet count at time of diagnosis is less than or equal to 30,000/mcL. 2) For continuation of therapy, plt count response to Promacta: a) Current plt count is 50,000-200,000/mcL OR b) Current plt count is less than 50,000/mcL and patient has not received appropriately titrated therapy for at least 16 weeks OR c) Current plt count is greater than 200,000/mcL and dosing will be adjusted to achieve and maintain an appropriate target plt count. Adequate platelet response = APR. Inadequate platelet response = IPR.

AGE RESTRICTION
PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
HCV:6mo, ITP/AA initial:6mo, ITP/AA APR reauth: Plan Yr, ITP IPR reauth:3mo, AA IPR reauth:16wks

OTHER CRITERIA
Liver function will be measured at baseline and regularly throughout treatment AND Alanine aminotransferase (ALT) levels must not be equal to or greater than 3x the upper limit of normal in patients with normal liver function or equal to or greater than 3x baseline in a patient with pre-treatment elevations in transaminases AND have any of the following characteristics: progressive, persistent for equal to or greater than 4 weeks, accompanied by increased direct bilirubin or symptoms of liver injury or evidence of hepatic decompensation.
PRODUCT(s) AFFECTED
MODAFINIL

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Fatigue associated with multiple sclerosis (MS). Excessive daytime sleepiness (EDS) due to myotonic dystrophy. Adjunctive/augmentation for treatment of depression in adults.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For the FDA-approved indication of excessive sleepiness due to obstructive sleep apnea/hypoapnea syndrome (OSAHS), patient CPAP history or status. For the FDA-approved indication of excessive sleepiness due to shift-work sleep disorder (SWSD), patients must be working at least 5 overnight shifts per month.

AGE RESTRICTION
Patients must be greater than or equal to 17 years of age.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Excessive sleepiness due to SWSD if the patient is working at least 5 overnight shifts per month. ADHD/ADD for patients who have tried two alternative medications for ADHD/ADD from two different
classes as follows: methylphenidate products (e.g., methylphenidate, dexamethasphenidate), amphetamines (e.g., mixed amphetamine salts, dextroamphetamine), atomoxetine, alpha agonists (e.g., Kapvay, Intuniv), bupropion or tricyclic antidepressants (TCAs e.g., imipramine, desipramine). Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression.
PRODUCT(s) AFFECTED
- REBIF
- REBIF REBIDOSE
- REBIF REBIDOSE TITRATION PACK
- REBIF TITRATION PACK

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
Prescribed by or after consultation with a neurologist or an MS specialist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
REGRANEX

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

EXCLUSION CRITERIA
Neoplasm(s) at site(s) of application.

REQUIRED MEDICAL INFORMATION
1) For the treatment of lower extremity diabetic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply AND 2) Good ulcer care practices including initial sharp debridement, pressure relief, and infection control will be performed.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
20 weeks

OTHER CRITERIA
N/A
**PRODUCT(s) AFFECTED**
- RELISTOR KIT 12 MG/0.6ML
- RELISTOR SOLUTION 12 MG/0.6ML
- RELISTOR SOLUTION 8 MG/0.4ML

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

**EXCLUSION CRITERIA**
Known or suspected mechanical gastrointestinal obstruction. At increased risk of recurrent obstruction due to the potential for gastrointestinal perforation.

**REQUIRED MEDICAL INFORMATION**
1) Relistor is being prescribed for opioid-induced constipation in an adult patient with advanced illness who is receiving palliative care when response to laxative therapy has not been sufficient OR 2) Relistor is being prescribed for opioid-induced constipation in an adult patient with chronic non-cancer pain AND 3) The patient is unable to tolerate oral medications OR 4) An oral drug indicated for opioid-induced constipation in an adult patient with chronic non-cancer pain has been tried. (Note: Examples are Amitiza or Movantik) AND 5) The patient experienced an inadequate treatment response or intolerance to an oral drug indicated for opioid-induced constipation in an adult patient with chronic non-cancer pain. (Note: Examples are Amitiza or Movantik) OR 6) An oral drug indicated for opioid-induced constipation in an adult patient with chronic non-cancer pain has not been tried. (Note: Examples are Amitiza or Movantik) AND 7) The patient has a contraindication to an oral drug indicated for opioid-induced constipation in an adult patient with chronic non-cancer pain (Note: Examples are Amitiza or Movantik).

**AGE RESTRICTION**
N/A

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

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

**COVERED USES**

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Latent TB screening w/ skin test or interferon gamma release assay before initiating Remicade/other biologic. The following apply to new starts only. For moderate to severe active Crohn's disease: 1) fistulizing disease OR 2) inadequate response to at least 3-mo trial of a self-inj TNF inhibitor (eg, Humira, Cimzia) or intolerance. For moderate to severe active UC: inadequate response to at least 1 conventional tx (eg, steroids, sulfasalazine [SSZ], azathioprine) or intolerance/contraindication (CI). For moderate to severe active RA: 1) Remicade used w/ MTX or leflunomide (LEF) OR intolerance/CI to MTX or LEF, AND 2) inadequate response to at least 3-mo trial of a self-inj TNF inhibitor (eg, Humira, Cimzia) or intolerance. For active AS/AxSpA: 1) inadequate response to at least 4-wk trial of NSAID at max recommended/tolerated dose OR intolerance/contraindication to NSAIDs, AND 2) at least 1 of the following: a) predominant axial disease b) inadequate response to a synthetic DMARD c) intolerance/contraindication to a synthetic DMARD or d) inadequate response to at least 3-mo trial of a self-inj TNF inhibitor (eg, Humira, Cimzia) or intolerance. For active PsA: 1) inadequate response to at least 3-mo trial of MTX, LEF, or SSZ OR intolerance/contraindication to MTX, LEF, or SSZ, 2) inadequate response to at least 3-mo trial of a self-inj TNF inhibitor (eg, Humira, Cimzia) or intolerance, 3) severe active PsA w/ ANY of the following: multiple swollen joints, structural damage w/ inflammation, clinically relevant extra-articular manifestations, 4) active enthesitis and/or dactylitis, or 5) predominant axial disease. For chronic moderate to severe plaque psoriasis: 1) at least 5% BSA affected or crucial body areas (eg, feet, hands, face) affected AND 2) inadequate response to at least 3-mo trial of a self-inj TNF inhibitor (eg, Humira) or intolerance. For JIA:
inadequate response to at least 3-mo trial of a self-inj TNF inhibitor (eg, Humira) or intolerance.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
REVLIMID

PRODUCT(s) AFFECTED
REVLIMID

COVERED USES

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For multiple myeloma: Revlimid (REV) will be used as primary, maintenance, or salvage therapy. If primary and the patient is a stem cell transplant (SCT) candidate, REV will be used with dexamethasone (dex), dex and bortezomib, or dex and carfilzomib. If primary and the patient is not a SCT candidate, REV will be used with dex OR melphalan and prednisone. If maintenance, REV will be used as monotherapy. If salvage and the patient will be retreated with the same regimen and they were a SCT candidate, REV will be used in combination with dex, dex and bortezomib, or dex and carfilzomib. If salvage and the patient will be retreated with the same regimen and they were not a SCT candidate, REV will be used in combination with dex OR melphalan and prednisone. If salvage and the patient will not be retreated with the same regimen, REV will be used as monotherapy or in combination with dex, dex and bortezomib, dex and cyclophosphamide, or dex and bendamustine. For myelodysplastic syndrome: patients must have low- to intermediate-1 risk MDS. If the patient has the 5q deletion, no further questions. If they do not, no further questions are required if their serum erythropoietin (EPO) level is greater than 500 mU/ml. If they do not have the deletion and their serum EPO level is less than 500 mU/ml, the patient must have failed epoetin or darbepoetin AND failed, had intolerance to, or a contraindication to immunosuppressive therapy. For mantle cell lymphoma: the disease is relapsed, refractory, or progressive. For systemic light chain amyloidosis:
REV will be used with either dex or dex AND cyclophosphamide. Chronic lymphocytic leukemia/small lymphocytic lymphoma: the disease is relapsed or refractory. For Hodgkin lymphoma: REV will be used as a single agent as third line or salvage therapy. For non-Hodgkin lymphoma: the disease is relapsed, refractory, or progressive. REV will be used as monotherapy or in combination with rituximab.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
RITUXAN SOLUTION 500 MG/50ML

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Primary CNS lymphoma, leptomeningeal metastases from lymphomas, Hodgkin's lymphoma (lymphocyte-predominant), non-Hodgkin's lymphoma subtypes [marginal zone lymphomas (splenic, MALT), Mantle cell lymphoma, Burkitt lymphoma, AIDS-related B-cell lymphoma, relapsed/refractory hairy cell leukemia, small lymphocytic lymphoma (SLL), post-transplant lymphoproliferative disorder (PTLD), primary cutaneous B-cell lymphoma], acute lymphoblastic leukemia, acquired blood factor VIII deficiency, autoimmune hemolytic anemia, chronic graft-versus-host disease (GVHD), multicentric Castleman's disease with HIV, refractory immune or idiopathic thrombocytopenic purpura (ITP), Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, Sjogren syndrome, thrombotic thrombocytopenic purpura, and prevention of Epstein-Barr virus (EBV)-related PTLD.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Prior to initiating therapy, patient has been screened for hepatitis B virus (HBV) infection with Hepatitis B serologic assays. For moderately to severely active rheumatoid arthritis (new starts only): Inadequate response to a self-injectable tumor necrosis factor (TNF) inhibitor OR Intolerance or contraindication to a self-injectable TNF inhibitor. Hematologic malignancies must be CD20-positive. For Burkitt lymphoma and ALL, Rituxan is used as a component of a chemotherapy regimen. For diffuse large B-cell lymphoma (DLBCL), patient meets one of the following: 1) has relapsed or refractory disease and will use Rituxan as a component of a chemotherapy regimen if patient is a candidate for high dose therapy with autologous stem cell rescue 2) has relapsed or refractory disease and is not a candidate for high dose therapy with autologous stem cell rescue OR 3) does not have relapsed or refractory disease and will use Rituxan as a component of a chemotherapy regimen. For Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA), Rituxan will be used in combination with glucocorticoids.
AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For rheumatoid arthritis, Rituxan is used in combination with MTX unless MTX is contraindicated or was not tolerated.
PRODUCT(s) AFFECTED
SAMSCA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For the treatment of clinically significant hypervolemic and euvolemic hyponatremia with serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).
PRODUCT(s) AFFECTED
SANDOSTATIN LAR DEPOT

COVERED USES
All FDA-approved indication not otherwise covered under Part D. Poorly differentiated (high-grade) neuroendocrine tumor (NET)/large or small cell, pancreatic endocrine tumors (Islet cell tumors), carcinoid tumors, lung NET, unresectable and recurrent meningiomas, thymic carcinomas.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For Acromegaly, must meet all of the following: 1) Clinical evidence of acromegaly, AND 2) Pre-treatment high IGF-1 level for age/gender, AND 3) Patient had an inadequate or partial response to surgery and/or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For acromegaly continuation of therapy: the IGF-1 level decreased or normalized.
**SOMATULINE DEPOT**

**PRODUCT(s) AFFECTED**
SOMATULINE DEPOT

**COVERED USES**
All FDA-approved indications not otherwise excluded from Part D, poorly differentiated (high-grade) neuroendocrine tumors (NET)/large or small cell, pancreatic endocrine tumors (Islet cell tumors), carcinoid tumors.

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
For Acromegaly, must meet all of the following: 1) Clinical evidence of acromegaly, AND 2) Pre-treatment high IGF-1 level for age/gender, AND 3) Patient had an inadequate or partial response to surgery and/or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
For acromegaly continuation of therapy: the IGF-1 level decreased or normalized.
**SOMAVER**

**PRODUCT(s) AFFECTED**
SOMAVER

**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: 1) Clinical evidence of acromegaly, AND 2) Pre-treatment high IGF-1 level for age/gender, AND 3) Patient had an inadequate or partial response to surgery and/or radiotherapy OR there is a clinical reason for why the patient has not had surgery or radiotherapy, AND 4) Patient had an inadequate response to octreotide or lanreotide OR patient is intolerant or has a contraindication to octreotide or lanreotide.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
For renewal, the IGF-1 level decreased or normalized.
Sovaldi

**Product(s) Affected**

Sovaldi

**Covered Uses**

All FDA-approved indications not otherwise excluded from Part D. Chronic hepatitis C genotype 5 or 6 infection.

**Exclusion Criteria**

N/A

**Required Medical Information**

Chronic hepatitis C infection confirmed by presence of HCV RNA in serum prior to treatment. Planned treatment regimen, genotype, prior treatment history, presence or absence of cirrhosis (compensated or decompensated [Child Turcotte Pugh class B or C]), presence or absence of HIV coinfection, presence or absence of resistance-associated variants (eg, NS3 Q80K polymorphism) where applicable, liver transplantation status if applicable. For patients with genotype 1, 2, 3, or 4 infection and hepatocellular carcinoma awaiting liver transplantation: must meet MILAN criteria. Coverage conditions and specific durations of approval will be based on current AASLD treatment guidelines.

**Age Restriction**

N/A

**Prescriber Restriction**

Must be prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or transplant specialist.

**Coverage Duration**

12 to 48 weeks depending on baseline host and viral factors
OTHER CRITERIA
For HCV/HIV coinfection, patient meets criteria for requested regimen and will not receive treatment with tipranavir. For patients prescribed a treatment regimen that includes Olysio, no prior treatment failure with an HCV protease inhibitor (eg, telaprevir, simeprevir, boceprevir, paritaprevir) despite adequate dosing and duration of therapy. MILAN criteria defined as: 1) tumor size 5cm or less in diameter in pts with single hepatocellular carcinoma OR 3 tumor nodules or less, each 3cm or less in diameter in pts with multiple tumors, and 2) no extrahepatic manifestations of the cancer or evidence of vascular invasion of tumor.
PRODUCT(s) AFFECTED
SPRYCEL

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Gastrointestinal stromal tumor (GIST).

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of CML or Ph+ ALL was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML, patient has experienced resistance, intolerance or toxicity to imatinib or an alternative tyrosine kinase inhibitor (e.g., nilotinib). For GIST, patient must have PDGFRA D842V mutation.

AGE RESTRICTION
For Ph+ ALL: 15 years of age or older. Other indications: 18 years of age or older

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
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
Ustekinumab should not be given in combination with a tumor necrosis factor (TNF) antagonist (eg, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab) or with anakinra.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Adults

PRESCRIBER RESTRICTION
Plaque psoriasis. Prescribed by or in consultation with a dermatologist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
Plaque psoriasis in adults. Patient has tried at least one of the following agents for at least 3 months: an oral therapy (eg, MTX, cyclosporine, or acitretin), oral methoxsalen plus PUVA, or a biologic agent (eg, adalimumab, etanercept, infliximab) or patient has experienced an intolerance to a trial of at least one oral or biologic therapy for plaque psoriasis, or the patient has a contraindication to one oral agent for psoriasis, as determined by the prescribing physician.
STIVARGA

PRODUCT(s) AFFECTED
STIVARGA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For unresectable advanced or metastatic colorectal cancer, KRAS (with or without NRAS) mutation testing is performed on either the primary tumor or metastases to confirm RAS mutation status. The patient must have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, and, if KRAS or NRAS wild type, an anti-EGFR therapy. Stivarga must be used as a single agent. For locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST), the patient must have been previously treated with imatinib or sunitinib.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
SUTENT

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Thyroid carcinoma (follicular, papillary, Hurthle cell, or medullary), angiosarcoma, solitary fibrous tumor, hemangiopericytoma, alveolar soft part sarcoma, chordoma (bone cancer), lung neuroendocrine tumor.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For renal cell carcinoma, disease is relapsed or medically unresectable and Sutent will be used as a single agent. For PNET, disease is unresectable, locally advanced, or metastatic. For GIST, patient experienced disease progression on imatinib or was intolerant to imatinib. For chordoma: disease is recurrent. For follicular, papillary, or Hurthle cell thyroid carcinoma: Nexavar is not an appropriate option for the patient. The disease is unresectable or metastatic. The disease is radioiodine-refractory. The disease is progressive or symptomatic. For medullary thyroid carcinoma: patient experienced progression on vandetanib or cabozantinib OR vandetanib or cabozantinib are not appropriate options.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year
OTHER CRITERIA
N/A
SYLATRON

PRODUCT(s) AFFECTED
SYLATRON

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Giant cell tumor of the bone.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For giant cell tumor of the bone, patient has unresectable disease OR surgical resection is likely to result in severe morbidity.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For melanoma, Sylatron must be requested within 84 days (12 weeks) of the surgical resection.
PRODUCT(s) AFFECTED
- SYMLINPEN 120
- SYMLINPEN 60

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

EXCLUSION CRITERIA
Recurrent severe hypoglycemia that required assistance during the past 6 months. Gastroparesis. Patient requires drug therapy to stimulate gastrointestinal motility. Hypoglycemia unawareness (i.e., inability to detect and act upon the signs or symptoms of hypoglycemia). HbA1c level greater than 9 percent.

REQUIRED MEDICAL INFORMATION
1) Diagnosis of type 1 or type 2 diabetes mellitus AND 2) The patient has demonstrated an inadequate treatment response, contraindication or been intolerant to metformin OR a sulfonylurea OR a thiazolidinedione OR insulin AND 3) The patient is currently receiving optimal mealtime insulin therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
If the patient has been receiving the Symlin for at least 3 months, patient demonstrated a reduction in HbA1c since starting Symlin therapy.
SYNRIBO

PRODUCT(s) AFFECTED
SYNRIBO

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
Oncologist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
TAFINLAR

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. CNS metastases, NSCLC.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For monotherapy in melanoma, patient must have a diagnosis of unresectable or metastatic melanoma AND the tumor must be positive for BRAF V600E mutation. For combination with Mekinist in melanoma, patient must have a diagnosis of unresectable or metastatic melanoma AND the tumor must be positive for either BRAF V600E or V600K mutation. For CNS metastases, the patient has a diagnosis of melanoma AND Tafinlar was active against primary tumor (melanoma) AND Tafinlar will be used as a single agent. For non-small cell lung cancer (NSCLC), the patient has BRAF V600E mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
TAGRISSO

PRODUCT(s) AFFECTED
TAGRISSO

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
PRODUCT(s) AFFECTED
TARCEVA

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Chordoma, renal cell carcinoma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For non-small cell lung cancer, Tarceva is used for locally advanced, recurrent, or metastatic disease. EGFR mutation testing was performed and is positive for EGFR exon 19 deletion or exon 21 (L858R) substitution mutation, Tarceva is used as either a first-line or second-line therapy. For first-line therapy, Tarceva is used as a single agent for the disease with locoregional recurrence with evidence of disseminated disease or with distant metastases. For second-line therapy, Tarceva is used following disease progression on erlotinib or afatinib, Tarceva is continued to be used as a single agent or used in combination with platinum-doublet therapy with or without bevacizumab. For EGFR mutation negative or unknown, Tarceva is used for the disease which progressed after chemotherapy as a second-line or third-line therapy. For pancreatic cancer, Tarceva is used in combination with gemcitabine for patients with locally advanced unresectable or metastatic disease. For chordoma, Tarceva is used as a single agent for the treatment of recurrent disease. For RCC, Tarceva is used as a single agent for patients with relapsed or medically unresectable stage IV disease with non-clear cell histology.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
**TARGRETIN**

**PRODUCT(s) AFFECTED**
- BEXAROTENE
- TARGRETIN

**COVERED USES**
All FDA-approved indications not otherwise excluded from Part D, mycosis fungoides, Sezary syndrome (capsules only), primary cutaneous CD30-positive T-cell lymphoproliferative disorder types: primary cutaneous anaplastic large cell lymphoma (capsules only) and lymphomatoid papulosis (capsules only), adult T-cell leukemia/lymphoma (gel only), primary cutaneous B-cell lymphoma types: primary cutaneous marginal zone lymphoma (gel only) and primary cutaneous follicle center lymphoma (gel only).

**EXCLUSION CRITERIA**
Pregnancy.

**REQUIRED MEDICAL INFORMATION**
For bexarotene capsules: Patient has any of the following types of cutaneous T-cell lymphomas: mycosis fungoides, Sezary syndrome, primary cutaneous anaplastic large cell lymphoma, and lymphomatoid papulosis. For primary cutaneous anaplastic large cell lymphoma: 1) The disease is CD30-positive, AND 2) Patient has multifocal lesions, AND 3) bexarotene will be used as a single agent. For lymphomatoid papulosis: 1) The disease is CD30-positive, AND 2) Patient has extensive lesions or symptomatic disease, AND 3) bexarotene will be used as a single agent. For Targretin gel: For cutaneous T-cell lymphoma, patient has a diagnosis of stage I to III mycosis fungoides. For primary cutaneous B-cell lymphoma: 1) Patient has any of the following types: a) primary cutaneous marginal zone lymphoma or b) primary cutaneous follicle center lymphoma AND 2) disease is confined to the skin.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A
COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
TASIGNA

PRODUCT(s) AFFECTED
TASIGNA

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), gastrointestinal stromal tumor (GIST).

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Diagnosis of CML or Ph+ ALL was confirmed by detection of the Philadelphia chromosome or BCR-ABL gene. For CML, patient has experienced resistance, intolerance or toxicity to imatinib or an alternative tyrosine kinase inhibitor (e.g., dasatinib). For Ph+ ALL, 1) patient has relapsed or refractory Ph+ ALL, OR 2) patient has received hematopoietic stem cell transplant after achieving complete response to induction chemotherapy. For GIST, patient must have progressed on imatinib, sunitinib or regorafenib.

AGE RESTRICTION
18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
TAZORAC

PRODUCT(s) AFFECTED
TAZORAC

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1) For patients being treated for plaque psoriasis Tazorac must be applied to less than 20 percent of the patient's body surface area AND 2) For patients being treated for plaque psoriasis a trial of at least one topical corticosteroid (e.g., clobetasol, fluocinonide, mometasone, triamcinolone) (patient may still be using a corticosteroid product in addition to Tazorac) OR 3) The patient experienced an adverse event, intolerance, or contraindication to topical corticosteroids.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For female patients who are able to bear children, the pregnancy status of the patient has been evaluated and the patient made aware of the potential risks of fetal harm and importance of birth control while using Tazorac.
TECFIDERA

PRODUCT(s) AFFECTED
TECFIDERA

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

EXCLUSION CRITERIA
Concurrent use with other disease-modifying agents used for multiple sclerosis (MS) [eg, Avonex, Rebif, Betaseron, Extavia, Copaxone, Tysabri, Gilenya, or Aubagio].

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Prescribed by or in consultation with a neurologist or MS specialist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
For use in MS, approve if the patient has a relapsing form of MS (includes relapsing-remitting MS, secondary-progressive MS with relapses, and progressive-relapsing MS) and the patient has tried interferon beta-1a intramuscular (Avonex), interferon beta-1a subcutaneous (Rebif), interferon beta-1b (Betaseron or Extavia), or glatiramer acetate (Copaxone) OR the patient has tried glatiramer acetate but cannot take an interferon beta therapy due to any of the following reasons: depression, suicidality, severe psychiatric disorder, woman who is pregnant or plans to become pregnant, or active liver disease or a history of
significant liver disease, history of seizures. Exceptions to having tried an interferon beta-1a or -1b product (Avonex, Betaseron, Extavia, or Rebif), or glatiramer acetate (Copaxone) can be made if the patient is unable to administer injections due to dexterity issues or visual impairment.
PRODUCT(s) AFFECTED
- TESTOSTERONE CYCIONATE SOLUTION 100 MG/ML
- TESTOSTERONE CYCIONATE SOLUTION 200 MG/ML

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Drug is being prescribed for hypogonadism in a male patient who had or currently has at least two confirmed low testosterone levels according to current practice guidelines or your standard lab reference values.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
TESTOSTERONE ENANTHATE SOLUTION 200 MG/ML

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1) Drug being prescribed for inoperable metastatic breast cancer in a female patient who is 1 to 5 years postmenopausal and who has had an incomplete response to other therapy for metastatic breast cancer OR 2) Drug is being prescribed for hypogonadism in a male patient who had or currently has at least two confirmed low testosterone levels according to current practice guidelines or your standard lab reference values OR 3) Drug is being prescribed for delayed puberty in a male patient.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
THALOMID

COVERED USES
All FDA-approved indications not otherwise excluded from Part D, systemic light chain amyloidosis, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma, recurrent apthous stomatitis, cachexia, HIV-associated diarrhea, Kaposi's sarcoma, Behcet's syndrome, graft-versus-host disease, Crohn's disease, myelofibrosis with myeloid metaplasia.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For systemic light chain amyloidosis: Thalomid will be used in combination with dexamethasone or dexamethasone and cyclophosphamide. For Waldenstrom's macroglobulinemia/lymphoplasmacytic leukemia, Thalomid will be used as monotherapy or in combination with rituximab. For multiple myeloma, Thalomid will be used as primary, maintenance, or salvage therapy. If primary and the patient is a stem cell transplant candidate, Thalomid will be used in combination with dexamethasone and bortezomib. If primary and the patient is not a stem cell transplant candidate, Thalomid will be used in combination with melphalan and prednisone. If maintenance, Thalomid will be used as a single agent. If salvage and the patient will be retreated with the same regimen and they are a transplant candidate, Thalomid will be used in combination with dexamethasone and bortezomib. If salvage and the patient will be retreated with the same regimen and they are not a transplant candidate, Thalomid will be used in combination with melphalan and prednisone. If salvage and the patient will not be treated with the same regimen as primary therapy, Thalomid will be used as monotherapy for steroid intolerant patients, or in combination with dexamethasone, dexamethasone and bortezomib, DT-PACE (dexamethasone, cisplatin, doxorubicin, cyclophosphamide, and etoposide), or VTD-PACE (dexamethasone, bortezomib, cisplatin, doxorubicin, cyclophosphamide, and etoposide). For cachexia, cachexia must be due to cancer or HIV-infection. For Kaposi's sarcoma, the patient must be HIV-positive. For graft-versus-host disease, use must be for the treatment of chronic or recurrent disease that is refractory to other therapies. Patient must be a bone marrow transplant recipient. For Crohn's disease, the
patient must have failed or been intolerant to prior therapy.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
N/A
TOPAMAX/ZONEGRAN

PRODUCT(s) AFFECTED
- TOPIRAMATE 100 MG
- TOPIRAMATE 25 MG
- TOPIRAMATE CAP SPRINK 15 MG
- TOPIRAMATE ER
- TOPIRAMATE TAB 200 MG
- TOPIRAMATE TAB 50 MG
- ZONISAMIDE 100 MG
- ZONISAMIDE 50 MG
- ZONISAMIDE CAP 25 MG
- TOPIRAMATE 200 MG
- TOPIRAMATE 50 MG
- TOPIRAMATE CAP SPRINK 25 MG
- TOPIRAMATE TAB 100 MG
- TOPIRAMATE TAB 25 MG
- TROKENDI XR
- ZONISAMIDE 25 MG
- ZONISAMIDE CAP 100 MG
- ZONISAMIDE CAP 50 MG

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
TOPICAL IMMUNOMODULATORS

PRODUCT(s) AFFECTED
ELIDEL

COVERED USES
All FDA-approved indications not otherwise excluded from Part D, Psoriasis on the face or body skin folds.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
1) The short-term or noncontinuous chronic use to treat psoriasis on the face or body skin folds OR 2) The short-term or noncontinuous chronic use to treat mild to moderate atopic dermatitis (eczema).

AGE RESTRICTION
2 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
The patient experienced an inadequate treatment response, intolerance, or contraindication to at least one medium or higher potency topical steroid when Elidel will not be used on the face, body skin folds, genital area, armpit, or around the eyes.
TOPICAL TESTOSTERONE PRODUCTS

PRODUCT(s) AFFECTED
- ANDROGEL PUMP
- TESTOSTERONE GEL 10 MG/ACT (2%)
- TESTOSTERONE GEL 25 MG/2.5GM (1%)
- TESTOSTERONE GEL 50 MG/5GM (1%)
- AXIRON
- TESTOSTERONE GEL 12.5 MG/ACT (1%)

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

EXCLUSION CRITERIA
Female.

REQUIRED MEDICAL INFORMATION
The patient had or currently has a confirmed low testosterone level (according to standard lab reference values).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
TRACLEER

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
NYHA Functional Class II to IV symptoms. PAH (WHO Group 1) was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) pretreatment pulmonary vascular resistance is greater than 3 Wood units.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
TRELSTAR

PRODUCT(s) AFFECTED
- TRELSTAR
- TRELSTAR LA MIXJECT
- TRELSTAR DEPOT MIXJECT
- TRELSTAR MIXJECT

COVERED USES
All FDA-approved indications not otherwise excluded from Part D, recurrent prostate cancer, intermediate or high risk prostate cancer in combination with radiation therapy, or very high risk prostate cancer with or without radiation therapy.

EXCLUSION CRITERIA
Use as neoadjuvant therapy prior to radical prostatectomy is not approvable.

REQUIRED MEDICAL INFORMATION
If the patient has metastatic disease, node positive disease, or recurrent disease as defined as a biochemical failure after previous therapy, then no further information is required. If the patient has none of the abovementioned criteria and has intermediate or high risk stratification, then Trelstar must be used with external beam radiation therapy. If the patient has none of the abovementioned criteria and has very high risk stratification, Trelstar may be used with external beam radiation unless the patient is not a candidate for definitive therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
TYKERB

PRODUCT(s) AFFECTED
TYKERB

COVERED USES
All FDA-approved indications not otherwise excluded from Part D, metastatic CNS lesions.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For advanced, recurrent, or metastatic HER2-positive breast cancer, Tykerb must be used in combination with 1) capecitabine or trastuzumab (without cytotoxic therapy) for patients who have received prior trastuzumab-containing regimen, OR 2) aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) for postmenopausal women with hormone receptor positive disease. For metastatic CNS lesions, Tykerb must be used with capecitabine in patients with recurrent HER2-positive breast cancer.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
TYSABRI

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Use as monotherapy. For Crohn's disease (CD), patient must have an inadequate response, intolerance or contraindication to one conventional CD therapy (eg, corticosteroid, azathioprine, mesalamine) and one TNF-inhibitor (eg, Humira, Cimzia).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
MS: Plan Year. CD: initial = 3 months, renewal = Plan Year.

OTHER CRITERIA
Upon renewal for CD, patient's condition must have improved or stabilized with Tysabri treatment.
UPTRA VI

PRODUCT(s) AFFECTED
UPTRA VI

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
NYHA Functional Class II or III symptoms. PAH (WHO Group 1) was confirmed by right heart catheterization. For new starts only: 1) pretreatment mean pulmonary arterial pressure is greater than or equal to 25 mmHg, 2) pretreatment pulmonary capillary wedge pressure is less than or equal to 15 mmHg, and 3) pretreatment pulmonary vascular resistance is greater than 3 Wood units.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
**VALCHLOR**

**PRODUCT(s) AFFECTED**
VALCHLOR

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

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
Patient has received prior skin-directed therapy.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
N/A
PRODUCT(s) AFFECTED
VOLTAREN GEL 1 %

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
Patient has tried two (2) unique generic prescription strength non-steroidal anti-inflammatory drugs (NSAIDs) for the current condition unless patient has difficulty swallowing or cannot swallow, patient is at risk of NSAID-associated toxicity (e.g., previous gastrointestinal [GI] bleed, history of peptic ulcer disease, impaired renal function, cardiovascular disease, hypertension, heart failure, elderly patients with impaired hepatic function, or those taking concomitant anticoagulants), or patient is greater than or equal to 75 years of age.
PRODUCT(s) AFFECTED
VOTRIENT

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Uterine sarcoma, follicular, papillary, or Hurthle cell thyroid carcinoma.

EXCLUSION CRITERIA
Alanine transaminase (ALT) greater than 3 times the upper limit of normal (ULN) and bilirubin greater than 2 times the ULN OR total bilirubin greater than 3 times ULN.

REQUIRED MEDICAL INFORMATION
For renal cell carcinoma, the disease is relapsed or medically unresectable. Votrient will be used as a single agent. For soft tissue sarcoma, does not have an adipocytic soft tissue sarcoma or GIST. The patient has angiosarcoma or pleomorphic rhabdomyosarcoma. If so, Votrient will be used as a single agent. If not angiosarcoma or pleomorphic rhabdomyosarcoma, the patient has retroperitoneal/intra-abdominal sarcoma or extremity/superficial trunk sarcoma. If so, the disease is unresectable, progressive, or recurrent and Votrient will be used as a single therapy. For uterine sarcoma, the patient had stage I, II, III, or IV disease. If II, III, or IV, the medication will be used as a single agent. If the patient has stage I disease, the disease is medically inoperable and Votrient will be used as a single agent. For follicular, papillary, or Hurthle cell thyroid carcinoma, Nexavar is not an appropriate option for the patient. The disease is unresectable or metastatic. The disease is radioiodine-refractory. The disease is progressive or symptomatic.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION

200
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
VPRIV

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
Prescribed by, or in consultation with, a physician who specializes in the treatment of inherited metabolic disorders.

COVERAGE DURATION
Plan Year

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

**COVERED USES**
All FDA-approved indications not otherwise excluded from Part D, inflammatory myofibroblastic tumors, non-small cell lung cancer (NSCLC) with ROS1-positive tumors.

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
For NSCLC, the tumor is ROS1- or ALK-positive AND the patient has recurrent or metastatic disease. For IMT, the tumor is ALK-positive. For all indications, Xalkori is being used as a single agent.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**COVERAGE DURATION**
Plan Year

**OTHER CRITERIA**
N/A
PRODUCT(s) AFFECTED
- XELJANZ
- XELJANZ XR

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

EXCLUSION CRITERIA
Concurrent use with a biologic for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab) or a TNF inhibitor (eg, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil].

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
Rheumatoid Arthritis (RA), adults.

PRESCRIBER RESTRICTION
RA, prescribed by or in consultation with a rheumatologist.

COVERAGE DURATION
Plan Year

OTHER CRITERIA
RA, pt has tried MTX or another traditional DMARD (eg, leflunomide, sulfasalazine) for at least 3 months unless the patient has been shown to be intolerant AND the patient has tried at least one biologic DMARD for RA (eg, tocilizumab, anakinra, abatacept, rituximab) or a TNF inhibitor (eg, certolizumab, etanercept, adalimumab, infliximab, golimumab) for at least 3 months unless intolerant.
XENAZINE

PRODUCT(s) AFFECTED
- TETRABENAZINE - XENAZINE

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Chronic tics associated with Tourette's syndrome, tardive dyskinesia, hemiballismus, chorea not associated with Huntington's disease.

EXCLUSION CRITERIA
Patients who are actively suicidal or have untreated or inadequately treated depression.

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
- XEOMIN RECON SOLN 100 UNIT - XEOMIN RECON SOLN 50 UNIT

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
PRODUCT(s) AFFECTED
XGEVA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For bone metastases from prostate cancer (solid tumor), patient has castration-recurrent disease. For giant cell tumor of the bone, patient has unresectable disease or surgical resection is likely to result in severe morbidity. For hypercalcemia of malignancy, condition is refractory to intravenous (IV) bisphosphonate therapy (eg, zoledronic acid, pamidronate) defined as albumin-corrected serum calcium level of greater than 12.5 mg/dL despite IV bisphosphonate therapy.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Hypercalcemia of malignancy: initial = 2 months, renewals = Plan Yr. All other dx = Plan Yr.

OTHER CRITERIA
For hypercalcemia of malignancy renewal requests: patient has demonstrated a response to Xgeva therapy defined as albumin-corrected serum calcium level of 12.5 mg/dL or less. For bone metastases from solid tumors and giant cell tumor of the bone: patient will receive calcium and vitamin D supplementation as...
needed to treat or prevent hypocalcemia. Coverage under Part D will be denied if coverage is available under Part A or Part B as the medication is prescribed and dispensed or administered for the individual.
PRODUCT(s) AFFECTED
XIFAXAN

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Irritable Bowel Syndrome without constipation.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
N/A

AGE RESTRICTION
18 years of age or older for reduction in risk of overt hepatic encephalopathy (HE) recurrence.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Reduction in risk of overt HE recurrence - 6 mos, IBS w/o constipation -3 mos

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
For allergic asthma, Xolair will be used in combination with other medications for long-term control of asthma. Patient will have a rapid-acting beta2-agonist available for rescue therapy. For initial therapy, must meet ALL of the following criteria: 1) has a diagnosis of moderate to severe persistent asthma, 2) has positive skin test (or blood test) to at least 1 perennial aeroallergen, 3) has baseline IgE level at or above 30 IU/mL, 4) asthma is inadequately controlled despite use of inhaled corticosteroid at the optimal dose, and 5) patient is optimizing the use of a long-acting inhaled beta2-agonist, leukotriene modifier, or theophylline at the optimal dose. For continuation therapy, patient must have improved asthma control while on Xolair. For chronic idiopathic urticaria, patient initiating Xolair therapy must meet ALL of the following criteria: 1) patient has been evaluated for other causes of urticaria, 2) patient has had itchy hives for at least 6 weeks, 3) patient has remained symptomatic despite H1-antihistamine treatment, and 4) the dose of antihistamine has been optimized. For continuation therapy, patient’s symptom has been improved with Xolair treatment.

AGE RESTRICTION
12 years of age or older.

PRESCRIBER RESTRICTION
For chronic idiopathic urticaria: allergist.

COVERAGE DURATION
Plan Year
OTHER CRITERIA
Xolair will be administered in a controlled healthcare setting with access to emergency medications (e.g., anaphylaxis kit).
**PRODUCT(s) AFFECTED**
XTANDI

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

**EXCLUSION CRITERIA**
N/A

**REQUIRED MEDICAL INFORMATION**
For metastatic, castration-resistant disease, the patient has been previously treated with Zytiga unless the patient has a contraindication, or intolerance, to Zytiga therapy. For disease that is not castration-resistant, Xtandi will be used in combination with androgen deprivation therapy. Xtandi will be used to enhance the effectiveness of radiation therapy, to supplement androgen deprivation therapy if the patient experienced inadequate testosterone suppression, or to prevent androgen flare in androgen deprivation therapy naive patients.

**AGE RESTRICTION**
N/A

**PRESCRIBER RESTRICTION**
N/A

**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
Taking alcohol or sedative hypnotic agents while taking Xyrem.

REQUIRED MEDICAL INFORMATION
1) The drug is being prescribed for the treatment of cataplexy in a patient with narcolepsy OR 2) The drug is being prescribed for the treatment excessive daytime sleepiness in a patient with narcolepsy without cataplexy and 3) At least one CNS stimulant drug and one CNS wakefulness promoting drug have been tried and 4) The patient experienced an inadequate treatment response or intolerance to the CNS stimulant drug and CNS promoting wakefulness drug OR 5) the patient has a contraindication to a CNS stimulant drug or a CNS wakefulness promoting drug (NOTE: Examples of a CNS stimulant drug are amphetamine, dextroamphetamine, or methylphenidate. Examples of a CNS wakefulness promoting drug is modafinil or armodafinil. Coverage of modafinil or armodafinil or amphetamines or methylphenidates may require prior authorization).

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year
OTHER CRITERIA
If the request is for the continuation of Xyrem, the patient experienced a decrease in daytime sleepiness with narcolepsy or a decrease in cataplexy episodes with narcolepsy.
PRODUCT(s) AFFECTED
ZAVESCA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient has mild to moderate type 1 Gaucher disease. Diagnosis of Gaucher disease was confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by DNA testing. Enzyme replacement therapy is not a therapeutic option (e.g., due to constraints such as allergy, hypersensitivity, or poor venous access).

AGE RESTRICTION
18 years of age or older.

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
ZELBORAF

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Melanoma with BRAF V600K mutation, CNS metastases from primary tumor (melanoma), NSCLC with BRAF V600E mutation.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For melanoma, the tumor is positive for either BRAF V600E or V600K mutation. For CNS metastases, the patient has a diagnosis of melanoma AND Zelboraf was active against primary tumor (melanoma) AND Zelboraf will be used as a single agent. For non-small cell lung cancer (NSCLC), the patient has BRAF V600E mutation.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
ZOLINZA

PRODUCT(s) AFFECTED
ZOLINZA

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Mycosis fungoides, Sezary syndrome, multiple myeloma.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
For multiple myeloma: Zolinza will be used as salvage therapy in combination with bortezomib (Velcade)

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
ZYDELIG

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

EXCLUSION CRITERIA
History of serious allergic reactions including anaphylaxis or toxic epidermal necrolysis.

REQUIRED MEDICAL INFORMATION
For relapsed chronic lymphocytic leukemia, Zydelig is used in combination with rituximab. For relapsed follicular B-cell non-Hodgkin lymphoma and relapsed small lymphocytic lymphoma, patient has received at least two prior systemic therapies.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
Oncologist

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
ZYKADIA

PRODUCT(s) AFFECTED
ZYKADIA

COVERED USES
All FDA-approved indications not otherwise excluded from Part D. Recurrent ALK-positive NSCLC.

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient has recurrent or metastatic disease. The tumor is ALK-positive. Patient has progressed on or is intolerant to crizotinib.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A
PRODUCT(s) AFFECTED
ZYTIGA

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

EXCLUSION CRITERIA
N/A

REQUIRED MEDICAL INFORMATION
Patient has metastatic prostate cancer. Patient's disease is castration-resistant. Zytiga will be used in combination with prednisone.

AGE RESTRICTION
N/A

PRESCRIBER RESTRICTION
N/A

COVERAGE DURATION
Plan Year

OTHER CRITERIA
N/A