# 2018 GRS Premier Prior Authorization Document September 2018

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### **Abraxane**

#### **Products Affected**

ABRAXANE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For relapsed or refractory melanoma, individual is using as a single agent and Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 following at least one prior therapy. For ovarian cancer (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) individual is using as a single agent and Disease is persistent or recurrent.

### **Abstral**

### **Products Affected**

• ABSTRAL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Treatment of acute or postoperative pain OR treatment of migraine headache pain OR treatment of non-cancer related breakthrough pain.
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has tried and failed fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking Abstral (fentanyl) for cancer related breakthrough pain.

### **Actemra**

### **Products Affected**

• ACTEMRA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Tuberculosis, or invasive fungal infections or other active serious infections, or history if recurrent infections. Individuals who have not had a tuberculin skin test or Center for Disease Control recommended equivalent to evaluate for latent tuberculosis prior to initiating Actemra (tocilizumab). Using Actemra in combination with other TNF antagonists, IL-1R antagonists, janus kinase inhibitor, anti-cd20 monoclonal antibodies or selective co-stimulation modulators. At initiation of therapy, absolute neutrophil count (ANC) below 2000/mm3, platelet count below 100,000/mm3, or ALT or AST above 1.5 times the upper limit of normal.
Required Medical Information	
Age Restrictions	Member is 18 years of age or older, except for the diagnosis of JIA, PJIA. For JIA, PJIA patient is 2 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For rheumatoid arthritis (RA), agent is being used to reduce signs/symptoms or induce/maintain clinical response or inhibit progression of structural damage or to improve physical function. Member has had an inadequate response to ONE non-biological or biologic disease modifying anti-rheumatic drug (DMARD) such as methotrexate (MTX) or a tumor necrosis factor (TNF) antagonist drug AND individual has had a trial and inadequate response or intolerance to BOTH: Humira AND Enbrel. For Systemic Juvenile Idiopathic Arthritis (SJIA), agent is being used to reduce signs/symptoms or induce/maintain clinical response. Member has failed to respond to, is tolerant of, or has a medical contraindication to ONE corticosteroid or nonsteroidal anti-inflammatory drug (NSAID). For Polyarticular Juvenile Idiopathic Arthritis (PJIA), agent is being used to reduce signs/symptoms or induce/maintain clinical response. Member has failed to respond to, is intolerant of, or has a medical contraindication to ONE non-biologic DMARD (such as methotrexate) AND individual has had a trial and inadequate response or intolerance to BOTH: Humira AND Enbrel. For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Actemra (tocilizumab) or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Cimzia may be allowed without trial of preferred TNF agents (Enbrel/Humira). For Multicentric Castleman Disease (MCD), agent is being used as a single agent for tx of relapsed/refractory or progressive MCD. Individual is HIV (human immunodeficiency virus) and HHV-8 (human herpes-8) negative. And individual has no concurrent clinic

# **Actimmune**

### **Products Affected**

• ACTIMMUNE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Actiq

### **Products Affected**

• ACTIQ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Treatment of acute or postoperative pain OR treatment of migraine headache pain OR treatment of non-cancer related breakthrough pain
Required Medical Information	
Age Restrictions	Individual is 16 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has tried and failed fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking Actiq (fentanyl).

# **Adcetris**

### **Products Affected**

• ADCETRIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	For diagnosis of Hodgkin lymphoma with either one of the following: failure of autologous hematopoietic stem cell transplant (AHSCT) OR failure of at least two prior multi-agent chemotherapy regimens in those who are not AHSCT candidates OR as cytoreduction prior to hematopoietic stem cell transplant (autologous and allogeneic) for relapsed or refractory Hodgkin lymphoma OR as consolidation therapy after autologous stem cell transplant for ind at high risk of relapse or progression with any of the following: Primary refractory Hodgkin lymphoma or Relapsed Hodgkin lymphoma with an initial remission duration of less than 12 months or Extranodal involvement at the start of pre-transplantation salvage chemotherapy. For diagnosis of Systemic Anaplastic Large Cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen or has CD30+ cutaneous Anaplastic Large Cell lymphoma (ALCL).

# **Adcirca**

- ADCIRCA
- tadalafil (antihypertensive)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use in combination with phosphodiesterase-5 (PDE5) inhibitors [such as but not limited to, Cialis (tadalafil)] or use in combination with organic nitrates [such as but not limited to, isosorbide mono/dinitrate or nitroglycerin] or guanylate cyclase stimulators [such as but not limited to, Adempas (riociguat)]. For the treatment of benign prostatic hypertension or erectile dysfunction. Diagnosis of severe hepatic impairment (Child-Pugh Class C), pulmonary veno-occlusive disease (PVOD), severe renal impairment (creatinine clearance less than or equal to 30 mL/min) or on dialysis. Individual has a known degenerative retinal disorder (such as but not limited to, retinitis pigmentosa).
Required Medical Information	Catheterization-proven diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has WHO functional class II- IV symptoms.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Addyi

### **Products Affected**

• ADDYI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use in individuals who cannot abstain from alcohol use. Treatment of HSDD in postmenopausal women OR men. Use for enhancement of sexual performance. Use in individuals with hepatic impairment OR utilizing moderate (such as but not limited to atazanavir, ciprofloxacin, diltiazem, erythromycin, fluconazole, fosamprenavir, verapamil, grapefruit juice) or strong CYP3A4 inhibitors (examples include, but not limited to ketoconazole, itraconazole, posaconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, boceprevir, telaprevir, telithromycin, conivaptan) OR concomitant use with CYP3A4 inducers (such as but not limited to, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, St. John's Wort).
Required Medical Information	
Age Restrictions	18 years old
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Individual has Acquired, Generalized Hypoactive Sexual Desire Disorder (HSDD)/Acquired Female Sexual Interest Arousal Disorder (FSIAD) for at least 24 weeks characterized by low sexual desire that causes marked distress or interpersonal difficulty AND it is confirmed that the diagnosis of HSDD/FSIAD is not caused by any of the following: i) A co-existing psychiatric condition, OR ii) A co-existing medical condition that could contribute to sexual dysfunction, OR iii) Problems within a relationship, OR iv) Major life stressor (such as, loss of income, death of a family member), OR v) Effects of a medication or other drug substance.

# Adempas

### **Products Affected**

• ADEMPAS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use in combination with nitrates (such as but not limited to, nitroglycerin) or nitric oxide donors (such as but not limited to, amyl nitrite) in any form OR Use in combination with phosphodiesterase (PDE) inhibitors [such as, PDE-5 inhibitors (sildenafil, tadalafil, vardenafil) or nonspecific PDE inhibitors (dipyridamole, theophylline)].
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has catheterization-proven diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 AND has WHO functional class II-IV symptoms. Or individual has catheterization-proven diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 AND Individual has WHO functional class II-IV symptoms AND using for one of the following: Persistent or recurrent pulmonary hypertension after at least 180 days following surgical treatment with pulmonary endarterectomey OR Inoperable (via pulmonary endarterectomey) CTEPH OR diagnosis of severe hepatic impairment (Child-Pugh class C) OR diagnosis of pulmonary veno-occlusive disease (PVOD) OR individual is on dialysis or has creatinine clearance less than 15mL/min.

# **AFINITOR**

- AFINITOR
- AFINITOR DISPERZ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Afrezza**

### **Products Affected**

 AFREZZA INHALATION CARTRIDGE WITH INHALER 12 UNIT, 4 UNIT, 4 UNIT (30)/ 8 UNIT (60), 4 UNIT (60)/ 8 UNIT (30), 4 UNIT (90)/ 8 UNIT (90), 4 UNIT/8 UNIT/ 12 UNIT (60), 8 UNIT, 8 UNIT (60)/ 12 UNIT (30)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individuals with a diagnosis of chronic lung disease, such as asthma or chronic obstructive pulmonary disease. Individuals who smoke cigarettes or who recently (within 6 months) quit smoking. Using as a treatment for diabetic ketoacidosis.
Required Medical Information	Individual has had a physical examination including detailed medical history to identify potential lung disease.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of diabetes mellitus and using for one of the following: 1. For type 1 diabetes, individual will be using concurrently with long-acting insulin. OR 2. For type 2 diabetes, individual has inadequate control, intolerance, or contraindication to at least 2 oral anti-diabetic medications.

# **Aimovig**

- AIMOVIG AUTOINJECTOR
- AIMOVIG AUTOINJECTOR (2 PACK)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial 3 months, continuation 1 year.

PA Criteria	Criteria Details
Other Criteria	For initial requests: (I) Individual has a diagnosis of one of the following: (a) Episodic migraine defined as at least 4 and fewer than 15 migraine days per month and fewer than 15 headache days per month on average during the previous 3 month period OR (b) Chronic migraine defined as a headache occurring on 15 or more days per month for more than 3 months, which, on at least 8 days per month, has features of a migraine headache (ICHD-3 beta) AND (II) Individual is using for migraine prophylaxis at a frequency of 4 or more migraine days per month. And (III) Individual has had a trial of and inadequate response or intolerance to two agents for migraine prophylaxis (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence, ICSI 2013, high quality evidence): (a)The following antidepressants: amitriptyline, venlafaxine or (b) One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol or (c) The following calcium channel blocker: verapamil or (d) One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin or (e) Botox (for chronic migraine). For Renewal requests: (I) Individual has a reduction in the number of headache days per month AND (II) Individual has obtained clinical benefit deemed significant by individual or prescriber.

# **Aldurazyme**

### **Products Affected**

• ALDURAZYME

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis is confirmed by: (a) Documented deficiency in alpha-L-iduronidase enzyme activity of less than 10% of the lower limit of normal range as measured in fibroblasts or leukocytes or (b)Documented alpha-L-iduronidase gene sequencing.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For dx of mucopolysaccharidosis I (MPS I) AND Individual has one of the following forms of MPS I: (1) Hurler OR (2) Hurler-Scheie OR (3) Scheie with moderate to severe symptoms manifestations including any of the following: (a) Cardiac valve abnormalities (such as aortic or mitral valve regurgitation, with or without insufficiency or stenosis) or (b) Corneal clouding, open-angle glaucoma, and retinal degeneration, progressive or (c) Craniofacial or growth retardation or (d) Frequent, moderate to severe upper respiratory infections or (e) Hepatosplenomegaly or (f) Hernias (such as hiatal, inguinal, or umbilical) or (g) Neurological symptoms resulting from cervical instability or cervical spinal cord compression or (h) Skeletal and joint involvement, progressive (such as, arthropathy, back pain, joint stiffness, lumbar spondylolisthesis, lumbar spinal compression, osteopenia, or osteoporosis).

# Alecensa

### **Products Affected**

• ALECENSA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Alimta**

### **Products Affected**

• ALIMTA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Aliqopa

### **Products Affected**

ALIQOPA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initial 1 year. Continuation 6 months.
Other Criteria	For initial use in the treatment of follicular lymphoma, Individual has received at least two prior systemic therapies and have not had previous treatment with another PI3-kinase inhibitor previously (for example, idelalisib [Zydelig]). For continued use, there is objective evidence of continuing clinical benefit (for example, complete response, partial response, or stable disease) verified at least every 6 months that is objectively measured.

### Aloxi

### **Products Affected**

- ALOXI
- PALONOSETRON INTRAVENOUS SOLUTION 0.25 MG/2 ML
- palonosetron intravenous solution 0.25

mg/5 ml
• palonosetron intravenous syringe

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

# Alpha1-Proteinase Inhibitor

- ARALAST
- ARALAST NP
- GLASSIA
- PROLASTIN

- PROLASTIN-C
- ZEMAIRA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Alpha 1 proteinase inhibitors may not be approved for individuals with IgA antibodies.
Required Medical Information	Documented alpha-1 antitrypsin level is less than or equal to 11micro-mol/L. Individual has clinically evident emphysema and one of the following: Moderate airflow obstruction is evidenced by forced expiratory volume (FEV1) of 30-65 percent of predicted value, prior to initiation of therapy OR a rapid decline in lung function as measured by a change in FEV1 greater than 120 ml/year.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Alunbrig**

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLETS, DOSE PACK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Amphetamine Salts - B**

- ADDERALL ORAL TABLET 10 MG, 12.5 MG, 15 MG, 20 MG, 30 MG, 5 MG, 7.5 MG
- ADDERALL XR
- dextroamphetamine-amphetamine oral
- capsule, extended release 24hr
- dextroamphetamine-amphetamine oral tablet 10 mg, 12.5 mg, 15 mg, 20 mg, 30 mg, 5 mg, 7.5 mg
- MYDAYIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For dx ADHD, 3 years of age or older for immediate release, 6 years of age or older for extended-release. For Narcolepsy, 6 years of age or older for immediate release
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Ampyra**

- AMPYRA
- dalfampridine

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Member has a history of seizures, OR moderate or severe renal impairment (defined as creatinine clearance less than or equal to 50 mL/min)
Required Medical Information	For initial approval, member has been objectively assessed for functional impairment related to ambulation AND documentation has been provided. For renewal, member achieved and sustained clinically significant improvement in ambulation related functional status AND documentation has been provided. Documentation may include chart notes, consultation notes.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Intial approval 12 weeks, renewal 1 year
Other Criteria	

# **Anadrol 50**

### **Products Affected**

• ANADROL-50

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Anadrol 50 may not be used to not replace other supportive measures for anemia such as transfusion, correction of iron, folic acid, B12 or pyridoxine deficiency, antibacterial therapy, or the appropriate use of corticosteroids. Using to enhance athletic ability. Individual has a diagnosis of Carcinoma of the prostate or breast in male individuals or Carcinoma of the breast in females with Hypercalcemia. Individual has a diagnosis of nephrosis (nephrotic phase of nephritis). Individual has a diagnosis of severe hepatic dysfunction.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Individual has a diagnosis of a deficient red cell production- associated anemia, such as but not limited to: acquired aplastic anemia, congenital aplastic anemia, myelofibrosis, or myelotoxic drug-associated hypoplastic anemia.

# Androxy

### **Products Affected**

androxy

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For Delayed puberty: age 14 years of age or older. For all other: 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	Individual is a male and has a dx of (1) primary hypogonadism (congenital or acquired) such as but not limited to: Cryptorchidism OR Bilateral torsion OR Vanishing testis syndrome OR Orchiectomy OR Klinefelter Syndrome OR Chemotherapy OR Toxic damage from alcohol or heavy metals OR Idiopathic primary hypogonadism. Or (2) Hypogonadotropic hypogonadism (congenital or acquired), such as but not limited to: Idiopathic luteinizing hormone-releasing hormone (LHRH deficiency) OR Pituitary-hypothalamic injury or (3) delayed puberty and is using to stimulate puberty and currently show few to no signs of puberty or (4) is a female using for breast cancer and is 1 to 5 years postmenopausal or a premenopausal female who has benefited from oophorectomy and is considered to have a hormone-responsive tumor.

# **Apokyn**

### **Products Affected**

APOKYN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Erectile Dysfunction (ED) use
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Aranesp**

### **Products Affected**

• ARANESP (IN POLYSORBATE)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Anemia in patients due to other factors such as iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic diseases (such as sickle cell anemia, thalassemia, and porphyria). Sudden loss of response with severe anemia and low reticulocyte count. Treatment of in any indication not listed in criteria including anemia of prematurity. Anemia in cancer patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure. Anemia in cancer patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy. Continued use when the hemoglobin level exceeds 11.0 g/dL unless otherwise specified in the criteria. Use beyond 12 weeks in the absence of response in individuals with chronic renal failure. Use beyond 8 weeks in the absence of response in individuals with myelodysplastic syndrome (MDS). Use beyond 8-9 weeks in the absence of response or if transfusions are still required in individuals with metastatic, non-myeloid cancer being treated with myelosuppressive chemotherapy agents known to produce anemia. Continued use beyond 6 weeks after therapy with myelosuppressive chemotherapy known to produce anemia is completed. Pre-operative use for individuals who are willing to donate autologous blood.

PA Criteria	Criteria Details
Required Medical Information	Hemoglobin (Hgb) levels are less than 10 g/dL, prior to initiation of therapy (unless otherwise specified) AND the individual iron status reveals, transferrin saturation at least 20% or ferritin at least 80 ng/mL or bone marrow demonstrates adequate iron stores AND For individuals with hypertension, blood pressure is adequately controlled before initiation of therapy and closely monitored and controlled during therapy. For MDS, endogenous erythropoietin level is less than 500 mU/ml. For tx of anemia due to chemotherapy known to produce anemia, chemo is planned for a minimum of 2 months and the dx is non-myeloid cancer and the anticipated outcome is not cure. For anemia associated with CKD ON dialysis use is to achieve and maintain hgb levels within the range of 10.0 to 11.0 g/dL. For anemia associated with CKD NOT ON dialysis use is to achieve and maintain hgb levels of 10.0g/dL.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	8wk.
Other Criteria	

# Arcalyst

### **Products Affected**

• ARCALYST

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use in combination with other IL-1 inhibitors or tumor necrosis factor (TNF) inhibitors. Individual is receiving live vaccines. Exhibiting evidence of active or chronic infection(s), including tuberculosis, or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to initiating treatment with rilonacept.
Required Medical Information	
Age Restrictions	Individual is 12 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Arzerra**

### **Products Affected**

ARZERRA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **AUBAGIO**

### **Products Affected**

• AUBAGIO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with other immunomodulatory agents (such as Gilenya, tecfidera, Tysabri, Copaxone, Extavia, Plegridy, Rebif, Avonex or Betaseron). Individual has an active acute or chronic infection at the initiation of therapy or has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to initiation of therapy.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Member has been on Aubagio in the past 180 days OR member has tried therapy with ONE of the following agents: Avonex (interferon beta-1a) OR Plegridy (interferon beta-1a) OR Betaseron (interferon beta-1b) OR Tecfidera (dimethyl fumarate) OR Copaxone (glatiramer).

# Austedo

### **Products Affected**

• AUSTEDO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is suicidal or has untreated or inadequately treated depression. Individual has hepatic impairment. Individual is currently utilizing monoamine oxidase inhibitors (MAOIs), reserpine or tetrabenazine.
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **AVASTIN**

### **Products Affected**

AVASTIN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Avastin may be approved for Diabetic macular edema, Established neovascular "wet" AMD, Macular edema from branch retinal vein occlusion, Macular edema from central retinal vein occlusion, Neovascular glaucoma, Pseudoxanthoma elasticum, radiation retinopathy, Retinopathy of prematurity, diabetic retinopathy with or w/o diabetic macular edema, or Other rare causes of choroidal neovascularization for one or more of the following conditions: angioid streaks or choroiditis (including, but not limited to histoplasmosis induced choroiditis) or degenerative myopia, idiopathic or retinal dystrophies or trauma. For metastatic Colon, Rectal, or small bowel adenocarcinoma, Avastin is used in combination with 5FU based chemotherapy irinotecan or oxaliplatin and has not progressed on more than 2 lines of bevacizumab containing regimen. For NSCLC, Avastin is being used in combination with both platinum based therapies with a taxane or pemetrexed with no hx of hemoptysis for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic nonsquamous NSCLC. Maintenance therapy for NSCLC is approved when Avastin was prev used as a first-line combination regimen AND used as a single agent AND can be used until disease progression. For Metastatic Breast Carcinoma, HER2-negative disease, Avastin is being used as first-line therapy in combination with paclitaxel or paclitaxel protein bound. For Metastatic Clear Cell Renal Carcinoma, Avastin is being used as first-line therapy in combination with interferon or as a single agent for relapsed or medically unresectable stage IV disease with predominant clear cell histology in individuals who have progressed on prior cytokine therapy. For primary central nervous system tumors who have failed radiation therapy, bevacizumab will be used in a single line of therapy AND tumor to be treated is a WHO Grade III/IV glioma (includes but is not limited to): Anaplastic astrocytoma, Progressive or recurrent ependymoma that has failed radiation therapy, Anaplastic gl

PA Criteria	Criteria Details
	recurrent primary peritoneal cancer, bevacizumab will be used in a single line of therapy AND used for relapsed or refractory disease and used as a single agent or in combination with other chemotherapy. For malignant mesothelioma, in combination with cisplatin or carboplatin and pemetrexed with no history of bleeding or thrombosis. For maintenance therapy, Bevacizumab was previously administered as an agent in a first-line combination chemotherapy regimen and used as a single agent until disease progression.

### **Banzel**

- BANZEL ORAL SUSPENSION
- BANZEL ORAL TABLET 200 MG, 400 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	1 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Baraclude**

- BARACLUDE
- entecavir

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Member has a diagnosis of Chronic Hepatitis B virus (HBV) infection with evidence of active viral replication AND either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. And if member is coinfected with HIV, member is using in combination with highly active antiretroviral therapy (HAART)
Age Restrictions	2 years of age and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Bavencio**

### **Products Affected**

BAVENCIO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Receiving treatment with another PD-1 agent (for example, Opdivo (nivolumab) or Keytruda (pembrolizumab)). Receiving therapy for an autoimmune disease or chronic condition requiring treatment with systemic immunosuppressant.
Required Medical Information	Current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 for metastatic merkel cell carcinoma
Age Restrictions	12 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Beleodaq

### **Products Affected**

• BELEODAQ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Benlysta

### **Products Affected**

• BENLYSTA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For initial treatment, individual has a Clinical diagnosis of SLE per the American College of Rheumatology [ACR] criteria AND Unequivocally positive ANA (anti-nuclear antibody) titer greater than or equal to 1:80 or anti-dsDNA (double stranded DNA antibody) greater than or equal to 30 IU/mL AND SLE is active as documented by a SELENA-SLEDAI score greater than or equal to 6 while on current treatment regimen AND There is no evidence of severe renal disease (proteinuria greater than 6 gm/day, serum creatinine greater than 2.5 mg/dl, or requiring renal dialysis) AND There is no evidence of active central nervous system lupus (e.g. psychosis and seizures) AND SLE remains active while on corticosteroid, antimalarials, and/or immunosuppressants for at least the last 30 days. For continuation of therapy, individual has a clinical diagnosis of SLE per the American College of Rheumatology [ACR] criteria AND documentation of previous improvement in disease activity following treatment with belimumab indicating a therapeutic response AND there is no evidence of severe renal disease AND there is no evidence of active central nervous system lupus.
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	

## **Berinert**

### **Products Affected**

BERINERT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Prophylaxis for HAE attacks.
Required Medical Information	HAE to be confirmed by a C4 level below the lower limit of normal (as defined by the laboratory performing the test) and either a C1 inhibitor antigenic level below the lower limit of normal (as defined by the lab performing test) or a C1 inhibitor functional level below the lower limit of normal (as defined by the lab performing the test).
Age Restrictions	Individual is 5 years or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion) and using Berinert for acute HAE attacks.

# Blincyto

### **Products Affected**

• BLINCYTO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	

## **Bosulif**

### **Products Affected**

• BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has Philadelphia chromosome positive Chronic Myeloid Leukemia (Ph+ CML) in chronic phase AND has documented resistance, intolerance, contraindication or warning to BOTH Gleevec and Sprycel. (Warnings may include, but not limited to pulmonary arterial hypertension, pleural or pericardial effusion, cardiac abnormalities).

# **Botox-Myobloc-Dysport**

- BOTOX
- DYSPORT
- MYOBLOC
- XEOMIN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Botulinum toxin is considered cosmetic as a treatment of skin wrinkles or other cosmetic indications and is not approvable.
Required Medical Information	For Cervical Dystonia (spasmodic torticollis) of moderate or greater severity when all of the following criteria are met: History of recurrent clonic and/or tonic involuntary contractions of one or more of the following muscles: sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles, and Sustained head tilt and/or abnormal posturing with limited range of motion in the neck, and The duration of the condition is greater than 6 months. Subsequent injections for the treatment of cervical dystonia of moderate or greater severity when all the following criteria is met: there is a response to initial treatment documented in the medical records and patient still meets criteria above. For prevention of chronic migraine, patient must have migraine on 15 or more days per month with HA lasting 4 hours per day or longer AND first episode at least 6 months ago AND symptoms persist despite trials of at least ONE agent in ANY 2 classes of medications used to prevent migraines, antidepressants, antihypertensives, antiepileptics. Continuing tx medically nec when migraine HA frequency was reduced by at least 7 days per month by end of initial 6 month trial OR duration was reduced by at least 100 hours per month by end of initial trial.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year, chronic migrains 6months

PA Criteria	Criteria Details
Other Criteria	Treatment of primary hyperhidrosis. Treatment of secondary hyperhidrosis. Treatment of significant drooling in patients who are unable to tolerate scopolamine. Treatment neurogenic overactive bladder (also referred to as detrusor overactivity or detrusor sphincter dyssynergia) that is inadequately controlled with anticholinergic therapy. Treatment of idiopathic overactive bladder in adults who are unresponsive to or intolerant of a trial of anticholinergic therapy.

## **Braftovi**

### **Products Affected**

• BRAFTOVI ORAL CAPSULE 50 MG, 75 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	BRAF V600E or V600K mutation results must be confirmed (written or verbal attestation is acceptable).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	

### **Briviact**

- BRIVIACT INTRAVENOUS
- BRIVIACT ORAL SOLUTION
- BRIVIACT ORAL TABLET 10 MG, 100 MG, 25 MG, 50 MG, 75 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 16 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Buphenyl**

- BUPHENYL
- sodium phenylbutyrate

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Management of acute hyperammonemia
Required Medical Information	Using as adjunctive therapy for chronic management of hyperammonemia
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Cabometyx

### **Products Affected**

 CABOMETYX ORAL TABLET 20 MG, 40 MG, 60 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Calquence

### **Products Affected**

CALQUENCE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Caprelsa

- CAPRELSA ORAL TABLET 100 MG, 300 MG
- vandetanib oral tablet 100 mg, 300 mg

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Carbaglu

### **Products Affected**

• CARBAGLU

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Cayston

### **Products Affected**

CAYSTON

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has a forced expiratory volume in 1 second (FEV1) of less than 25% or greater than 75% of predicted
Required Medical Information	
Age Restrictions	7 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Celebrex

- CELEBREX
- celecoxib

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE prescription Non-Steroidal Anti-Inflammatory Drugs (NSAID) or salicylates

# Cerdelga

### **Products Affected**

• CERDELGA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use of glucosylceramide synthase inhibitor in conjunction with one another or in conjunction with a substrate reduction therapy (SRT) agent or enzyme replacement therapy (ERT) agent. Use in an ultrarapid metabolizers of CYP2D6. Individual has moderate or severe renal impairment or end-stage renal disease (ESRD). Individual has mild, moderate or severe hepatic impairment or cirrhosis OR individual has pre-existing cardiac disease or long QT syndrome.
Required Medical Information	Presence of type 1 Gaucher disease is confirmed by either of the following: Glucocerebrosidase activity in the white blood cells or skin fibroblasts less than or equal to 30% of normal activity, OR genotype testing indicating mutation of two alleles of the glucocerebrosidase genome. And patient has clinically significant manifestations of Type 1 gauchers disease including any of the following: (A) skeletal disease (demonstrated by ANY of the following: avascular necrosis, erlenmeyer flask deformity, lytic disease, marrow infiltration, osteopenia, osteosclerosis, pathological fracture, joint deterioration or replacement) OR (B) individual presents with at least 2 of the following: clinically significant hepatomegaly as confirmed by medical imaging [such as but not limited to, volumetric magnetic resonance imaging (MRI)], clinically significant splenomegaly as confirmed by medical imaging [such as but not limited to, volumetric (MRI)], hgb less than or equal to 11.5 grams per dl for females or 12.5 grams per dl for males or 1 gram per dl below lower limit for normal for age and sex, platelet counts less than or equal to 120,000 mm3 OR (C) individual is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as confirmed by a FDA-approved genotype test.
Age Restrictions	Individual is 18 years of age or older.

PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Chantix

### **Products Affected**

- CHANTIX
- CHANTIX CONTINUING MONTH BOX
- CHANTIX CONTINUING MONTH PAK
- CHANTIX STARTING MONTH BOX

CHANTIX STARTING MONTH PAK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	At least 18 years of age or older
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	

## Cholbam

### **Products Affected**

• CHOLBAM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Used to treat extrahepatic manifestations (such as but not limited to neurologic symptoms) of SED-associated-BASDs or PDs.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial therapy: 3 months. Continuation therapy: 1 year
Other Criteria	For initial therapy: (A) Diagnosis of bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs) including but not limited to 3 beta-hydroxy-delta 5-C27-steroid oxidotrductase defects OR (B) Diagnosis of peroximal disorders (PDs) including but not limited to Zellweger spectrum disorders AND (C) Individual has one of the following: (a) Manifestations of liver disease (for example, jaundice, hepatomegaly) (b) steatorrhea (c) Complications from decreased fat soluble vitamin (such as but not limited to vitamin D and K) absorption (for example, rickets, hypocalcemia, bleeding). For maintenance therapy: Meets the initial request criteria AND has had a clinical improvement (symptoms, lab values) in liver function and/or cholestasis AND has not developed a complete biliary obstruction.

## Cimzia

- CIMZIA
- CIMZIA POWDER FOR RECONST
- CIMZIA STARTER KIT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections prior to initiating Cimzia (certolizumab pegol) Individuals who have not had a tuberculin skin test or Center for Disease Control recommended equivalent to evaluate for latent tuberculosis prior to initiating Cimzia (certolizumab pegol). Using Cimzia in combination with other TNF antagonists, non-TNF immunomodulatory drugs: abatacept, anakinra, natalizumab, tofacitinib or rituximab.
Required Medical Information	
Age Restrictions	Member is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For Crohn's Disease, agent is being used to reduce signs/symptoms OR induce/maintain clinical response. Also member has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (e.g. 5-ASA products, systemic corticosteroids, or immunosuppressants) AND Member has had trial and an inadequate response or is intolerant to Humira. For Rheumatoid Arthritis, agent is being used to reduce signs/symptoms OR induce/maintain clinical response OR improve physical function. Also member has failed to respond to, is intolerant of, or has a medical contraindication to ONE nonbiologic DMARDs AND Member has had a trial and an inadequate response or is intolerant to BOTH: Humira AND Enbrel. For Psoriatic Arthritis, agent is being used to reduce signs/symptoms OR induce/maintain clinical response OR improve physical function. Also mbr has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as nonbiologic DMARDs) AND has had a trial and an inadequate response or is intolerant to BOTH: Humira AND Enbrel. For Active Ankylosing Spondylitis (AS), agent is being used to reduce signs/symptoms. Also mbr has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as NSAIDs or non-biologic DMARDs) AND has had a trial and an inadequate response or is intolerant to BOTH: Humira AND Enbrel. For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Cimzia or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Cimzia may be allowed without trial of preferred TNF ag

# Cinqair

### **Products Affected**

CINQAIR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has blood eosinophil counts (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease and known or suspected parasitic infection) greater than or equal to 400 cells/microliter in the prior 12 months. The individual has pretreatment forced expiratory volume in one second (FEV1) less than 80% predicted AND FEV1 reversibility of at least 12% and 200mL after albuterol (salbutamol) administration AND a baseline Asthma Control Questionnaire-7 (ACQ-7) score of greater than or equal to 1.5
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For initial requests, mbr must have a diagnosis of eosinophilic asthma, and has symptoms that are inadequately controlled with a minimum of 12 months of maintenance ICS (for example, daily fluticasone at a dosage of 440mcg [or equivalent]), unless the individual is intolerant of, or has a medical contradiction to these agents. Individual has experienced at least 1 asthma exacerbation in the prior 12 months requiring uninterrupted oral, intramuscular or intravenous corticosteroid administration for more than 3 days. For Maintenance Therapy: Treatment has resulted in clinical improvement as documented by either i) Decreased utilization of rescue medications OR ii) A decreased frequency of exacerbation (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroid) OR iii) An increase in percent predicted FEV1 from pretreatment baseline OR iv) A reduction in reported asthma-related symptoms, such as, but not limited to wheezing, shortness of breath, coughing, fatigue, sleep disturbance or asthmatic symptoms upon awakening

# Cinryze

### **Products Affected**

• CINRYZE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	HAE Type I/II to be confirmed by a C4 level below the lower limit of normal (as defined by the laboratory performing the test) and ANY of the following: 1. C1 inhibitor antigenic level below the lower limit of normal (as defined by the lab performing test). 2. C1 inhibitor functional level below the lower limit of normal (as defined by the lab performing the test). Or 3. The presence of a known HAE-causing C1-INH mutation. HAE Type III was confirmed by: C1 inhibitor (C1-INH) antigenic level is normal as defined by the laboratory performing the test AND C4 level is normal as defined by the laboratory performing the test.
Age Restrictions	6 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a history of moderate or severe attacks and is using Cinryze as prophylaxis for short-term use prior to surgery, dental procedures or intubation OR for long-term prophylaxis and member has failed, or is intolerant to, or has contraindication to 17-alphaalkylated androgens or antifibrinolytic agents.

## Cometriq

### **Products Affected**

 COMETRIQ ORAL CAPSULE 100 MG/DAY(80 MG X1-20 MG X1), 140 MG/DAY(80 MG X1-20 MG X3), 60 MG/DAY (20 MG X 3/DAY)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Copaxone

- COPAXONE SUBCUTANEOUS SYRINGE 20 MG/ML, 40 MG/ML
- COPAXONE SUBCUTANEOUS SYRINGE KIT
- glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml
- glatopa subcutaneous syringe 20 mg/ml, 40 mg/ml

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual with primary progressive MS (PPMS). Individual with secondary progressive MS (SPMS) without relapsing disease. Treatment of MS with glatiramer acetate in combination with any IFN beta-1b (i.e., Betaseron, Extavia, Avonex, Rebif) or in combination with natalizumab
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For Brand Copaxone 20mg requests, Individual also has had a trial and inadequate response or intolerance to Glatopa/glatiramer acetate 20 mg/mL.

## Corlanor

### **Products Affected**

CORLANOR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has a heart rate maintained exclusively by a pacemaker. Individual has severe hypotension (blood pressure less than 90/50 mmgHg). Individual has severe hepatic impairment (Child-Pugh Class C).
Required Medical Information	
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual is using for the treatment of New York Heart Association (NYHA) class II, III or IV heart failure symptoms

## Cosentyx

- COSENTYX
- COSENTYX (2 SYRINGES)
- COSENTYX PEN
- COSENTYX PEN (2 PENS)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using Cosentyx in combination with a biologic DMARD such as Enbrel (etanercept), Humira (adalimumab), certolizumab pegol (Cimzia), Remicade (infliximab), or Stelara (ustekinumab). Using in combination with other immunosuppressive therapy such as phototherapy. Individuals with tuberculosis, invasive fungal infection, other active serious infections or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or a Centers of Disease Control and Prevention (CDC)-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Cosentyx.
Required Medical Information	Individual has moderate to severe plaque psoriasis with either of the following: Individual has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For plaque psoriasis, agent is being used to either reduce signs/symptoms OR induce/maintain clinical response AND individual has failed to respond to/intolerant of or has contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine or methotrexate) AND Individual has had a trial of and an inadequate response or is intolerant to BOTH Enbrel and Humira. For active Ankylosing Spondylitis (AS) agent is being used to either reduce signs/symptoms or induce/maintain clinical response AND individual has failed to respond to/intolerant of or has a medical contraindication to ONE conventional therapy including (NSAIDs or nonbiologic DMARDs) AND Individual has had a trial of and an inadequate response or is intolerant to BOTH Enbrel AND Humira. For Psoriatic Arthritis (PsA) agent is being used to either reduce signs/symptoms OR induce/maintain clinical response AND individual has failed to respond to/intolerant of or has a medical contraindication to conventional drug therapy (such as non biologic DMARDs or TNF antagonist) AND Individual has had a trial of and an inadequate response or is intolerant to BOTH Enbrel AND Humira. For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Cosentyx or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Cosentyx may be allowed without trial of preferred TNF agents (Enbrel/Humira).

## Cotellic

### **Products Affected**

• COTELLIC

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Copy of the test results must be provided that document the BRAF V600E or V600K mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual is using Cotellic (cobimetinib) in combination with Zelboraf (vemurafenib).

### Cresemba

### **Products Affected**

• CRESEMBA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has diagnosis or history of familial short QT syndrome. Use in combination with strong CYP3A4 inhibitors (such as but not limited to ketoconazole) OR strong CYP3A4 inducers (such as but not limited to rifampin).
Required Medical Information	
Age Restrictions	18 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual initiated treatment in an inpatient setting and requires continued treatment of invasive aspergilliosis or mucormycosis in an outpatient setting. For invasive aspergillosis individual has an inadequate response/intolerance to or contraindication to voriconazole or liposomal amphotericin B (ATS 2011, IDSA 2008). For invasive mucormycosis individual has had an inadequate response/intolerance to or contraindication to amphotericin B (ATS 2001).

# Cyramza

### **Products Affected**

• CYRAMZA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	

# D.H.E Inj

- D.H.E.45
- dihydroergotamine injection

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For migraine attacks with aura in adults meeting the following International Headache Society diagnostic criteria: At least two or more headache attacks (must also meet criteria ac): (a) Aura consisting of one of the following fully reversible aura symptoms: 1. visual symptoms (such as, flickering lights, spots or lines) OR 2. Sensory symptoms (for example, pins and needles, numbness) OR 3. Speech and/or language (for example, aphasia) OR 4. Motor (for example, weakness) OR 5. Brainstem (for example, ataxia or vertigo) OR 6. Retinal (for example, blindness) AND (b) At least two or more of the following: 1. At least one aura symptom develops gradually over five or more minutes, and/or 2 or more aura symptoms occur in succession or 2. Each individual aura lasts 5 to 60 minutes or 3. At least 1 aura symptoms is unilateral or 4. The aura is accompanied, or followed within 60 minutes, by headache AND (c) Individual's headache is not attributed to another headache disorder (for example, transient ischemic attack). For migraine attacks without aura in adults meeting the following International Headache Society diagnostic criteria: At least five (5) or more headache attacks (must also meet criteria ad.): (a) Headaches lasting 4-72 hours (untreated or unsuccessfully treated). AND (b) Headache has at least two (2) or more of the following characteristics: 1. Unilateral location 2. Pulsating quality 3. Moderate or severe pain intensity 4. Aggravation by or causing avoidance of routine physical activity (such as, walking or climbing stairs). AND (c) Individuals headache is accompanied by 1 or more of the following: 1. Nausea, vomiting or both 2. Photophobia or phonophobia. AND (d) Individual's headache is not attributed to another headache disorder (for example, transient ischemic attack).
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For cluster headache episodes in adults meeting the following International Headache Society diagnostic criteria: At least five or more attacks (must also meet criteria ad.): (a) Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes if untreated. AND (b) Headache is accompanied by at least one or both of the following: 1. One or more of the following symptoms or signs, ipsilateral to the headache: (i) conjunctival injection and/or lacrimation (ii) nasal congestion and/or rhinorrhea (iii) eyelid edema (iv) forehead and facial sweating (v) forehead and facial flushing (vi) miosis and ptosis (vii) sensation of fullness in the ear OR 2. A sense of restlessness or agitation. AND (c) Attacks have a frequency from one every other day to eight per day for more than half of the time the disorder is active. AND (d) Individual's headache is not attributed to another headache disorder. DHE may also be may be approved for: Status migrainosus or rebound withdrawal type of headaches OR individual has only received narcotics for severe migraine or cluster headaches.

## **DAKLINZA**

#### **Products Affected**

• DAKLINZA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	A copy of the baseline quantitative hepatitis C virus (HCV) RNA test result is provided to document baseline level of viremia. Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016) AND One of the following: (a) Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and a positive HCV RNA test result for at least 6 months following either a positive baseline result or reactive HCV antibody test (AASLD/IDSA 2016,CDC 2013) OR (b) individual is unable to delay treatment for 6 months owing to concurrent factors [such as but not limited to advanced liver disease (metavir fibrosis stage of F3 or F42), post-liver transplant recipients, co-infection with HIV or HBV, coexistent liver diseases (such as nonalcoholic steatohepatitis), chronic HCV infection-associated extrahepatic manifestations (such as membranoproliferative glomerulonephritis, glomerular disease, cryoglobulinemia syndrome)] (AASLD/IDSA 2016) AND (c) Documentation is provided for a diagnosis of chronic CHC infection which includes genotype (AASLD/IDSA 2016), a reactive HCV antibody (CDC 2013), and a subsequent positive HCV RNA result (CDC 2013).
Age Restrictions	18 years of age or older
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, Individual has had a prior trial and inadequate response to Harvoni. For GT 4, individual has had a prior trial and inadequate response to Harvoni or Epclusa. OR individual is currently on and completing a course of therapy with the requested regimen.

# **Daliresp**

#### **Products Affected**

• DALIRESP

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is using to treat acute bronchospasm OR moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment OR using concomitantly with strong cytochrome P450 enzyme inducer (such as but not limited to phenobarbital, carbamazepine or phenytoin)
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual is currently or will be concomitantly using with a long-acting bronchodilator.

## **Darzalex**

#### **Products Affected**

DARZALEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Has received treatment with daratumumab or another anti-CD38 agent
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Desoxyn

- DESOXYN
- methamphetamine

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 6 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of attention deficit hyperactivity disorder (ADHD) AND has had an appropriate trial of one of the following: (a) methylphenidate containing agent OR (b) amphetamine containing agent (such as, amphetamine/dextroamphetamine, lisdexamfetamine, or dextroamphetamine).

# **Dextroamphetamine IR**

- zenzedi oral tablet 10 mg, 5 mgZENZEDI ORAL TABLET 15 MG, 2.5 MG, 20 MG, 30 MG, 7.5 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Member is using for ADHD, Narcolepsy.
Age Restrictions	For ADHD 3yrs and older. For Narcolepsy age 6 years and older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Dificid**

#### **Products Affected**

• DIFICID

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has had a trial and inadequate response or intolerance to or has a contraindication to a course of oral vancomycin with or without a trial of metronidazole.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	
Coverage Duration	30 days
Other Criteria	

# **Doptelet**

#### **Products Affected**

DOPTELET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Doptelet should not be administered to individuals with chronic liver disease in an attempt to normalize platelet counts
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Doxil**

- DOXIL
- doxorubicin, peg-liposomal
- lipodoxlipodox 50

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### DPP4

#### **Products Affected**

- KOMBIGLYZE XR ORAL TABLET, ER MULTIPHASE 24 HR 2.5-1,000 MG, 5-1,000 MG, 5-500 MG
- ONGLYZA ORAL TABLET 2.5 MG, 5

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had a trial and inadequate response or intolerance to metformin OR Individual has a contraindication to metformin therapy [such as but not limited to, renal insufficiency (eGFR less than 45 mL/min/1.73 m2)] AND Individual has had a trial and inadequate response or intolerance to Januvia (sitagliptin) or Tradjenta (linagliptin).

MG

### **Duavee**

#### **Products Affected**

• DUAVEE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	May not be approved for the following: (1) If individual had a hysterectomy (2) Individual has undiagnosed abnormal uterine bleeding (3) Individual has known, suspected, or past history of breast cancer (4) Individual has active or past history of venous thromboembolism (5) Individual has active or past history of arterial thromboembolism (6) Individual has known hepatic impairment or disease OR (7) Individual has known protein C, protein S, or antithrombin deficiency or other known thrombophilic disorders.
Required Medical Information	
Age Restrictions	Age 18 through age 75
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Duopa

#### **Products Affected**

• DUOPA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For advanced Parkinsons disease with complicated motor fluctuations that have not been adequately controlled with optimal medical therapy with any TWO of the following: Oral levodopacarbidopa, a Dopamine agonist [such as, but limited to Apokyn (apomorphine), Mirapex (pramipexole), Requip (ropinirole) and Neupro (rotigotine)], a catechol-0-methyl transferase (COMT) inhibitor [such as, but not limited to Comtan (entacapone) and Tasmar (tolcapone)], or a monoamine oxidase B (MAO)-B inhibitor [such as, but not limited to Eldepryl (selegiline), and Azilect (rasagiline)].

# **Dupixent**

### **Products Affected**

DUPIXENT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	A)Chronic atopic dermatitis that has been present for 3 years or more AND B) failure of topical pharmacological therapy as indicated by one or more of the following: 1) Daily treatment of topical corticosteroids of medium to higher potency for the maximum treatment period indicated in the product prescribing information has failed to achieve and maintain remission of low or mild disease activity state OR 2) topical calcineurin inhibitors (for example, Elidel, Protopic) if topical corticosteroids are not indicated for the maximum treatment period indicated in the product prescribing information has failed to achieve and maintain remission of low or mild disease activity state OR 3) Topical treatment is medically inadvisable as defined by treatments which have side effects or safety concerns which outweigh potential treatment benefits as evidenced by any of the following: Intolerance to treatment, hypersensitivity reactions, significant skin atrophy or systemic effects AND C) One of the following: Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated OR systemic treatment (for example, immunosuppressants) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated.

# **Duragesic Patch**

- DURAGESIC
- fentanyl

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is requesting or using as an as-needed analgesic OR Individual has one of the following conditions: (a) Significant respiratory depression OR (b) Acute or severe bronchial asthma or hypercarbia OR (c) Known or suspected paralytic ileus.
Required Medical Information	
Age Restrictions	Individual is 2 years of age or older
Prescriber Restrictions	
Coverage Duration	Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

PA Criteria	Criteria Details
Other Criteria	For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure). AND already receiving at least 60 mg/day of oral morphine, 30 mg/day of oral oxycodone, 8 mg/day of oral hydromorphone, or an equianalgesic dose of another opioid AND Individual is not opioid analgesic dose of another opioid AND Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic. For continued use, Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline.

## Duzallo

#### **Products Affected**

• DUZALLO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documentation provided for why Duzallo (lesinurad and allopurinol) combination agent is clinically necessary (written or verbal attestation is acceptable).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had a trial and inadequate response (unable to achieve target serum uric acid levels) to allopurinol AND has had a trial and adequate response to allopurinol and lesinurad when used at the same time.

## **EGR Cialis BPH**

- CIALIS
- tadalafil oral tablet 2.5 mg, 5 mg

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Erectile dysfunction. Currently on nitrate therapy.
Required Medical Information	Individual has a diagnosis of benign prostatic hyperplasia (BPH) [with or without ED]
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **EGR Liptruzet**

#### **Products Affected**

• LIPTRUZET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has had a trial of generic statin at any dose and provider attests the member has experienced failure, contraindication, or intolerance to a generic statin. Or Individual is currently on a product that interacts with generic statin.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **EGR Simponi ARIA**

#### **Products Affected**

SIMPONI ARIA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use of golimumab in combination with other TNF antagonists, abatacept, tofacitinib, or anakinra. Tuberculosis, invasive fungal infections, other active serious infections, or a history of recurrent infections. Individuals who have not had a TST or a CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating Simponi (golimumab).
Required Medical Information	Agent is being used for the following reasons: 1. To reduce signs or symptoms or 2.To induce or maintain clinical response or 3.To improve physical function.
Age Restrictions	Individual is 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For RA, individual is taking in combination with methotrexate or with another immunosuppressive agent if the individual is intolerant to methotrexate AND individual has tried and failed to respond to, is intolerant of, or has a medical contraindication to ONE nonbiologic DMARD AND individual has had a trial of and an inadequate response or is intolerant to BOTH: Humira AND Enbrel. OR the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Simponi Aria or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Simponi Aria may be allowed without trial of preferred TNF agents (Enbrel/Humira).

# **Egrifta**

#### **Products Affected**

• EGRIFTA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is currently pregnant or breast-feeding. Lipodystrophy of anatomic sites aside from the abdomen. Lipodystrophy not associated with HIV infection. Individuals who do not show a clear response as judged by the degree of reduction in visceral adipose tissue measured by waist circumference or CT scan. Weight loss management. In individuals with a history of disruption of the hypothalamic-pituitary (HPA) axis due to hypophysectomy, hypopituitarism, pituitary tumor, pituitary surgery, head irradiation, or head trauma.
Required Medical Information	For initial requests, individual has a body mass index (BMI) is greater than 20 kg/m2 AND waist circumference and a waist-to-hip ratio are both at least 2.5 standard deviations above normal based on age and gender AND fasting blood glucose (FBG) is less than 150 mg/dL (8.33 mmol/L) AND no history of type 1 diabetes or insulin-treated type 2 diabetes AND no active malignancy (e.g., a potential cancer which is being evaluated or a diagnosed cancer which is being treated). For continuation, individual must demonstrate there is a clear response in reduction of visceral adipose tissue measured by waist circumference or computed tomography (CT) scan.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initial 6 months, renewal 1 year.
Other Criteria	

# **Elaprase**

#### **Products Affected**

• ELAPRASE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documented deficiency in iduronate 2-sulfatase enzyme activity as measured in fibroblasts or leukocytes combined with normal enzyme activity level of another sulfatase OR Documented iduronate 2-sulfatase gene mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has symptoms attributable to MPS II such as: (a) Developmental delay or cognitive impairment or (b) Frequent infections or (c) Hearing loss or (d) Hepatosplenomegaly or (e) Hernias or (f) Impaired respiratory function or (g) Joint pain or (h) Skeletal deformities or (i) Sleep apnea or (j) Valvular heart disease.

## Elidel

#### **Products Affected**

• ELIDEL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 2 years of age and older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual had a trial of and inadequate response or intolerance to one topical prescription strength corticosteroid.

## **ELIGARD\_GNRH**

- ELIGARD
- ELIGARD (3 MONTH)
- ELIGARD (4 MONTH)
- ELIGARD (6 MONTH)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Following radical prostatectomy as adjuvant therapy when lymph node metastases are present OR Locally advanced disease OR Other advanced, recurrent, or metastatic disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Elitek**

#### **Products Affected**

• ELITEK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has a diagnosis of glucose-6-phosphate dehydrogenase (G6PD) deficiency.
Required Medical Information	Individual is receiving treatment in a setting appropriate for providing necessary monitoring and supportive care for tumor lysis syndrome AND Individual has not received a course of Elitek therapy in the past.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 days
Other Criteria	Individual has been diagnosed with leukemia, lymphoma or other hematologic malignancy with risk factors for tumor lysis syndrome AND Individual is receiving chemotherapy.

## **Emflaza**

#### **Products Affected**

• EMFLAZA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documentation has been provided for excessive weight-gain with prednisone (increase of greater than 0.5 Z score from prior growth curve expectations [American Academy of Pediatrics/CDC Weight for Age Growth Chart, Z-score data files, CDC, Weight-for-age charts, 2 to 20 years, selected weight z-scores in kilograms, by sex and age]) AND Weight gain is likely to be a direct result of prednisone use.
Age Restrictions	Individual is 5 years of age or older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For initial treatment of Duchenne Muscular Dystrophy (DMD) AND Individual has had a 6 month trial of oral prednisone (AAN 2016, DrugPoints B, IIa). For continuation following initiation of Emflaza (deflazacort), individual has experienced a return to baseline status on growth chart (American Academy of Pediatrics/CDC Weight for Age Growth Chart, Z-score data files, CDC, Weight-for-age charts, 2 to 20 years, selected weight z-scores in kilograms, by sex and age). For additional approval durations: individual has maintained baseline status on growth chart.

# **Empliciti**

### **Products Affected**

• EMPLICITI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Emsam**

#### **Products Affected**

• EMSAM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individuals with pheochromocytoma OR Individual is currently taking one of the following: (1) Selective serotonin reuptake inhibitors (SSRIs) (for example, fluoxetine) OR (2) Serotonin and norepinephrine reuptake inhibitors (SNRIs) (for example, venlafaxine) OR (3) Tricyclic antidepressants (clomipramine or imipramine) OR (4) Opiate analgesics (meperidine, tramadol, methadone, pentazocine) OR (5) Dextromethorphan OR (6) Carbamazepine.
Required Medical Information	Individual has no known contraindications to the use of a monoamine oxidase inhibitor (MAOI).
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Enbrel**

#### **Products Affected**

- ENBREL MINI
- ENBREL SUBCUTANEOUS RECON SOLN
- ENBREL SUBCUTANEOUS SYRINGE

25 MG/0.5ML (0.51), 50 MG/ML (0.98 ML)

ENBREL SURECLICK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Entanercept used in combination with other TNF antagonist or in combination with the following non-TNF immunomodulatory drugs: abatacept (Orencia), anakinra (Kineret), or tofacitinib citrate, or cyclophosphamides. Tuberculosis, invasive fungal infection, or other active serious infection. Individual who have not had a tuberculin skin test or a CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating etanercept.
Required Medical Information	For chronic moderate to severe plaque psoriasis with either of the following: Individual has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).
Age Restrictions	Individual is 18 years of age or older, except for the diagnosis of JIA and plaque psoriasis. For JIA individual is 2 years of age or older. For plaque psoriasis, 4 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year except for Initial high dose tx chronic plaque psoriasis 12 wk

PA Criteria	Criteria Details
Other Criteria	For Ankylosing Spondylitis, agent is used to reduce signs or symptoms of the disease. Also individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapies: (such as NSAIDs or nonbiologic DMARDs). For Moderate to severe Chronic Plaque Psoriasis agent is being used to reduce signs/symptoms OR to induce/maintain clinical response. Also individual has failed to respond to, is intolerant of, or has a medical contraindication to phototherapy OR ONE other systemic therapies (such as, methotrexate, acitretin, or cyclosporine). For moderately to severely active Rheumatoid Arthritis agent is being used to reduce signs/symptoms OR to induce/maintain clinical response OR inhibit the progression of structural damage OR improve physical function. Also individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE nonbiologic DMARD. For Moderate to severe active Polyarticular-course JIA (previously known as JRA), agent is being used to reduce signs/symptoms OR to induce/maintain clinical response. Also individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE nonbiologic DMARD. For Psoriatic Arthritis, agent is being used to reduce signs/symptoms OR to induce/maintain clinical response OR inhibit the progression of structural damage OR improve physical function. Also individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE nonbiologic DMARD.

### **Entresto**

#### **Products Affected**

• ENTRESTO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is pregnant/ wishing to become pregnant OR breastfeeding OR has a history of angioedema related to previous ACE inhibitor or ARB therapy OR has severe hepatic impairment (Child-Pugh C). OR Individual will be utilizing an angiotensin-converting enzyme (ACE) inhibitor OR angiotensin receptor blocker (ARB) in combination with Entresto (sacubitril/valsartan). Individual will be utilizing Entresto (sacubitril/valsartan) in combination with Tekturna (aliskiren)/Tekturna HCT (aliskiren/hydrochlorothiazide) and has a diagnosis of diabetes or renal impairment (eGFR less than 60 mL/min/1.73 m2).
Required Medical Information	Individual has a left ventricular ejection fraction less than or equal to 40%.
Age Restrictions	Individual is 18 years or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Entyvio**

### **Products Affected**

• ENTYVIO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Entyvio used in combination with other TNF antagonists blockers, non-TNF antagonists immunomodulatory drugs, such as or Tysabri (natalizumab). Tuberculosis, other active, severe infections, or a history of recurrent infections. Individuals who have not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to Entyvio. New or worsening neurological signs or symptoms of John Cunningham virus (JCV) infection or risk of progressive multifocal leukoencephalopathy (PML).
Required Medical Information	
Age Restrictions	Individual is 18 years or older.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For UC or CD, individual is using to reduce signs/symptoms or induce/maintain clinical remission/response AND has failed to respond to, lost response to, is intolerant of, or has a medical contraindication to tumor necrosis factor (TNF) antagonists or conventional therapy [such as aminosalicylates/5-ASA products (for example, mesalamine, sulfasalazine), an immunomodulator (such as azathioprine, 6-mercaptopurine (6-MP) or an immunosuppressive drug)] or has failed to respond to, lost response to, is intolerant of or has demonstrated dependence on systemic corticosteroids AND Individual has had a trial and an inadequate response or is intolerant to Humira OR the TNF agent (Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Entyvio or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Entyvio may be allowed without trial of preferred TNF agents (Humira).

# **Epclusa**

### **Products Affected**

• EPCLUSA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	A copy of the baseline quantitative hepatitis C virus (HCV) RNA test result is provided to document baseline level of viremia AND One of the following: (1) Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016, CDC 2013). OR (2) Individual is unable to delay treatment for 6 months owing to concurrent factors [such as but not limited to, advanced liver disease (Metavir fibrosis stage of F3 or F42), post-liver transplant recipients, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), coexistent liver diseases (such as nonalcoholic steatohepatitis), chronic HCV infection-associated extrahepatic manifestations (such as membranoproliferative glomerulonephritis, glomerular disease, cryoglobulinemia syndrome)] (AASLD/IDSA 2016) AND Documentation is provided for a diagnosis of chronic CHC infection, which includes a reactive HCV antibody (CDC 2013) and a subsequent positive HCV RNA result (CDC 2013). Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016).
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

# **Epidiolex**

### **Products Affected**

• EPIDIOLEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	2 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Epogen and Procrit**

- EPOGEN
- PROCRIT
- RETACRIT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Anemia in patients due to other factors such as iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic diseases (such as sickle cell anemia, thalassemia, and porphyria). Sudden loss of response with severe anemia and low reticulocyte count. Treatment of anemia in patients with cancer not treated by chemotherapy known to produce anemia. Treatment of in any indication not listed in criteria including anemia of prematurity. Anemia in cancer patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure. Anemia in cancer patients receiving hormonal agents, therapeutic biologic products, or radiotherapy unless receiving concomitant myelosuppressive chemotherapy. Continued use when the hemoglobin level exceeds 11.0 g/dL unless otherwise specified in the criteria. Use beyond 12 weeks in the absence of response in individuals with chronic renal failure. Use beyond 8 weeks in the absence of response or if transfusions are still required in individuals with myelosyplastic syndrome (MDS). Use beyond 8-9 weeks in the absence of response or if transfusions are still required in individuals with metastatic, nonmyeloid cancer being treated with myelosuppressive chemotherapy agents known to produce anemia. Continued use beyond 6 weeks after therapy with myelosuppressive chemotherapy known to produce anemia is completed. Pre-operative use for patients who are willing to donate autologous blood.

PA Criteria	Criteria Details
Required Medical Information	Hemoglobin (Hgb) levels are less than 10.0 g/dL, prior to initiation of therapy (unless otherwise specified) AND the individual iron status reveals, transferrin saturation at least 20% or ferritin at least 80 ng/mL or bone marrow demonstrates adequate iron stores AND For individuals with uncontrolled hypertension, blood pressure is adequately controlled before initiation of therapy and closely monitored and controlled during therapy. For MDS, endogenous erythropoietin level is less than 500 mU/ml. For anemia related to zidovudine in HIV-infected patients when the dose of zidovudine is less than or equal to 4200 mg per week, endogenous erythropoietin level is less than or equal 500 mU/ml. Reduction of Allogeneic Blood Transfusion in Pre-Operative Surgery Patients: Patient's hgb is greater than 10.0 and less than or equal to 13.0 g/dL, individual is scheduled to undergo elective, noncardiac, nonvascular surgery, individual is at high risk for perioperative transfusions with significant, anticipated blood loss, individual is unable or unwilling to donate autologous blood, Antithrombotic prophylaxis has been considered. For tx of anemia due to chemotherapy known to produce anemia, chemo is planned for a minimum of 2 months and the dx is non-myeloid cancer and the anticipated outcome is not cure. For anemia associated with CKD ON dialysis use is to achieve and maintain hgb levels within the range of 10.0 to 11.0 g/dL. For anemia associated with CKD NOT ON dialysis use is to achieve and maintain hgb levels of 10.0g/dL.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	8wk.
Other Criteria	For Hepatitis C, patient is concomitantly treated with combination of ribavirin and interferon alfa, or ribavirin and peginterferon alfa. Myelosuppressive drugs known to produce anemia in individuals with a diagnosis of chronic inflammatory disease. Allogeneic bone marrow transplantation.

### **Eraxis**

### **Products Affected**

• ERAXIS(WATER DILUENT)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Erbitux**

### **Products Affected**

• ERBITUX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Erbitux is used in combination with other anti-VEGF agents (e.g., bevacizumab). Erbitux is used in more than one line of therapy.
Required Medical Information	For stage IV, kras wild type colon, rectal, colorectal, small bowel, or anal adenocarcinoma when used as a single agent or as part of combination therapy. For squamous cell carcinoma of the Head and/or Neck cancer, Erbitux is used in combination with radiation therapy, for the treatment of locally or regionally advanced disease. Or as a single agent for the treatment of patients with recurrent or metastatic disease for whom prior platinum-based therapy has failed. Or in combination with platinum-based therapy with 5-FU (fluorouracil) as first-line treatment for individuals with recurrent locoregional disease or metastatic SCCHN. OR as a single agent or in combination therapy with or without radiation therapy for any of the following indications, unresectable locoregional recurrence or second primary in individuals who have received prior radiation therapy OR resectable locoregional recurrence in individuals who have not received prior radiation therapy OR distant metastases.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Erivedge

### **Products Affected**

• ERIVEDGE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Erleada

### **Products Affected**

• ERLEADA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	

### **Erwinase**

### **Products Affected**

• ERWINAZE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	History of serious thrombosis with prior L-asparaginase therapy. History of pancreatitis with prior L-asparaginase therapy. History of serious hemorrhagic events with prior L-asparaginase therapy.
Required Medical Information	Individual is using Erwinase as a component of a multi-agent chemotherapeutic regimen AND is using for Acute lymphoblastic lymphoma or acute lymphocytic leukemia (ALL) or Extranodal natural killer T-cell lymphoma, nasal type (ENKL). Individual has developed a documented systemic allergic reaction or anaphylaxis to prior treatment with Oncaspar (Pegaspargase).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Esbriet**

- ESBRIET ORAL CAPSULE
- ESBRIET ORAL TABLET 267 MG, 801 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individuals using in combination with Ofev (nintedanib). Individuals currently taking fluvoxamine. Individuals with end-stage renal disease (ESRD). Individuals with severe hepatic impairment (child pugh class C) or end-stage liver disease.
Required Medical Information	Diagnosis of idiopathic pulmonary fibrosis (IPF) is confirmed by: Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity AND High resolution computed tomography (HRCT) with or without surgical lung biopsy. Individual has documented pulmonary function tests within prior 60 days with a Forced Vital Capacity (% FVC) greater than or equal to 50%.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Ethyol**

- amifostine crystalline ETHYOL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Evekeo**

- amphetamine sulfate oral tablet 10 mg, 5 mg
- EVEKEO ORAL TABLET 10 MG, 5 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, agitated states or individual has a history of drug abuse. Individual is using for exogenous obesity.
Required Medical Information	
Age Restrictions	3 years of age or older for attention deficit hyperactivity disorder (ADHD). 6 years of age or older for narcolepsy.
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	

## Exjade

### **Products Affected**

• EXJADE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 2 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Exondys 51**

### **Products Affected**

• EXONDYS 51

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has a confirmed mutation of the DMD gene that is amenable to exon 51 skipping
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Eylea

### **Products Affected**

• EYLEA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Fabrazyme**

#### **Products Affected**

FABRAZYME

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of Fabry disease is confirmed with either of the following: (a) Documentation of complete deficiency or less than 5% of mean normal alpha-galactosidase A enzyme activity in leukocytes, dried blood spots or serum (plasma) analysis or (b) Documented galactosidase alpha gene mutation by gene sequencing.
Age Restrictions	Individual is 8 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has one or more symptoms or physical findings attributable to Fabry disease, such as: (a) Acroparesthesias or (b) Angiokeratomas or (c) Corneal verticillata (whorls) or (d) Decreased sweating (anhidrosis or hypohidrosis) or (e) Personal or family history of exercise, heat, or cold intolerance or (f) Personal or family history of kidney failure.

## **Farydak**

#### **Products Affected**

• FARYDAK ORAL CAPSULE 10 MG, 15 MG, 20 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Faslodex**

### **Products Affected**

• FASLODEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Fentora**

#### **Products Affected**

• FENTORA BUCCAL TABLET, EFFERVESCENT 100 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using for treatment of acute or postoperative pain OR migraine headache pain OR non-cancer related pain.
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has tried and failed fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking Fentora (fentanyl) for cancer related breakthrough pain.

## **Ferriprox**

### **Products Affected**

FERRIPROX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Fetzima**

#### **Products Affected**

 FETZIMA ORAL CAPSULE,EXT REL 24HR DOSE PACK MG, 80 MG

• FETZIMA ORAL CAPSULE, EXTENDED RELEASE 24 HR 120 MG, 20 MG, 40

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	May not be approved for treatment of fibromyalgia
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For MDD, individual has had a trial of TWO of the following: Desvenlafaxine ER, desvenlafaxine Fumerate ER, fluoxetine, fluvoxamine, escitalopram, citalopram, paroxetine, sertraline, mirtazapine, immediate-release venlafaxine, extended-release venlafaxine or bupropion.

## **Firazyr**

### **Products Affected**

• FIRAZYR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Prophylaxis for HAE attacks.
Required Medical Information	HAE Type I/II to be confirmed by a C4 level below the lower limit of normal (as defined by the laboratory performing the test) and either a C1 inhibitor antigenic level below the lower limit of normal (as defined by the lab performing test) or a C1 inhibitor functional level below the lower limit of normal (as defined by the lab performing the test). HAE Type III was confirmed by: C1 inhibitor (C1-INH) antigenic level is normal as defined by the laboratory performing the test AND C4 level is normal as defined by the laboratory performing the test.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion)and using Firazyr for acute HAE attacks.

### **Firmagon**

#### **Products Affected**

 FIRMAGON KIT W DILUENT SYRINGE SUBCUTANEOUS RECON SOLN 120 MG, 80 MG SOLN 120 MG, 80 MG

• FIRMAGON SUBCUTANEOUS RECON

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Following radical prostatectomy as adjuvant therapy when lymph node metastases are present OR Locally advanced disease OR Other advanced, recurrent, or metastatic disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Flector Patch**

#### **Products Affected**

• FLECTOR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is using for perioperative pain in the setting of coronary artery bypass graft (CABG) surgery. Individual is using on non-intact or damaged skin resulting from any etiology, including exudative dermatitis, eczema, infection lesions, burns or wounds.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	Individual is using for the treatment of acute pain from one of the following: (a) Minor strain OR (b) Sprain OR (c) Contusion.

### **Forteo**

### **Products Affected**

• FORTEO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is not using Forteo (teriparatide) in combination with any of the following: Prolia (denosumab), Bisphosphonates, Evista (raloxifene), Miacalcin/Fortical (calcitonin nasal spray), or Recalst (zolendronic acid).
Required Medical Information	A Bone Mineral Density (BMD) and a T-score must be provided with all requests. Osteoporosis is defined as a BMD T-Score of less than or equal to -2.5 as compared to young adult reference population OR a Clinical diagnosis based on a history of a low trauma fracture (fragility fracture) at high risk for fracture OR associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5mg or greater of prednisone for at least 3 months) at high risk for fracture. In the absence of fragility fracture, BMD T-Scores greater than -2.5 (closer to 0 or positive) are not considered osteoporotic. High risk for fracture is defined as follows: Hx of osteoporotic fracture, OR multiple risk factors for fractures (including but not limited to prior low-trauma fracture as an adult, advanced age, gender, ethnicity, low bone mineral density, low body weight, family history of osteoporosis, use of glucocorticoids (daily dosage equivalent to 5mg or greater of prednisone for at least 3 months), cigarette smoking, excessive alcohol consumption [3 or more drinks/day], secondary osteoporosis (such as, rheumatoid arthritis), early menopause, height loss or kyphosis, fall risk and low calcium intake, OR Failure or intolerance to other osteoporosis therapy.
Age Restrictions	
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	2 years. Requests to continue therapy beyond 24 months (2 years) should not be approved.
Other Criteria	Individual has one of the following: (A) Individual has had a trial of an oral bisphosphonate therapy OR (B) Intolerance or contraindications to oral bisphosphonate as defined by having at least one of the following: 1. Hypersensitivity to TWO oral bisphosphonates (one of which must be alendronate) 2. Inability to sit or stand upright for at least 30 minutes, 3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.). 4. Uncorrected hypocalcemia.

### **Fusilev**

#### **Products Affected**

- FUSILEV
- LEVOLEUCOVORIN INTRAVENOUS RECON SOLN 175 MG
- levoleucovorin intravenous recon soln 50

mg

• levoleucovorin intravenous solution

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **GamaSTAN**

- GAMASTAN
- GAMASTAN S/D

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual with isolated immunoglobulin A (IgA) deficiency. Individual with severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections. Prophylaxis of viral hepatitis type B. Routine post-exposure prophylaxis or treatment of rubella, poliomyelitis, mumps, or varicella. Allergy or asthma in individuals who have normal levels of immunoglobulin.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Pre-Exposure of HAV, mbr will get IM inj prior to exposure AND mbr has no clinical manifestations of hepatitis A AND is unvaccinated (CDC 2007/2015) along with one of the following: unable to receive HAV vaccine (such as, contraindication to or unavailability of the vaccine) OR mbr is considered high-risk (such as but not limited to, travel to an endemic area, older adults, immunocompromised, or diagnosis of chronic liver disease) and will receive a simultaneous dose of HAV vaccine unless contraindicated. Post-Exposure of HAV, mbr will get IM inj within 2 weeks of exposure AND mbr has no clinical manifestations of hepatitis A AND is unvaccinated (CDC 2007/2015) along with one of the following: unable to receive HAV vaccine (such as, contraindication to or unavailability of the vaccine) OR mbr is considered high-risk (such as but not limited to, immunocompromised, diagnosis of chronic liver disease, or vaccine contraindication). For post exposure prophylaxis of rubeola, must be given within 6 days of exposure and not concomitantly with a vaccine containing the measles virus AND eligible exposed, nonimmune individuals will receive a vaccine containing the measles virus freather receiving intramuscular immune globulin (CDC 2013) AND used in mbr considered at risk for severe disease and complications: infants or previously unvaccinated and ineligible to receive a vaccine containing the measles virus (such as, but not limited to, vaccine containing the measles virus (such as, but not limited to, vaccine containing the measles virus (such as, but not limited to, vaccine containing the measles virus (such as, but not limited to, vaccine containing the measles virus (such as, but not limited to, vaccine containing the measles virus (such as, but not limited to, vaccine containing the measles virus (such as, but not limited to, vaccine containing the measles virus (such as, but not limited to, vaccine containing the measles virus (such as, but not limited to, vaccine containing the measles virus (such as, but not limite

### **Gattex**

- GATTEX 30-VIAL
- GATTEX ONE-VIAL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For diagnosis of Short Bowel Syndrome (SBS) defined as having less than 200 cm of functional small intestine remaining as a result of one of the following (label, AGA 2003, Buchman et al. 2003): Acquired through surgical bowel resection OR Congenital (jejunal or ileal intestinal atresia) AND individual is has been dependent on parenteral nutrition/intravenous (PN/IV) support. For at least 12 months AND requires PN at least 3 times per week.

### **Gauchers**

- CEREZYME
- ELELYSO
- VPRIV

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use of enzyme replacement therapy (ERT) agents in conjunction with one another or in conjunction with a substrate reduction therapy (SRT) agent. Use of ERT agents for the treatment of type 2 gaucher disease.

PA Criteria	Criteria Details
Required Medical Information	Type 1 Gaucher is confirmed by: Glucocerebrosidase activity in white blood cells or skin fibroblasts less than or equal to 30% of normal activity, OR genotype tests indicating mutation of two alleles of the glucocerebrosidase genome. And mbr has clinically significant manifestations of gauchers including any of the following for type 1,3: [Adults] skeletal disease (demonstrated by ANY of the following: avascular necrosis, erlenmeyer flask deformity, lytic disease, marrow infiltration, osteopenia, osteosclerosis, pathological fracture, radiological evidence of joint deterioration) OR mbr presents with at least 1 of the following: clinically significant hepatomegaly/splenomegaly, hgb less than or equal to 11.5 gm/dl for females and less than 12.5 gm/dl for males or 1 gm/dl below lower limit for normal for age and sex, platelet counts less than or equal to 120,000 mm3. [Children] abdominal or bone pain, hepatosplenomegaly, documented growth fx not associated with other conditions, cachexia, exertional limitation, fatigue, evidence of skeletal involvement including but not limited to erlenmeyer flask deformity, anemia with hgb less than 2 grams per dl below lower limit of normal for age and sex, platelet count less than 60,000 mm3 and or documented abnormal bleeding episodes. Type 3 gauchers is confirmed by genotype testing indicating presence of 2 homopathic alleles for neuropathic gaucher disease. And mbr has clinically significant manifestations of gauchers listed above in type 1 AND Neurological findings are consistent with the presence of type 3 gaucher disease: Neurological examination, eye movement examination, neuro-ophthalmological investigation with direct opthalmoloscopy, measurement of peripheral hearing (electro-acoustical emission in small children, pure tone audiometry in older patients), brain imaging preferably by MRI or CT, diagnostic brain stem evoked responses, EEG, intelligence quotient testing when appropriate and reasonable.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Gazyva

### **Products Affected**

GAZYVA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	

# Gilenya

### **Products Affected**

• GILENYA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with other MS disease modifying agents (such as, Aubagio, Tecfidera, Tysabri, Copaxone/Glotopa, Extavia, Rebif, Avonex, Plegridy, Betaseron). Individual has history or presence of Mobitz Type II second- or third-degree atrioventricular (AV) block or sick sinus syndrome, unless individual has a functioning pacemaker. Individual has a baseline QTc interval greater than or equal to 500 ms. Individual is being treated with Class Ia (such as quinidine, procainamide, or disopyramide) or Class III [such as amiodarone, Multaq (dronedarone), Tikosyn (dofetilide), or sotalol] anti-arrhythmic drugs. Individual has had a recent (within the past 6 months) occurrence of one of the following: Myocardial infarction, Unstable angina, Stroke, Transient ischemic attack (TIA), Decompensated heart failure requiring hospitalization, Class III/IV heart failure.
Required Medical Information	I. Individual has had a trial and inadequate response or intolerance to one of the following: Avonex (interferon beta-1a), Plegridy (interferon beta-1-a), Betaseron (interferon beta-1b), Tecfidera (dimethyl fumarate), Copaxone (glatiramer). OR II. Individual has high disease activity despite treatment with a disease modifying drug (Aubagio, Avonex, Plegridy, Rebif, Betaseron, Extavia, Copaxone/Glatopa, Tecfidera) defined as the following: At least 1 relapse in the previous year while on therapy AND At least 9 T2-hyperintense lesions in cranial MRI OR At least 1 Gadolinium-enhancing lesion. OR III. Individual is treatment naive (no previous history of use of disease modifying drugs such as Aubagio, Avonex, Plegridy, Rebif, Betaseron, Extavia, Copaxone/Glatopa, Tecfidera) AND IV. Individual has rapidly evolving severe relapsing multiple sclerosis defined as the following: Two or more disabling relapses in 1 year AND One or more Gadolinium-enhancing lesions on brain MRI.

PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Gilotrif**

### **Products Affected**

• GILOTRIF

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For individuals with metastatic non-small cell lung cancer (NSCLC), a Copy of the test results from a FDA-approved companion diagnostic test must be provided that document the exon 19 deletions or exon 21 (L858R) substitution mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Gleevec

- GLEEVEC ORAL TABLET 100 MG, 400 MG
- imatinib oral tablet 100 mg, 400 mg

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Gleostine

### **Products Affected**

• GLEOSTINE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Granix

### **Products Affected**

• GRANIX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use as prophylaxis for FN during concomitant chemotherapy and radiation therapy. Continued use if no response is seen within 28-42 days (individuals who have failed to respond within this time frame are considered non-responders).
Required Medical Information	Prognostic factors predictive of clinical deterioration: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10to the power of 9/L) neutropenia, Age greater than 65 years, Uncontrolled primary disease, Pneumonia, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than or equal to 20% based on chemotherapy in patients who have other patient specific risk factors for FN including any of the following: Individual age greater than 65 years, Poor performance status (ECOG status 3-4),, Previous episodes of FN, Bone marrow involvement by tumor producing cytopenias, preexisting neutropenia (ANC less than 1500mm3),, Poor nutritional status (baseline albumin less than or equal to 3.5g/dL or body mass index [BMI] less than 20), poor renal function (GFR less than 60mL/min), liver dysfunction, The presence of open wounds, advanced cancer or Other serious comorbidities.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Adjunctive use in neutropenic patients who are at high risk for infection-associated complications or have any of the prognostic factors predictive of clinical deterioration.

## Grastek

### **Products Affected**

• GRASTEK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction. History of eosinophilic esophagitis. Or, individual is receiving concomitant therapy with other allergen immunotherapy products.
Required Medical Information	For grass pollen induced allergic rhinitis, individual has a documented positive skin test OR positive in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. Individual has had a trial of, and inadequate symptom control or intolerance to (1) nasal steroid and (1) non-sedating antihistamine AND individual has a documented prescription for an auto-injectable epinephrine product.
Age Restrictions	Individual is between the ages of 5 years and 65 years old.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Treatment is initiated at least 12 weeks before the expected onset of grass pollen season and is continued throughout the season.

# Haegarda

## **Products Affected**

• HAEGARDA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Hereditary angioedema (HAE) was confirmed by a C4 level below the lower limit of normal as defined by the laboratory performing the test AND ANY of the following (a, b, or c): (a) C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test or (b) C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test or (c) Presence of a known HAE-causing C1-INH mutation.
Age Restrictions	12 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a history of moderate or severe attacks and is using Haegarda as prophylaxis for short-term use prior to surgery, dental procedures or intubation OR for long-term prophylaxis and member has failed, or is intolerant to, or has contraindication to 17-alpha-alkylated androgens or antifibrinolytic agents.

## Halaven

### **Products Affected**

• HALAVEN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Halven is used as a single agent and in a single line of therapy for recurrent or metastatic breast cancer. Member has previously received at least two chemotherapeutic regimens for locally recurrent or metastatic disease. Individual is using in combination with trastuzumab (Herceptin) in the treatment of locally recurrent or metastatic HER2+ breast cancer with: (a) Symptomatic visceral disease OR (b) Either hormone receptor-negative disease or hormone receptor-positive and endocrine refractory disease. For soft tissue sarcoma, agent is used as a single agent in a single line of therapy and has previously received at least 2 chemotherapeutic regimens for locally recurrent or metastatic disease.

## Harvoni

### **Products Affected**

HARVONI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	

DA Cuitoui-	Critaria Dataila
PA Criteria	Criteria Details
Required Medical Information	A copy of the baseline quantitative HCV RNA test result is provided to document baseline level of viremia and ONE of the following: (1) Documentation is provided for a diagnosis of chronic Hepatitis C virus (CHC) infection, which includes Genotype and a positive HCV RNA test result for at least 6 months following either a positive baseline result HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016. CDC 2013) OR (2) Individual is unable to delay treatment for 6 months owing to concurrent factors [such as but not limited to, advanced liver disease (Metavir fibrosis stage of F3 or F42), post-liver transplant recipients, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), coexistent liver diseases (such as nonalcoholic steatohepatitis), chronic HCV infection-associated extrahepatic manifestations (such as membranoproliferative glomerulonephritis, glomerular disease, cryoglobulinemia syndrome)] (AASLD/IDSA 2016) AND Documentation is provided for a diagnosis of chronic CHC infection, which includes genotypea (AASLD/IDSA 2016), a reactive HCV antibody (CDC 2013), and a subsequent positive HCV RNA result (CDC 2013). Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2015). Individual also has one of the following: Genotype 1 and compensated liver disease (with or without cirrhosis) OR Genotype 1 or 4 and decompensated liver disease with cirrhosis OR Genotype 4, 5, or 6 and compensated liver transplantation (AASLD/IDSA 2014) OR Genotype 1 or 4 and compensated liver disease with or without cirrhosis following allograft liver transplantation (ASSLD/IDSA 2015).
Age Restrictions	12 years of age or older.
Prescriber Restrictions	
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

## Hepsera

- adefovir
- HEPSERA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	12 years of age and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Hetlioz

### **Products Affected**

• HETLIOZ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Horizant

### **Products Affected**

• HORIZANT ORAL TABLET EXTENDED RELEASE 300 MG, 600 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For diagnosis post herpetic neuralgia (PHN), individual has had a trial of immediate release gabapentin. For diagnosis restless leg syndrome (RLS) individual has had a trial of or contraindication/intolerance to either pramipexole OR Ropinirole.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **HP Acthar**

### **Products Affected**

• ACTHAR H.P.

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has a corticosteroid-responsive condition, including but not limited to acute exacerbation of multiple sclerosis AND Individual has no contraindications to or is not limited by contraindication to or intolerance of glucocorticoid effects AND there is clear documentation of why all other well established routes for corticosteroid therapy (for example, oral prednisone and intravenous methylprednisolone) cannot be used.
Age Restrictions	For West Syndrome, infant and children less than 2 years of age.
Prescriber Restrictions	
Coverage Duration	6 month
Other Criteria	

## **HRM Age**

- amitriptyline
- amitriptyline-chlordiazepoxide
- ANAFRANIL
- chlorpromazine
- clomipramine
- desipramine
- imipramine hcl
- imipramine pamoate
- NEMBUTAL SODIUM
- NORPRAMIN
- · pentobarbital sodium

- perphenazine-amitriptyline
- · phenobarbital oral elixir
- phenobarbital oral tablet 100 mg, 15 mg, 16.2 mg, 30 mg, 32.4 mg, 60 mg, 64.8 mg, 97.2 mg
- · phenobarbital sodium
- SURMONTIL
- TOFRANIL
- TOFRANIL-PM
- trimipramine

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	The physician has indicated the requested medication is not causing adverse effects OR individual has a contraindication or has a clinical reason not to use a safer alternative (prescriber acknowledgement that medication benefits outweigh potential risks is sufficient).
Age Restrictions	Members that are 64 years of age or younger are NOT subject to the prior authorization requirements. Prior Authorization applies to members that are 65 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## HRM Age AU

- **ACTIVELLA**
- ALAGESIC LQ
- ALLZITAL
- ALORA
- AMBIEN
- AMBIEN CR
- AMRIX
- **AMYTAL**
- ANGELIQ
- arbinoxa
- armour thyroid
- ascomp with codeine
- benztropine
- BONJESTA
- **BUPAP**
- butalbital compound oral capsule
- BUTALBITAL COMPOUND ORAL **TABLET**
- butalbital compound w/codeine
- butalbital-acetaminop-caf-cod
- butalbital-acetaminophen
- butalbital-acetaminophen-caff
- butalbital-aspirin-caffeine
- **BUTISOL ORAL ELIXIR**
- BUTISOL ORAL TABLET 30 MG, 50 MG ELESTRIN
- capacet
- carbinoxamine maleate
- carisoprodol
- carisoprodol-asa-codeine
- carisoprodol-aspirin
- **CENESTIN**
- chlorpropamide oral tablet 100 mg, 250 mg
- chlorzoxazone
- clemastine oral syrup
- clemastine oral tablet 2.68 mg
- CLIMARA
- **CLIMARA PRO**
- codeine-butalbital-asa-caff
- COGENTIN
- COMBIPATCH
- COMFORT PAC-CYCLOBENZAPRINE
- COMPLETE ALLERGY MEDICINE

- cyclobenzaprine
- cvproheptadine
- DEMEROL (PF) INJECTION SOLUTION 100 MG/2 ML. 25 MG/0.5 ML. 50 MG/ML, 75 MG/1.5 ML
- demerol (pf) injection solution 100 mg/ml
- DEMEROL (PF) INJECTION SYRINGE
- **DEMEROL INJECTION**
- DEMEROL ORAL TABLET 100 MG, 50 MG
- dexchlorpheniramine maleate
- DIABETA ORAL TABLET 1.25 MG, 2.5 MG, 5 MG
- DICLEGIS
- digitek oral tablet 250 mcg
- digox oral tablet 250 mcg
- digoxin injection solution
- digoxin oral tablet 250 mcg
- diphenhydramine hcl
- dipyridamole
- disopyramide phosphate
- **DIVIGEL**
- DYTUSS
- EDLUAR
- ENJUVIA
- ergoloid
- **ESGIC**
- ESTRACE ORAL
- **ESTRADERM**
- estradiol oral
- estradiol transdermal patch semiweekly
- estradiol transdermal patch weekly
- estradiol-norethindrone acet
- ESTRASORB
- **ESTROGEL**
- estropipate
- **EVAMIST**
- FEMHRT LOW DOSE
- FEXMID
- **FIORICET**
- FIORICET WITH CODEINE
- FIORINAL

- FIORINAL-CODEINE #3
- FLEXERIL
- FURADANTIN
- fyavolv
- GLUCOVANCE
- glyburide micronized oral tablet 1.5 mg, 3 mg, 6 mg
- glyburide oral tablet 1.25 mg, 2.5 mg, 5 mg
- glyburide-metformin oral tablet 1.25-250 mg, 2.5-500 mg, 5-500 mg
- GLYNASE ORAL TABLET 1.5 MG, 3 MG, 6 MG
- guanfacine oral tablet
- hydroxyzine hcl
- hydroxyzine pamoate
- INDOCIN
- indomethacin
- indomethacin sodium
- INTERMEZZO
- jevantique lo
- jinteli
- ketorolac injection cartridge
- ketorolac injection solution
- ketorolac injection syringe 30 mg/ml
- ketorolac intramuscular
- ketorolac oral
- LANOXIN INJECTION
- LANOXIN ORAL TABLET 187.5 MCG, 250 MCG
- lopreeza
- LORZONE
- MACROBID
- MACRODANTIN
- margesic
- marten-tab
- MEGACE ES
- megestrol oral suspension 625 mg/5 ml
- MENEST
- MENOSTAR
- meperidine (pf)
- meperidine injection
- meperidine oral solution
- meperidine oral tablet 100 mg, 50 mg
- meprobamate oral tablet 200 mg, 400 mg

- metaxall
- metaxalone
- methocarbamol
- methyldopa
- methyldopa-hydrochlorothiazide
- methyldopate
- mimvey
- mimvey lo
- MINIVELLE
- nifedipine oral capsule
- nitrofurantoin
- nitrofurantoin macrocrystal
- nitrofurantoin monohyd/m-cryst
- norethindrone ac-eth estradiol oral tablet 0.5-2.5 mg-mcg, 1-5 mg-mcg
- NORFLEX
- NORPACE
- NORPACE CR
- np thyroid
- OGEN 2.5
- ORBIVAN
- ORBIVAN CF
- orphenadrine citrate
- ORPHENADRINE COMPOUND
   ORPHENADRINE COMPOUND-DS
- PALGIC
- PARAFON FORTE DSC
- pentazocine-naloxone
- PERSANTINE
- phenadoz
- PHENERGAN INJECTION
- phenergan rectal
- PHRENILIN FORTE(WITH CAFFEINE)
- PREFEST
- PREMARIN ORAL
- PREMPHASE
- PREMPRO
- PROCARDIA
- promethazine
- promethazine vc
- promethazine-phenylephrine
- promethegan
- REPAN
- reserpine
- ROBAXIN
- ROBAXIN-750

- RYVENT
- seconal sodium
- SILENOR
- SKELAXIN
- SOMA
- SONATA ORAL CAPSULE 10 MG, 5 MG
- TALWIN
- tencon
- TENEX
- thyroid (pork)
- ticlopidine
- TIGAN
- trihexyphenidyl
- trimethobenzamide
- VANATOL LQ
- VANATOL S
- VISTARIL
- VIVELLE-DOT
- zaleplon oral capsule 10 mg, 5 mg
- zebutal
- zolpidem
- ZOLPIMIST

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	The physician has indicated the requested medication is not causing adverse effects OR individual has a contraindication or has a clinical reason not to use a safer alternative (prescriber acknowledgement that medication benefits outweigh potential risks is sufficient).
Age Restrictions	Members that are 64 years of age or younger are NOT subject to the prior authorization requirements. Prior Authorization applies to members that are 65 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	

## **Human Growth Hormone**

- NORDITROPIN FLEXPRO
- NORDITROPIN NORDIFLEX
- OMNITROPE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use of GH tx when applicable criteria have not been met may not be approved for, but not limited to, the following: Renal transplant, Anabolic tx, except for AIDS, provided to counteract acute or chronic catabolic illness (e.g. surgery, trauma, cancer,chronic hemodialysis) producing catabolic (protein wasting) changes in both adult and ped. Anabolic tx to enhance body mass or strength for professional, recreational or social reasons, Constitutional delay of growth and development. Cystic fibrosis, GH Tx in combo with GnRH agonist (Lupron-leuprolide) as a Tx of precocious puberty. Hypophosphatemic rickets, osteogenesis imperfecta, osteoporosis, Short Stature associated with GH insensitivity (Laron Syndrome). Therapy in older adults with normally occurring decrease in GH, who are not congenitally GH deficient and who have no evidence of organic pituitary dz (this is referred to as age-related GH deficiency). Tx of CHF, burn patients, fibromyalgia, glucocorticoid-induced growth failure. Tx of HIV lipodystrophy (fat redistribution syndrome), also referred to as altered body habitus (e.g. buffalo hump), associated with antiviral therapy in HIV-infected patients. Tx of intrauterine growth restriction (IUGR)or Russell-Silver Syndrome that does not result in SGA. Tx of obesity. Other etiologies of SS where GH has not been shown to be associated with an increase in final height, including but not limited to achondrodoplasia and other skeletal dysplasias. GH tx used for reconstruction is terminated when BA =16 yr (M), or = 14 yr (F) is reached OR Epiphyseal fusion has occurred OR Mid-parenteral height is achieved. For individuals being treated for GHD due to trauma or aneurysmal subarachnoid hemorrhage, GHD must be reconfirmed at 12 months after the event for therapy to continue. If retesting is not confirmatory for GHD, continued Tx is considered not medically necessary. Child over 12: an X-ray report with evidence that epiphyses have closed or SMR of 3 or more

PA Criteria	Criteria Details
Required Medical Information	For idiopathic GHD, has signs/sym of GHD, GV 2 SD below ageappropriate mean or ht 2.25 SD below age-appropriate mean and A subnormal (SubNL) response (less than10ng/ml)to 2GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml)OR 2other pit hormone deficiencies and low IGF-1 OR mbr has cranial irradiation with low IGF1 and normal thyroid tests. Child born SGA(birth wt or length 2 or more SD below the mean for gest age), Child fails to manifest catch up growth by age 4 yr(ht 2 or more SD below the mean for age, gender) AND Other causes for SS have been ruled out. Transitioning adolescent: GH tx has been stopped for at least a month, and GHD has been reconfirmed: idiopathic isolated GHD(SubNL response to 2 GH stim tests, OR SubNL response (GH conc of less than10 ng/mL) to 1 provocative test and low IGF-I/IGFBP-3) OR multiple pit hormone deficiency, (SubNL response to 1 provocative GH test and/or low IGF-I/IGFBP-3) or for mbr with cranial irradiation, low IGF with normal thyroid or any of the following, known genetic mutation associated with def GH production or secretion or Hypothalamic-pit tumor or structural defect or 3 other pit hormone deficiencies. Adult GHD must be confirmed/reconfirmed: SubNL response in adults to 2 GH stim tests (GH conc of less than or equal to 5 ng/ml when using insulin induced hypoglycemia OR GH conc of less than or equal to 4.1ng/ml when using arginine) OR SubNL response to 1 stim test for adults with hypothalamic or pit dz and 1 pit hormone deficits OR 3 other pit hormone deficiencies. Reconstructive GH tx who dont have GHD may be approved if either mean ht is at least 2.25 but less than 2.5SD below the mean for age, gender and GV is less than the 10th percentile over 1yr or mean ht is at least 2.5SD below the mean for age, gender for conditions known responsive to GH.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Cont of GH tx in child is approved when doubling of pre-tx growth rate or an inc in pre-tx growth rate of 3cm/yr or more seen in the first yr of tx, for tx continuing past the 1st yr, growth remains above 2.5cm/yr (doesnt apply to child with prior hypopit). GH may be approved for Adolescents with childhood onset GHD who have completed linear growth. GH for Short bowel syndrome in individuals receiving specialized nutritional support.

## Humira

- HUMIRA PEDIATRIC CROHN'S START
   SUBCUTANEOUS SYRINGE KIT 40
   MG/0.8 ML, 40 MG/0.8 ML (6 PACK), 80
   MG/0.8 ML, 80 MG/0.8 ML-40 MG/0.4
   ML
- HUMIRA PEN
- HUMIRA PEN CROHN'S-UC-HS START SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.8 ML, 80 MG/0.8 ML
- HUMIRA PEN PSORIASIS-UVEITIS SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.8 ML, 80 MG/0.8 ML-40 MG/0.4 ML
- HUMIRA SUBCUTANEOUS SYRINGE KIT 10 MG/0.1 ML, 10 MG/0.2 ML, 20 MG/0.2 ML, 20 MG/0.4 ML, 40 MG/0.4 ML, 40 MG/0.8 ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using adalimumab in combination with other TNF agents, Abatacept, tofacitinib, or Kineret (anakinra). Tuberculosis, invasive fungal infection, or other active serious infections. Patients Individuals who have not had a tuberculin skin test or CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating adalimumab.
Required Medical Information	For Chronic moderate to severe plaque psoriasis with either of the following: Patient has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia) AND agent is used to reduce signs/symptoms OR to induce/maintain clinical response.
Age Restrictions	Patient is 18 years of age or older for all indications except JIA and Crohns disease. Patient must be at least 2 years old for JIA. Patient must be at least 6 years of age for Crohns disease.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For moderate to severe active RA: agent is being used for any of the following reasons: To reduce signs/symptoms OR induce/maintain clinical response OR inhibit the progression of structural damage OR improve physical function and individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE nonbologic DMARD. For Psoriatic Arthritis, agent is being used to reduce signs/symptoms OR induce/maintain clinical response OR inhibit the progression of structural damage OR improve physical function and individual has failed to respond to, is intolerant of, has medical contraindication to ONE conventional therapy (such as non-biologic DMARDs). For moderate to severe JIA, agent is being used to reduce signs/symptoms OR induce/maintain clinical response AND individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE nonbologic DMARD. For Ankylosing Spondylitis, agent is being used to reduce signs/symptoms AND individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as NSAIDs or nonbiologic DMARDs). For Crohn's disease agent is being used to reduce signs/symptoms OR induce/maintain clinical remission AND individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (e.g. 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressants) or has lost response to or is intolerant to infliximab/infliximab-dyyb. For chronic moderate to severe plaque psoriasis, patient has failed to respond to, is intolerant of, or has a medical contraindication to phototherapy or ONE other systemic therapy (e.g. methotrexate, acitretin, or cyclosporine). For moderately to severely active Ulcerative Colitis (UC), agent is used to reduce signs/symptoms OR induce/maintain clinical remission AND individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 5-ASA products, Sulfasalazine,
	of, or has a medical contraindication to conventional therapy (such as corticosteroids or immunosuppressive drugs [for example, azathioprine, cyclosporine, or methotrexate]). For moderate to severe Hidradenitis Suppurativa (Hurley stage II or Hurley stage III disease) AND has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as oral antibiotics).

## **Ibrance**

### **Products Affected**

• IBRANCE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Iclusig

### **Products Affected**

• ICLUSIG ORAL TABLET 15 MG, 45 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has T315I-positive Chronic Myeloid Leukemia in chronic phase AND has documented resistance, intolerance, contraindication or warning to BOTH Gleevec and Sprycel. (Warnings may include, but not limited to pulmonary arterial hypertension, pleural or pericardial effusion, cardiac abnormalities).

## **I**dhifa

### **Products Affected**

• IDHIFA ORAL TABLET 100 MG, 50 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## llaris

### **Products Affected**

• ILARIS (PF)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Tuberculosis, invasive fungal infection, other active serious infection, or a history of recurrent infection. Individual who have not had a tuberculin skin test or a CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating llaris (canakinumab). Using llaris in combination with other biologic disease-modifying antirheumatic drugs (DMARDs), tumor necrosis factor (TNF) antagonists, IL-1R antagonists, Janus kinase inhibitors, or an IL-6 receptor antagonist.
Required Medical Information	
Age Restrictions	For cryopyrin-associated periodic syndromes age 4 years and older and for systemic juvenile idiopathic arthritis 2 years of age and older.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For SIJA, agent is being used to reduce signs/symptoms or induce/maintain clinical response and individual has failed to respond to, intolerant of, or has a medical contraindication to ONE corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs). For FMF, individual has active type 1 FMF disease with genetic confirmation of the diagnosis (MEFV gene exon 10 mutation) and documented recurrent, active disease (that is, at least one flare per month) and has failed to respond to, or is intolerant of colchicine therapy. For HIDS/MKD, individual has HIDS with genetic confirmation of the diagnosis by deoxyribonucleic acid (DNA) analysis or enzymatic studies (that is, mutations in the MVK gene or markedly reduced mevalonate kinase activity) and documented prior history of greater than or equal to three febrile acute flares within a 6-month period when not receiving prophylactic treatment. For TRAPS, genetic confirmation of the diagnosis (TNFRSF1A gene mutation) and has chronic or recurrent disease activity defined as six flares in a 12-month period.

# llumya

## **Products Affected**

• ILUMYA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using in combination with other immunosuppressive therapy (such as other biologic drugs or phototherapy). Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections. Individual has not had a tuberculin skin test or a Centers for Disease Control and Prevention-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Ilumya.
Required Medical Information	Diagnosis of moderate to severe plaque psoriasis with either of the following: Patient has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year.

PA Criteria	Criteria Details
Other Criteria	For a dx of chronic plaque psoriasis, agent is used for any of the following reasons: To reduce signs/symptoms or To induce/maintain clinical response AND individual has failed to respond to, is intolerant of, or has a medical contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND member has had a trial of and an inadequate response or is intolerant to BOTH: Humira and Enbrel. For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Ilumya or (b) Individuals age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Ilumya may be allowed without trial of preferred TNF agents (Enbrel/Humira).

## **Imbruvica**

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **I**mfinzi

### **Products Affected**

• IMFINZI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	History of immunodeficiency or severe autoimmune disease. Requires systemic immunosuppression, active immune-medicated disease, severe or life-threatening infections or untreated central nervous system (CNS) metastases. Has received treatment with another anti-PD-1 or anit-PD-L1 agent
Required Medical Information	Inoperable or metastatic transitional-cell urothelial carcinoma histologically or cytologically confirmed.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has inoperable or metastatic urothelial carcinoma AND Either the disease has progressed during or following platinum-containing therapy OR disease has progressed within 12 months of neoadjuvant or adjuvant treatment with platinum-containing therapy

## Incivek

### **Products Affected**

• INCIVEK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using in combination with another serine NS3/4A protease inhibitor, a NS5B polymerase inhibitor, or a NS5A inhibitor. Individual has received previous treatment for hepatitis C virus (HCV) with one of the following: An interferon-based triple therapy regimen, which includes ribavirin and an oral direct-acting antiviral [such as but not limited to, Incivek (telaprevir), Victrelis (boceprevir), Olysio (simeprevir), or Sovaldi (sofosbuvir)] OR A therapy regimen containing a NS5A protein inhibitor [such as but not limited to, Harvoni (ledipasvir/sofosbuvir) or ombitasvir] OR A therapy regimen containing a serine NS3/4A protease inhibitor [such as but not limited to, Incivek (telaprevir), Victrelis (boceprevir), Olysio (simeprevir), paritaprevir, or asunaprevir] OR A therapy regimen containing a NS5B polymerase inhibitor [such as but no limited to, Sovaldi (sofosbuvir) or dasabuvir].
Required Medical Information	Documentation must be provided of a diagnosis of Hep C genotype 1 AND using in combination with peginterferon alfa and ribavirin AND individual has compensated liver disease (with or without cirrhosis). A copy of the baseline quantitative HCV RNA test result is provided to document baseline level of viremia. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and laboratory data.
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	12 weeks

PA Criteria	Criteria Details
Other Criteria	Individual will have access to sufficient quantity to complete entire course of therapy. Individual has had a prior trial and inadequate response to Harvoni OR individual is currently on and completing a course of therapy with the requested regimen.

## Increlex

### **Products Affected**

• INCRELEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has an active or suspected malignancy. Individual has closed epiphyses (closed bone growth plates signifying end of potential growth). Individual has a diagnosis of secondary forms of IGFD (such as but not limited to, GH deficiency, untreated malnutrition, untreated hypothyroidism). Growth velocity is less than 2 cm total growth in 1 year. Final adult height has been reached.
Required Medical Information	For initial treatment of growth failure associated with one of the following (1) Growth failure with severe primary IGFD as defined by: Height standard deviation score of less than or equal to -3.0 AND Basal IGF-1 standard deviation score of less than or equal to -3.0 AND normal or elevated growth hormone levels (greater than 10ng/mL on standard GH stimulation tests) are present OR (2) GH gene deletion who have development of neutralizing antibodies to GH.
Age Restrictions	2 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For Continuation of treatment with Increlex (mecasermin), Growth velocity is greater than or equal to 2cm (greater than equal to 2.0 cm) total growth in 1 year AND Final adult height has not been reached.

## Ingrezza

### **Products Affected**

• INGREZZA ORAL CAPSULE 40 MG, 80 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Has congenital long QT-syndrome or arrhythmia associated with a prolonged QT interval. Individual is currently using a strong CYP 3A4 inducer (examples, rifampin, carbamazepine, phenytoin, St. John's wort). Individual is currently using a monoamine oxidase inhibitor (MAOI) (examples, isocarboxazid, phenelzine, selegiline)
Required Medical Information	Tardive dyskinesia confirmed by the following (DSM-5): A) At least 60 days of stable (drug, dose) neuroleptic medication exposure (either typical or first generation antipsychotic agents [such as, chlorpromazine, haloperidol, fluphenazine], atypical or second-generation antipsychotic agents [such as, clozapine, risperidone, olanzapine, quetiapine, aripiprazole], or certain dopamine receptor-blocking used in treatment of nausea and gastroparesis [such as prochlorperazine, promethazine, metoclopramide] AND B) Presence of involuntary athetoid or choreiform movements lasting at least 30 days.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Inlyta

### **Products Affected**

• INLYTA ORAL TABLET 1 MG, 5 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Interferons for MS**

- AVONEX
- AVONEX (WITH ALBUMIN)
- BETASERON
- PLEGRIDY

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Members with primary progressive MS. Members with secondary progressive MS without relapsing disease. Treatment of MS with IFN beta-1a (for example, Avonex, Rebif, Plegridy) or IFN beta-1b (for example Betaseron, Extavia) in combination with glatiramer acetate (Copaxone) or in combination with natalizumab (Tysabri).
Required Medical Information	Members with a single demyelinating episode with consistent MRI findings, considered at high risk for clinically definite MS OR Member with MS with relapsing or remitting disease (RRMS) OR Members with secondary progressive MS (SPMS) with a history of superimposed relapses.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Intuniv

- guanfacine oral tablet extended release 24 hr
- INTUNIV ER

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual is using for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD).
Age Restrictions	Individual is 6 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had a trial of ONE generic stimulant medication unless either of the following applies: individual or individuals family has a history of substance diversion/abuse OR Individual has a diagnosis of anxiety or a tic disorder (such as, Tourettes Syndrome)

### Istodax

- ISTODAX
- ROMIDEPSIN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **ITRACONAZOLE**

- itraconazole oral capsuleSPORANOX ORAL CAPSULE
- SPORANOX PULSEPAK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	For fingernail/toenail onychomycosis 12 weeks. For all other indications 1 year.
Other Criteria	For second-line non-onychomycosis indications include tinea infections (including, but limited to tinea versicolor, tinea cruris, tinea corporis, tinea pedis, tinea manuum, and tinea capitis) where the individual has received at least one prior topical therapy: clotrimazole, ketoconazole, econazole, or nystatin.

### **IVIG**

- GAMUNEX
- GAMUNEX-C
- OCTAGAM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), medical records must indicate clinical presentation is not consistent with other polyneuropathies (Igm neuropathy, hereditary neuropathy, diabetic neuropathy) and ONE of the following clinical and electrodiagnostic criteria are met: proximal weakness or sensory dysfunction caused by neuropathy and nerve conduction studies confirm electodiagnostic evidence of a demyelinating neuropathy in at least 2 limbs. OR distal muscle weakness and results of diagnostic testing meet recognized set of diagnostic criteria as established by AAN, Saperstien, or INTAC. Continued use of IG for CDIP requires clinically significant improvement in neurological symptoms as documented on physical exam AND continued need is demonstrated by documentation that attempts on an annual basis to titrate the dose or the interval of therapy result in worsening symptoms. For Multifocal Motor Neuropathy (MMN) patient presents with asymmetric weakness that predominantly affects distal muscles AND nerve conduction studies confirm a demyelinating neuropathy is present (conduction block, slowing, or abnormal temporal dispersion in at least one nerve) OR clinical history or exam do not suggest upper motor neuron disease (no bulbar weakness, no upper motor neuron signs) and GM-1 antibody titers are elevated. OR after initial exam and electrodiagnostic testing clinical presentation suggests MMN but the diagnosis remains uncertain. Continued use for MMN requires clinical results document an improvement in strength and function within 3 weeks of start of infusion and need is demonstrated by documentation that attempts on an annual basis to titrate the dose or interval of therapy result in worsening of symptoms.
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	To reduce the risk of graft-versus-host disease associated with interstitial pneumonia (infectious or idiopathic) and infections (cytomegalovirus infections, Varicella-zoster virus infection, and recurrent bacterial infection) in allogeneic bone marrow transplant (BMT) recipients in the first 100 days after transplantation. Dermatomyositis, refractory (IVIG is used as a second line treatment of dermatomyositis. Corticosteroids are first-line treatments of dermatomyositis.) Myasthenia Gravis, severe refractory. Polymyositis, routine use of IG is not recommended. IG may be considered in patients with severe polymyositis for whom other treatments have been unsuccessful, have become intolerable, or are contraindicated. Stiff-person syndrome not controlled by other therapies. Toxic shock syndrome caused by staphylococcal or streptococcal organisms refractory to several hours of aggressive therapy. Tx of chronic parvovirus B19 infection and severe anemia associated with bone marrow suppression. Refractory auto-immune mucocutaneous blistering diseases including: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, epidermolysis bullosa acquisita. Tx of primary humoral immunodeficiency (PI) when: hx of recurrent sinopulmonary infection req antibiotic tx AND lack of, or inadequate response to immunization AND no evidence of renal (nephrotic syndrome) and gastrointestinal (e.g. protein losing enteropathy) as causes of hypogammaglobulinemia (HGG) AND initial pre-tx total serum IgG is below the lower limit of age adj lab ref range or more than 2 SD below adj mean. Tx of other PI when: no evidence of renal/GI causes of HGG AND initial pre-tx total serum IgG is more than 2 SD below adj mean. Tx of other PI when: no evidence of renal/GI causes of HGG AND initial pre-tx total serum IgG is more than 2 SD below adj mean. Tx of other PI when: no evidence of renal/GI causes of HGG AND initial pre-tx total serum IgG subclasses are below lower limit of age adj lab ref range or more than 2 SD below

PA Criteria	Criteria Details
	hematuria, petechiae, bruising, gastrointestinal bleeding, gingival bleeding) or platelet count less than 20,000 (adult) or 30,000 (child). For hypogammaglobulinemia and recurrent bacterial infection associated with B-cell chronic lymphocytic leukemia (CLL) that includes both: Documented hx of recurrent bacterial infection or an active infection not responding to antimicrobial therapy AND Documentation that total IgG is less than 500mg/dL.

## **I**xempra

### **Products Affected**

• IXEMPRA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Jadenu

- JADENU
- JADENU SPRINKLE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For dx non-transfusion-dependent thalassemia (NTDT) syndrome, 10 years of age or older. For dx of chronic iron overload, 2 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Jakafi

#### **Products Affected**

 JAKAFI ORAL TABLET 10 MG, 15 MG, 20 MG, 25 MG, 5 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Jetrea**

### **Products Affected**

• JETREA (PF)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	"Individual has any of the following: Proliferative diabetic retinopathy, Neovascular age-related macular degeneration, Retinal vascular occlusion, Aphakia, High myopia (more than ?8 diopters), Uncontrolled glaucoma, Macular hole greater than 400 ?m in diameter, Vitreous opacification, Lenticular or zonular instability, History of retinal detachment in either eye, Prior vitrectomy in the affected eye, Prior laser photocoagulation of the macula in the affected eye, Prior treatment with ocular surgery, intravitreal injection or retinal laser photocoagulation in the previous 3 months."
Required Medical Information	Posterior segment optical coherence tomography (OCT) demonstrates all of the following: there is vitreous adhesion within 6-mm of the fovea (center of macula) AND elevation of the posterior vitreous cortex (outer layer of the vitreous). Individual has best-corrected visual acuity of 20/25 or worse in the eye to be treated with ocriplasmin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Jevtana**

### **Products Affected**

• JEVTANA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For hormone-refractory metastatic prostate cancer, individual has a Eastern Cooperative Oncology Group (ECOG) performance status is 0-2.

# **Juxtapid**

### **Products Affected**

• JUXTAPID

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has a clinical diagnosis of homozygous familial hypercholesterolemia (HoFH), based on the presence of the following: (A) Genetic confirmation of two (2) mutant alleles at the LDL receptor, apoB, PCSK9 or ARH adaptor protein gene locus OR (B) One of the following: 1. an untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) OR 2. Treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) AND one of the following: (i) cutaneous or tendonous xanthoma before age of 10 years OR (ii) untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than 190 mg/dL).
Age Restrictions	18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had an adequate trial and titration of Repatha OR Repatha is not acceptable due to concomitant clinical situations, such as but not limited to a known disease state or medication contraindication which is not also associated with Juxtapid.

## **Jynarque**

### **Products Affected**

• JYNARQUE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has an uncorrected abnormal blood sodium level or urinary outflow obstruction OR unable to sense or appropriately respond to thirst OR has dx of hypovolemia OR is anuric OR has underlying significant liver disease (not including uncomplicated polycystic liver disease) OR will be concurrently utilizing a strong CYP3A inhibitor (such as clarithromycin, ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir or nefazodone)
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Kadcyla

### **Products Affected**

• KADCYLA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Tumor(s) have been evaluated with an assay validated to predict HER2 positive (HER2+) protein overexpression. Individuals are considered HER2 positive (HER2+) as documented by one of the following, immunohistochemistry (IHC) 3+ or In Situ hybridization (ISH) positive by any of the following: Single probe average HER2 copy number greater than or equal to 6.0 signals/cell OR Dual-probe HER2/CEP 17 ratio greater than or equal to 2.0 OR Dual-probe HER2/CEP 17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For metastatic breast cancer, individual has previously received trastuzumab and a taxane, separately or in combination. AND has either received prior therapy for metastatic disease OR developed disease recurrence during or within six (6) months of completing adjuvant therapy. Kadcyla is only used in a single line of therapy.

### **Kalbitor**

### **Products Affected**

KALBITOR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Prophylaxis for HAE attacks.
Required Medical Information	HAE to be confirmed by a C4 level below the lower limit of normal (as defined by the laboratory performing the test) and either a C1 inhibitor antigenic level below the lower limit of normal (as defined by the lab performing test) or a C1 inhibitor functional level below the lower limit of normal (as defined by the lab performing the test).
Age Restrictions	12 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion) and using Kalbitor for acute HAE attacks.

## Kalydeco

- KALYDECO ORAL GRANULES IN PACKET 50 MG, 75 MG
- KALYDECO ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using Kalydeco (ivacaftor) monotherapy, without concurrent use of lumacaftor, for the F508del mutation in the CFTR gene.
Required Medical Information	Member has a diagnosis of cystic fibrosis (CF). A copy of CF mutation analysis test results must be provided. Results must document a mutation in the CFTR gene.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Kanuma

### **Products Affected**

KANUMA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis has been confirmed by one of the following: (1) A dried blood spot (DBS) test demonstrating deficient lysosomal acid lipase (LAL) activity or (2) Documented molecular genetic test revealing mutations in the lipase A, lysosomal acid type (LIPA) gene.
Age Restrictions	For diagnosis of lysosomal acid lipase deficiency (LAL-D) disorder [also known as Wolman disease (WD)], individual is equal to or less than 4 year of age. For diagnosis of LAL-D disorder [also known as cholesteryl ester storage disease (CESD)], individual is greater than 4 years of age.
Prescriber Restrictions	
Coverage Duration	Initial request: 6 months, Maintenance: 1 year
Other Criteria	For diagnosis of LAL-D disorder [also known as cholesteryl ester storage disease (CESD)], Individual has a baseline alanine aminotransferase (ALT) level greater than or equal to 1.5 times the upper limit of normal (ULN). Maintenance therapy requests for Kanuma (sebelipase alfa) may be approved if the following criteria are met: Individual has a diagnosis of LAL-D disorder as confirmed during initial therapy request AND Documentation is provided that clinically significant improvement in symptoms and/or lab values has been achieved and sustained.

## Keveyis

#### **Products Affected**

KEVEYIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has a diagnosis of hepatic insufficiency OR severe pulmonary obstruction OR a known hypersensitivity to sulfonamides OR individual is concurrently using high-dose aspirin.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial 3 months, renewal 1 year
Other Criteria	For initial therapy, individual experiences greater than or equal to one episode of muscle weakness per week. For continuation therapy documentation has been provided that individual has achieved and sustained clinically significant improvement in the number of episodes of muscle weakness experienced per week.

### Kevzara

### **Products Affected**

KEVZARA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using in combination with other biologic disease modifying anti-rheumatic drugs such as anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators, or tumor necrosis factor antagonists. At initiation of therapy, absolute neutrophil count less than 2000/mm3, platelet count less than 150,000/mm3, alanine aminotransferase or aspartate aminotransferase greater than 1.5 times the upper limits of normal. Tuberculosis, invasive fungal infection, or other active serious infections or a history of recurrent infections. Individual has not had a tuberculin skin test or Centers for Disease Control and Prevention-recommended equivalent to evaluate for latent tuberculosis prior to initiating sarilumab.
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For Rheumatoid Arthritis, agent is being used to reduce signs/symptoms OR induce/maintain clinical response OR inhibit the progression of structural damage OR improve physical function. Also member has failed to respond to, is intolerant of, or has a medical contraindication to ONE nonbiologic DMARDs AND Member has had a trial and an inadequate response or is intolerant to BOTH: Humira AND Enbrel. For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Kevzara or (b) Individuals age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Kevzara may be allowed without trial of preferred TNF agents (Enbrel/Humira).

# Keytruda

### **Products Affected**

• KEYTRUDA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Previous treatment with another programmed death receptor-1 (PD-1) blocking antibody agent. OR Presence of human immunodeficiency virus (HIV) infection, hepatitis B virus infection, or hepatitis C virus infection. Receiving therapy for an autoimmune disease or chronic condition requiring treatment with an immunosuppressant.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	A)For the treatment of unresectable or metastatic melanoma, Keytruda is being used as a single agent AND first line therapy in untreated disease or as second line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy and Current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. B) For first line tx of metastatic NSCLC, used as a single agent, cytologically confirmed stage IV NSCLC and Tumor expresses D_L1 gene on at least 50% of tumor cells and No sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) translocations and has not undergone previous systemic therapy for metastatic disease and ECOG status of 0-2. C) For metastatic non-small cell lung cancer (NSCLC) as a second or subsequent line of therapy, Keytruda is being used as a single agent AND Tumors with PD-L1 gene expression level greater than or equal to 1% with demonstrated disease progression on or after platinum-containing chemotherapy AND when ALK or EGFR genomic tumor aberrations are present, must have demonstrated has disease progression on U.S. Food and Drug Administration (FDA) approved therapy for the aberrations prior to receiving pembrolizumab OR Being used in combination with pemetrexed (Alimta) and carboplatin as first-line treatment for metastatic nonsquamous NSCLC AND ECOG performance status of 0-2. D) For the tx of recurrent, unresectable or metastatic head and neck squamous cell carcinoma (HNSCC), used as a single agent and tumor expresses PD-L1 gene and demonstrated disease progression on or after platinum-containing chemotherapy and ECOG performance status of 0-2. E) For the tx of Merkel-cell carcinoma (MCC), being used as a single agent and Presence of metastatic or recurrent locoregional MCC determined to be not amendable to definitive surgery or radiation therapy and ECOG performance status of 0-2.

### **Kineret**

### **Products Affected**

KINERET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is using Kineret in combination with other tumor necrosis factor (TNF) antagonists. Tuberculosis or other active serious infections or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC) Prevention-recommended equivalent to evaluate for latent tuberculosis prior to initiating Kineret. In combination with Xeljanz (tofacitinib) or with NONTNF immunomodulatory drugs [such as but not limited to Actemra (tocilizumab) or Orencia (abacept)]
Required Medical Information	
Age Restrictions	For RA, individual is 18 years of age or older. For SJIA, individual is 2 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For RA, agent is being used for any of the following: to reduce signs/symptoms or to induce/maintain clinical response or to inhibit progression of structural damage or to improve physical function AND Individual has had a trial and an inadequate response to is intolerant to ONE DMARD AND Individual has had a trial and an inadequate response to or is intolerant to BOTH: Humira AND Enbrel or if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with kineret or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis. Kineret may be allowed without trial of preferred TNF agents (Enbrel/Humira). For systemic juvenile idiopathic arthritis (SJIA) (Quartier et al, 2011, ACR 2013), agent is used to reduce signs/symptoms or to induce/maintain clinical response AND has failed or had an inadequate response to, is intolerant of, or has a contraindication to at least one corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs).

### Kisqali

- KISQALI FEMARA CO-PACK ORAL TABLET 200 MG/DAY(200 MG X 1)-2.5 MG, 400 MG/DAY(200 MG X 2)-2.5 MG, 600 MG/DAY(200 MG X 3)-2.5 MG
- KISQALI ORAL TABLET 200 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Korlym

### **Products Affected**

KORLYM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	History of unexplained vaginal bleeding. Current endometrial hyperplasia with atypia or endometrial carcinoma. Diagnosis of severe hepatic impairment (Child Pugh Class C). Concomitant use with any of the following: (1) Long term systemic corticosteroids for serious medical conditions or illnesses OR (2) Simvastatin or lovastatin OR (3) CYP3A substrates with narrow therapeutic ranges (such as but not limited to cyclosporine, fentanyl, sirolimus, tacrolimus) OR (4) Agents or co-morbid conditions which prolong the QT interval
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Initial therapy: Individual is not a candidate for surgery that is expected to correct the cause of endogenous Cushing's Syndrome OR disease persists or recurs following surgery intended to correct the cause of endogenous Cushing's Syndrome. For continuation of therapy: Individual continues to meet the initial request approval criteria AND has experienced an improvement in or stabilization of glucose control as assessed by fasting serum glucose test, oral glucose tolerance test or hemoglobin A1c test.

## Krystexxa

### **Products Affected**

KRYSTEXXA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has asymptomatic hyperuricemia. Individual has a known glucose-6-phosphate dehydrogenase (G6PD) deficiency.
Required Medical Information	Individual has 1 or more of the following: 3 or more gout flares in the previous 18 months OR 1 or more tophus OR History of chronic gouty arthropathy, defined clinically or radiographically as joint damage due to gout. Individual has a baseline serum uric acid of 6 mg/dL or greater prior to initiating pegloticase.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has chronic, treatment-refractory gout and has undertaken lifestyle modifications, such as weight loss for obese individuals (weight control) or avoidance of, or limiting alcohol consumption or dietary intake of meats and fish high in purine content AND Individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE of the following conventional therapies: A xanthine oxidase inhibitor (allopurinol or febuxostat) or combination therapy of 1 xanthine oxidase inhibitor given with a uricosuric agent (for example, probenecid).

### Kuvan

### **Products Affected**

KUVAN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	If blood phenylalanine levels do not decrease from baseline at a dose of 10mg/kg/day administered for up to one month. The dose may be increased up to 20mg/kg/day. Individuals are non-responders if phenylalanine levels do not decrease after 1 month and tx should be discontinued
Required Medical Information	For initial requests, Individual has Dx of Hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4) responsive PKU. For continued use, individual is showing signs of continuing improvement as evidenced by blood phenylalanine levels.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial 8 weeks, 1 year for continuation
Other Criteria	

### **KYNAMRO**

#### **Products Affected**

KYNAMRO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has a clinical diagnosis of homozygous familial hypercholesterolemia (HoFH), based on the presence of the following: (A) Genetic confirmation of two (2) mutant alleles at the LDL receptor, apoB, PCSK9 or ARH adaptor protein gene locus OR (B) One of the following: 1. an untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) OR 2. Treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) AND one of the following: (i) cutaneous or tendonous xanthoma before age of 10 years OR (ii) untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than 190 mg/dL).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had an adequate trial and titration of Repatha OR Repatha is not acceptable due to concomitant clinical situations, such as but not limited to a known disease state or medication contraindication which is not also associated with Kynamro.

# **Kyprolis**

### **Products Affected**

KYPROLIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	For the treatment of Waldenstrom's macroglbulinemia when the following criteria are met: (a) Used as a primary agent, in combination with rituximab and dexamethasone OR (b) Used for relapsed disease when the primary therapy of carfilzomib, rituximab and dexamethasone was given and relapse is greater than 12 months after therapy.

### Lartruvo

### **Products Affected**

• LARTRUVO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a histologically confirmed diagnosis of late stage soft tissue sarcoma (locally advanced or metastatic) not previously treated with an anthracycline and Olaratumab is used in combination with doxorubicin and Radiotherapy or surgery is not a treatment option and Individual's current Eastern Cooperative Oncology Group (ECOG) performance status is 0-2. Individual has a histologically confirmed diagnosis of late stage soft tissue sarcoma (locally advanced or metastatic) not previously treated with an anthracycline and Olaratumab is used as monotherapy after eight cycles in combination with doxorubicin or after disease progression with doxorubicin and Radiotherapy or surgery is not a treatment option and Individual's current Eastern Cooperative Oncology Group (ECOG) performance status is 0-2.

### Latuda

#### **Products Affected**

 LATUDA ORAL TABLET 120 MG, 20 MG, 40 MG, 60 MG, 80 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For Schizophrenia, 13 years of age or older. For Monotherapy tx of major depressive episode associated with bipolar I disorder, age 10 or older. For all other indications, age 18 or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For schizophrenia, individual has had a trial of one of the following generic oral atypical antipsychotic agents: Risperidone, Olanzapine, Quetiapine fumarate, Paliperidone, or Ziprasidone.

### Lazanda

### **Products Affected**

• LAZANDA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Treatment of acute or postoperative pain, migraine headache pain OR non-cancer related breakthrough pain
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has tried and failed fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking Lazanda (fentanyl) for cancer related breakthrough pain.

### Lemtrada

#### **Products Affected**

• LEMTRADA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual with primary progressive MS. Individual with secondary progressive MS.
Required Medical Information	Individual is Human immunodeficiency virus (HIV) negative.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has received prior treatment with at least two alternative drug therapies indicated for the treatment of MS (for example, interferons, glatiramer) and failed to achieve an adequate response or experienced intolerance of these drug therapies.

### Lenvima

#### **Products Affected**

 LENVIMA ORAL CAPSULE 10 MG/DAY (10 MG X 1), 12 MG/DAY (4 MG X 3), 14 MG/DAY(10 MG X 1-4 MG X 1), 18 MG/DAY (10 MG X 1-4 MG X2), 20 MG/DAY (10 MG X 2), 24 MG/DAY(10 MG X 2-4 MG X 1), 4 MG, 8 MG/DAY (4 MG X 2)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Letairis

#### **Products Affected**

• LETAIRIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has idiopathic pulmonary fibrosis (IPF). Individual has a diagnosis of moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment. Individual is initiating therapy and has a diagnosis of clinically significant anemia.
Required Medical Information	Individual has catheterization-proven diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) AND individual has WHO Functional Class II-IV symptoms.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Leukine

#### **Products Affected**

• LEUKINE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individuals who are at high risk for infection-associated complications demonstrated by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10to the power of 9/L) neutropenia, Age greater than 65 years, Uncontrolled primary disease, Pneumonia, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have other patient specific risk factors for FN including any of the following: Individual age greater than 65 years, Poor performance status (ECOG status 3-4), Previous episodes of FN, Bone marrow involvement by tumor producing cytopenias, preexisting neutropenia (ANC less than 1500mm3), Poor nutritional status (baseline albumin less than or equal to 3.5g/dL or body mass index [BMI] less than 20), poor renal function (GFR less than 60mL/min), liver dysfunction, The presence of open wounds, advanced cancer or Other serious comorbidities
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Adjunctive use in neutropenic patients who are at high risk for infection-associated complications. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy. For administration shortly after the completion of induction or repeat induction chemotherapy of acute myeloid leukemia (AML) for individuals over 55 years of age. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm3 or experiencing recurrent infection. For radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected. After accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome). After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution OR when engraftment is delayed or has failed. To mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT).

## **Lidoderm Patch**

- lidocaine topical adhesive patch,medicated
   LIDODERM
- ZTLIDO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Lonsurf

#### **Products Affected**

• LONSURF

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Lotronex**

- alosetron
- LOTRONEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual is a Female with Severe diarrhea-predominant Irritable Bowel Syndrome (IBS) defined as including diarrhea and 1or more of the following: Frequent and severe abdominal pain/discomfort, Frequent bowel urgency or fecal incontinence, Disability or restriction of daily activities due to IBS. Member is female AND Member has chronic symptoms of IBS that have persisted for 6 months or longer AND does not have an anatomic or biochemical abnormality of the gastrointestinal tract.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a documented trial of, an inadequate response or intolerance TWO (2) of the following medications: (a) Loperimide (b) antispasmodics (for example, dicyclomine), or (c) tricyclic antidepressants (AGA 2014).

## Lucentis

#### **Products Affected**

• LUCENTIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Lumizyme

#### **Products Affected**

LUMIZYME

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For infantile-onset Pompe disease, dx is confirmed with acid alphaglucosidase deficiency (GAA) activity in skin fibroblasts of less than 1% of the normal mean or by GAA gene sequencing AND presence of symptoms (for example respiratory and/or skeletal muscle weakness) of infantile-onset Pompe disease AND evidence of hypertrophic cardiomyopathy. For non-infantile onset (late-onset) Pompe disease, dx is confirmed by GAA enzyme assay which shows reduced enzyme activity less than 40% of the lab specific normal mean value AND confirmed by a second GAA enzyme activity assay in a separate sample (from purified lymphocytes, fibroblasts or muscle) or by GAA gene sequencing AND forced vital capacity (FVC) 30 -79% of predicted value while in the sitting position AND postural drop in FVC (in liters) of 10% or more from upright to supine position AND ability to walk 40 meters on a 6-minute walk test (assistive devices permitted) AND muscle weakness in the lower extremities.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Lupaneta

- LUPANETA PACK (1 MONTH)LUPANETA PACK (3 MONTH)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For initial or retreatment of endometriosis

### **Lupron Depot**

- LUPRON DEPOT
- LUPRON DEPOT (3 MONTH)
- LUPRON DEPOT (4 MONTH)
- LUPRON DEPOT (6 MONTH)
- LUPRON DEPOT-PED
- LUPRON DEPOT-PED (3 MONTH) INTRAMUSCULAR SYRINGE KIT 11.25 MG, 30 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7, or prostate specific antigen (PSA) value of 10-20 ng/mL) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR following radical prostatectomy as adjuvant therapy when lymph node metastases are present OR Locally advanced disease OR Other advanced, recurrent, or metastatic disease. For Gynecology Uses: Initial treatment/retreatment of endometriosis (not to continue beyond 6 months) OR Dysfunctional uterine bleeding OR Preoperative treatment as adjunct to surgical treatment of uterine fibroids (leiomyoma uteri). May be used to reduce size of fibroids to allow for a vaginal procedure, prior to surgical treatment (myomectomy or hysterectomy) in patients with documented anemia. To induce amenorrhea in women in certain populations including menstruating women diagnosed with severe thrombocytopenia or aplastic anemia. For Endocrine Uses: Precocious puberty, defined as beginning of secondary sexual characteristics before age 8 in girls and before age 9 in boys. Ovarian Cancer (including fallopian tube cancer and primary peritoneal cancer):Hormonal therapy for clinical relapse in individuals with stage II-IV granulosa cell tumors or Hormonal therapy for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer as a single agent for persistent dz or recurrence.
Age Restrictions	
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	1 year, except for Endometriosis:6months, Uterine Fibroids:3months
Other Criteria	For Gender Dysphoria in Adolescents: Fulfills the DSM V criteria for gender dysphoria AND has experienced puberty to at least Tanner stage 2 AND has (early) pubertal changes that have resulted in an increase of their gender dysphoria AND does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment AND has psychological and social support during treatment AND demonstrates knowledge and understanding of the expected outcomes of GnRH analog treatment.

# **Lupron Kit IR**

#### **Products Affected**

• leuprolide

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7, or prostate specific antigen (PSA) value of 10-20 ng/mL) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR following radical prostatectomy as adjuvant therapy when lymph node metastases are present OR Locally advanced disease OR Other advanced, recurrent, or metastatic disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Lynparza

- LYNPARZA ORAL CAPSULE
- LYNPARZA ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Copy of the test results from a FDA-approved test must be provided that document the BRCA mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Lyrica

- LYRICA ORAL CAPSULE 100 MG, 150 MG, 200 MG, 225 MG, 25 MG, 300 MG, 50 MG, 75 MG
- LYRICA ORAL SOLUTION

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For neuropathic pain associated with diabetic peripheral neuropathy (DPN), individual had a trial of one of the following: (1) SNRI (such as, Cymbalta (duloxetine HCl) or venlafaxine IR/ER ((AACE 2015, ADA 2017)) (2) Tricyclic antidepressants (such as, amitriptyline, clomipramine, desipramine, nortriptyline) (AACE 2015, AAFP 2010, ADA 2017, NICE 2013) OR (3) Gabapentin (AACE 2015, ADA 2017, NICE 2013). For post herpetic neuralgia, member had a trial of one of the following: (1) Gabapentin (2) Lidocaine patch (Lidoderm) or (3) Gralise (may require PA) or (4) Tricyclic antidepressants (such as, amitriptyline, desipramine, nortriptyline) (IASP 2015, EFNS 2010). For Fibromyalgia, Individual had a Trial of and insufficient response or intolerance to TWO of the following: (1) Savella (milnacipran) (2) Cymbalta (duloxetine HCl) (3)Gabapentin (CFCG 2012) (4) Tricyclic antidepressants (CFCG 2012) (5) Cyclobenzaprine (CFCG 2012) OR (6) Fluoxetine (CFCG 2012).

# Lyrica CR

#### **Products Affected**

• LYRICA CR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For neuropathic pain associated with diabetic peripheral neuropathy (DPN), individual had a trial of one of the following: (1) SNRI (such as, Cymbalta (duloxetine HCI) or venlafaxine IR/ER ((AACE 2015, ADA 2017)) (2) Tricyclic antidepressants (such as, amitriptyline, clomipramine, desipramine, nortriptyline) (AACE 2015, AAFP 2010, ADA 2017, NICE 2013) OR (3) Gabapentin (AACE 2015, ADA 2017, NICE 2013). For post herpetic neuralgia, member had a trial of one of the following: (1) Gabapentin (2) Lidocaine patch (Lidoderm) or (3) Gralise (may require PA) or (4) Tricyclic antidepressants (such as, amitriptyline, desipramine, nortriptyline) (IASP 2015, EFNS 2010).

### Makena

#### **Products Affected**

- hydroxyprogest(pf)(preg presv)HYDROXYPROGESTERONE CAP(PPRES)
- MAKENA

• MAKENA (PF)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Women with multiple gestations.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Singleton pregnancy and absence of preterm labor within the current pregnancy and individual is between 16 and 36 weeks of gestation with a singleton pregnancy. Prior history of a preterm delivery before 37 weeks gestation due to either spontaneous preterm labor or premature rupture of membranes.

## Mavyret

#### **Products Affected**

MAVYRET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Copy of the baseline quantitative HCV RNA test result is provided to document baseline level of viremia AND Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2017, CDC 2013). Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2017). Individual has compensated liver disease (with or without cirrhosis).
Age Restrictions	18 years of age or older.
Prescriber Restrictions	
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

# **Megace Suspension HRM**

- MEGACE
- megestrol oral suspension 400 mg/10 ml (10 ml), 400 mg/10 ml (40 mg/ml), 800 mg/20 ml (20 ml)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has been on the requested medication and the prescriber would like to continue member on the requested high risk medication. OR individual is using for the treatment of anorexia, cachexia, or unexplained weight loss in individuals with HIV/AIDS.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Megace Tabs HRM

#### **Products Affected**

megestrol oral tablet

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has been on the requested medication and the prescriber would like to continue member on the requested high risk medication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Mekinist**

#### **Products Affected**

• MEKINIST ORAL TABLET 0.5 MG, 2 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Copy of the test results must be provided that document the BRAF V600E or V600K mutation for unresectable or metastatic melanoma OR a copy of the test results must be provided that document BRAF V600E mutation for non-small cell lung cancer.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	

### **Mektovi**

#### **Products Affected**

MEKTOVI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	BRAF V600E or V600K mutation results must be confirmed (written or verbal attestation is acceptable).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	

## Mepron

- atovaquoneMEPRON

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Intolerance to trimethoprim-sulfamethoxazole (TMP-SMX)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Mepsevii

#### **Products Affected**

MEPSEVII

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial 6 months. Continuation 6 months.
Other Criteria	For initial use in individuals with a diagnosis of Mucopolysaccharidosis type VII based on leukocyte or fibroblast glucuronidase enzyme assay or genetic testing and individual has elevated urine glycosaminoglycans excretion at a minimum of 3-fold over the mean normal for age at screening. For continued use, individual has met all criteria for initial therapy and when there is documentation (written or verbal attestation) of clinically significant improvement or stabilization in clinical signs and symptoms of disease compared to the predicted natural history trajectory of disease.

## Methoxsalen

- 8-MOP
- methoxsalen
- OXSORALEN ULTRA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Methylphenidate

- APTENSIO XR
- CONCERTA ORAL TABLET EXTENDED RELEASE 24HR 18 MG, 27 MG, 36 MG, 54 MG
- COTEMPLA XR-ODT
- METADATE CD
- metadate er
- METHYLIN ER
- METHYLIN ORAL SOLUTION 10 MG/5 ML, 5 MG/5 ML
- METHYLIN ORAL TABLET
- METHYLIN ORAL TABLET, CHEWABLE
- methylphenidate hcl oral capsule, er biphasic 30-70
- methylphenidate hcl oral capsule,er biphasic 50-50 10 mg, 20 mg, 30 mg, 40 mg, 60 mg
- methylphenidate hcl oral solution 10

- mg/5 ml, 5 mg/5 ml
- methylphenidate hcl oral tablet extended release
- methylphenidate hcl oral tablet extended release 24hr 18 mg, 27 mg, 36 mg, 54 mg
- METHYLPHENIDATE HCL ORAL TABLET EXTENDED RELEASE 24HR 72 MG
- QUILLICHEW ER ORAL TABLET, CHEW, IR-ER. BIPHASIC 24HR 20 MG, 30 MG, 40 MG
- QUILLIVANT XR
- RELEXXII
- RITALIN LA ORAL CAPSULE,ER BIPHASIC 50-50 10 MG, 20 MG, 30 MG, 40 MG, 60 MG
- RITALIN SR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual is using for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) or Narcolepsy.
Age Restrictions	6 years of age and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Mircera

#### **Products Affected**

• MIRCERA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Continued use when the hemoglobin level exceeds 11.0 g/dL (except when the dose of methoxy polyethylene glycol-epoetin beta is adjusted to achieve and maintain target hemoglobin not to exceed 11.0 g/dL). Use beyond 12 weeks in the absence of response in individuals with chronic kidney disease. To treat anemia in individuals due to other factors such as cancer chemotherapy, iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic diseases (such as sickle cell anemia, thalassemia, and porphyria). As treatment in the presence of a sudden loss of response with severe anemia and a low reticulocyte count.
Required Medical Information	Hemoglobin (Hgb) levels are less than 10 g/dL, prior to initiation of therapy AND (prior to initiation) the individuals iron status, including transferrin saturation or serum ferritin or bone marrow, is evaluated and transferrin saturation at least 20% or ferritin at least 80 ng/mL or evidence of bone marrow demonstrates adequate iron stores AND For individuals with hypertension, blood pressure is adequately controlled before initiation of therapy and closely monitored and controlled during therapy. And individual has anemia associated with chronic kidney disease (CKD) and meets one of the following: Individual is on dialysis and the goal is to achieve and maintain hemoglobin levels within the range of 10.0 to 11.0 g/dL. OR Individual is not on dialysis and the goal is to achieve and maintain hemoglobin levels of 10.0 g/dL.
Age Restrictions	
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	12 weeks.
Other Criteria	

## **Modafinil**

- modafinil oral tablet 100 mg, 200 mg
  PROVIGIL ORAL TABLET 100 MG, 200 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For Narcolepsy type 1: confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following: 1. Clear cataplexy (defined as more than one episode of generally brief) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND 2.Multiple Sleep Latency Test (MSLT) showing one of the following: a. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014)OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR 3.Cerebrospinal fluid hypocretin-1 deficiency (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay). For Narcolepsy type 2: confirmed by 1.Multiple sleep latency test (MSLT) with one of the following: a.Mean sleep latency of less than 8 minutes with and evidence of two sleep-onset rapid eye movement periods (SOREMPs) ICSD-3, 2014) OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) AND 2.The absence of cataplexy AND 3.Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and Polysomnography.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For obstructive sleep apnea/hypopnea syndrome objectively confirmed by polysomnography (PSG) or home testing with portable monitor showing one of the following (AASM 2009): (1). Greater than 15 obstructive events (defined as apneas, hypopneas plus respiratory event related arousal) per hour of sleep OR (2) Greater than 5 obstructive events per hour of sleep and individual reports any of the following: a. Unintentional sleep episodes during wakefulness or b. Daytime sleepiness or c. Unrefreshing sleep or d. Fatigue or e. Insomnia or f. Waking up breath holding, gasping or choking or g. Bed partner describing loud snoring, breathing interruptions or both or h. Presence of comorbid conditions including hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation or type 2 diabetes mellitus. And has an Epworth Sleepiness Scale score greater than or equal to 10. For Shift-Work Sleep Disorder (SWSD) confirmed by all of the following: (1)No other medical disorder or mental disorder accounts for the symptoms AND (2)Symptoms do not meet criteria for any other sleep disorder (i.e. jet lag) AND (3)Symptoms have occurred for at least 3 months, AND (4)Individual has one of the following: a.Individual has excessive sleepiness or insomnia associated with a work period that occurs during the usual sleep phase OR b.Polysomnography demonstrates loss of a normal sleep-wake pattern (such as, disturbed chronobiological rhythmicity).

### Mozobil

#### **Products Affected**

MOZOBIL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using as a mobilizing agent for an allogeneic stem cell donor, mobilizer of leukemic cells or as a component of a conditioning regimen prior to an allogeneic hematopoietic stem cell transplant.
Required Medical Information	Using in combination with granulocyte colony stimulating factor (G-CSF) and after stem cell mobilization and collection, a subsequent autologous hematopoietic stem cell transplant is anticipated.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	Individual may use a maximum of up to four consecutive doses of plerixafor (Mozobil) injections per cycle for up to 2 cycles.

# Mulpleta

#### **Products Affected**

• MULPLETA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Used to normalize platelet counts in those with chronic liver disease
Required Medical Information	Individual has a platelet count of less than 50 X 109/L
Age Restrictions	18 years of age
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Mylotaarg**

#### **Products Affected**

• MYLOTARG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	

# Myozyme

#### **Products Affected**

MYOZYME

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	For the treatment of non-infantile onset (late-onset) Pompe disease.
Required Medical Information	Diagnosis of infantile-onset Pompe disease is confirmed with acid alpha-glucosidase deficiency (GAA) activity in skin fibroblasts of less than 1% of the normal mean or by GAA gene sequencing AND Presence of symptoms (for example respiratory and/or skeletal muscle weakness) of infantile-onset Pompe disease AND Evidence of hypertrophic cardiomyopathy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Naglazyme

### **Products Affected**

NAGLAZYME

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Mucopolysaccharidosis VI is confirmed by: (a) with an increase in dermatan sulfate in the urine and (b) Decrease in the activity of 4-sulphatase enzyme in the blood.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Namenda Line

#### **Products Affected**

- memantine oral capsule,sprinkle,er 24hr
- memantine oral solution
- memantine oral tablet 10 mg, 5 mg
- MEMANTINE ORAL TABLETS, DOSE PACK
- NAMENDA ORAL SOLUTION
- NAMENDA ORAL TABLET 10 MG, 5

MG

- NAMENDA TITRATION PAK
- NAMENDA XR ORAL CAP,SPRINKLE,ER 24HR DOSE PACK
- NAMENDA XR ORAL CAPSULE,SPRINKLE,ER 24HR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Members that are 50 years of age or older are NOT subject to the prior authorization requirements. Prior Authorization applies to members that are 49 years of age or younger.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of moderate to severe dementia of the Alzheimer's type.

# **Namzeric**

### **Products Affected**

NAMZARIC

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of moderate to severe dementia of the Alzheimer's type AND is stabilized on donepezil (Aricept) 10 mg and memantine (Namenda)/memantine XR concomitantly AND Individual is unable to utilize donepezil and memantine/XR separately for reasons such as but not limited to caregiver or administration concerns.

# **Natpara**

### **Products Affected**

NATPARA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Serum corrected total calcium levels maintained within therapeutic range on calcium supplements and active vitamin D forms alone OR serum corrected total calcium level of less than or equal to 7.5 mg/dL at initiation of therapy. Individual is using to treat hypoparathyroidism caused by a gene mutation in the calciumsensing receptor OR using to treat acute (duration of less than 6 months, Bilezikian et al. 2011) postoperative hypoparathyroidism OR Individual is at increased risk for osteosarcoma (such as but not limited to, concomitant Paget's disease of bone, open epiphyses, prior history of skeletal external beam or implant radiation therapy).
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Diagnosis of chronic (duration of greater than or equal to 18 months, mannstadt et, al 2013) hypoparathyroidism.

# Nerlynx

### **Products Affected**

• NERLYNX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Neulasta

- FULPHILA
- NEULASTA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individuals who are at high risk for infection-associated complications by any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10 to the power of 9/L) neutropenia, Age greater than 65 years, Uncontrolled primary disease, Pneumonia, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have other patient specific risk factors for FN including any of the following: Individual age greater than 65 years, Poor performance status (ECOG status 3-4), Previous episodes of FN, Bone marrow involvement by tumor producing cytopenias, preexisting neutropenia (ANC less than 1500mm3), Poor nutritional status (baseline albumin less than or equal to 3.5g/dL or body mass index [BMI] less than 20), poor renal function (GFR less than 60mL/min), liver dysfunction, The presence of open wounds, advanced cancer or Other serious comorbidities.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Adjunctive use in neutropenic patients who are at high risk for infection-associated complications. In an individual with acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm3 or experiencing recurrent infection. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution OR when engraftment is delayed or has failed.

# Neupogen

- NEUPOGEN
- NIVESTYM
- ZARXIO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Febrile neutropenic individuals who are at risk for infection-associated complications or have any of the following: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10to the power of 9/L) neutropenia, Age greater than 65 years, Uncontrolled primary disease, Pneumonia, Hypotension and multi organ dysfunction (sepsis syndrome), Invasive fungal infection, or Hospitalized at the time of the development of fever. Primary prophylaxis of FN in patients who have a risk of FN of 20% or greater based on chemotherapy regimens. OR when the risk of developing FN is greater than or equal to 10% and less than 20% based on chemotherapy in patients who have other patient specific risk factors for FN including any of the following: Individual age greater than 65 years, Poor performance status (ECOG status 3-4), Previous episodes of FN, Bone marrow involvement by tumor producing cytopenias, preexisting neutropenia (ANC less than 1500mm3), Poor nutritional status (baseline albumin less than or equal to 3.5g/dL or body mass index [BMI] less than 20), poor renal function (GFR less than 60mL/min), liver dysfunction, The presence of open wounds, advanced cancer or Other serious comorbidities
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Secondary Prophylaxis for patients who experienced a neutropenic complication from a prior cycle of chemotherapy (for which primary prophylaxis was not received), in which a reduced dose may compromise disease-free or overall survival or treatment outcome. Adjunctive use in neutropenic patients who are at high risk for infection-associated complications. Use in acute lymphocytic leukemia (ALL) after completion of the first few days of initial induction chemotherapy or first post-remission course of chemotherapy. Use in individuals with acute myeloid leukemia (AML) shortly after the completion of induction or repeat induction chemotherapy, or after the completion of consolidation chemotherapy for AML. For tx of moderate to severe aplastic anemia. Tx of severe neutropenia in individuals with hairy cell leukemia. For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm3 or experiencing recurrent infection. For dose dense therapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant treatment of breast cancer. For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic individuals with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia. For tx of (non-chemotherapy) drug-induced neutropenia. For tx of low neutrophil counts in individuals with glycogen storage disease type 1b. For tx of neutropenia associated with human immunodeficiency virus (HIV) infection and antiretroviral therapy. In individuals receiving radiation therapy in the absence of chemotherapy if prolonged delays secondary to neutropenia are expected. After accidental or intentional total body radiation of myleosuppressive doses (greater than 2 Grays [Gy] (such as Hematopoietic Syndrome of Acute Radiation Syndrome). After hematopoietic progenitor stem cell transplant (HPCT/HSCT) to promote myeloid reconstitution or when engraftment
	adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant.

# Neupro

### **Products Affected**

NEUPRO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had a previous trial of or has a contraindication to either Mirapex (pramipexole) or Requip (ropinirole). OR Individual is unable to swallow or take oral medications.

### **Nexavar**

### **Products Affected**

NEXAVAR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Ninlaro**

### **Products Affected**

NINLARO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	

# Nityr

### **Products Affected**

NITYR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual's plasma tyrosine level is maintained below 500 micromol/L to reduce risk of ocular symptoms, developmental delay, or hyperkeratotic plaques.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of hereditary tyrosinemia type 1 (HT-1) AND will be using in combination with a dietary restriction of phenylalanine and tyrosine.

# non-pegylated interferons

### **Products Affected**

• INTRON A

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For Hepatitis B when: HBeAg is either positive or negative AND Detectable levels of Hepatitis B DNA AND member has Compensated liver disease AND ALT at least 2X upper limit of normal
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1yr
Other Criteria	

# Northera

### **Products Affected**

• NORTHERA ORAL CAPSULE 100 MG, 200 MG, 300 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had a trial (resulting in inadequate response, therapeutic failure or intolerance) of at least one prior pharmacologic therapy (which may include midodrine or fludrocortisone) for treatment of symptoms of NOH.

## **Noxafil**

### **Products Affected**

NOXAFIL ORAL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	

### **NP Human Growth Hormone**

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE
- NUTROPIN
- NUTROPIN AQ
- NUTROPIN AQ NUSPIN
- SAIZEN

- SAIZEN CLICK.EASY
- SAIZEN SAIZENPREP
- SEROSTIM
- TEV-TROPIN
- ZOMACTON
- ZORBTIVE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.

PA Criteria	Criteria Details
Exclusion Criteria	Use of GH tx when applicable criteria have not been met may not be approved for, but not limited to, the following: Renal transplant, Anabolic tx, except for AIDS, provided to counteract acute or chronic catabolic illness (e.g. surgery, trauma, cancer,chronic hemodialysis) producing catabolic (protein wasting) changes in both adult and ped. Anabolic tx to enhance body mass or strength for professional, recreational or social reasons, Constitutional delay of growth and development. Cystic fibrosis, GH Tx in combo with GnRH agonist (Lupron-leuprolide) as a Tx of precocious puberty. Hypophosphatemic rickets, osteogenesis imperfecta, osteoporosis, Short Stature associated with GH insensitivity (Laron Syndrome). Therapy in older adults with normally occurring decrease in GH, who are not congenitally GH deficient and who have no evidence of organic pituitary dz (this is referred to as age-related GH deficiency). Tx of CHF, burn patients, fibromyalgia, glucocorticoid-induced growth failure. Tx of HIV lipodystrophy (fat redistribution syndrome), also referred to as altered body habitus (e.g. buffalo hump), associated with antiviral therapy in HIV-infected patients. Tx of intrauterine growth restriction (IUGR)or Russell-Silver Syndrome that does not result in SGA. Tx of obesity. Other etiologies of SS where GH has not been shown to be associated with an increase in final height, including but not limited to achondrodoplasia and other skeletal dysplasias. GH tx used for reconstruction is terminated when BA =16 yr (M), or = 14 yr (F) is reached OR Epiphyseal fusion has occurred OR Mid-parenteral height is achieved. For individuals being treated for GHD due to trauma or aneurysmal subarachnoid hemorrhage, GHD must be reconfirmed at 12 months after the event for therapy to continue. If retesting is not confirmatory for GHD, continued Tx is considered not medically necessary. Child over 12: an X-ray report with evidence that epiphyses have closed or SMR of 3 or more

PA Criteria	Criteria Details
Required Medical Information	For idiopathic GHD, has signs/sym of GHD, GV 2 SD below ageappropriate mean or ht 2.25 SD below age-appropriate mean and A subnormal (SubNL) response (less than10ng/ml)to 2GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml)OR 2other pit hormone deficiencies and low IGF-1 OR mbr has cranial irradiation with low IGF1 and normal thyroid tests. Child born SGA(birth wt or length 2 or more SD below the mean for gest age), Child fails to manifest catch up growth by age 4 yr(ht 2 or more SD below the mean for age, gender) AND Other causes for SS have been ruled out. Transitioning adolescent: GH tx has been stopped for at least a month, and GHD has been reconfirmed: idiopathic isolated GHD(SubNL response to 2 GH stim tests, OR SubNL response (GH conc of less than10 ng/mL) to 1 provocative test and low IGF-I/IGFBP-3) OR multiple pit hormone deficiency, (SubNL response to 1 provocative GH test and/or low IGF-I/IGFBP-3) or for mbr with cranial irradiation, low IGF with normal thyroid or any of the following, known genetic mutation associated with def GH production or secretion or Hypothalamic-pit tumor or structural defect or 3 other pit hormone deficiencies. Adult GHD must be confirmed/reconfirmed: SubNL response in adults to 2 GH stim tests (GH conc of less than or equal to 5ng/ml when using insulin induced hypoglycemia OR GH conc of less than or equal to 4.1ng/ml when using arginine) OR SubNL response to 1 stim test for adults with hypothalamic or pit dz and 1 pit hormone deficits OR 3 other pit hormone deficiencies. Reconstructive GH tx who dont have GHD may be approved if either mean ht is at least 2.25 but less than 2.5SD below the mean for age, gender and GV is less than the 10th percentile over 1yr or mean ht is at least 2.5SD below the mean for age, gender for conditions known responsive to GH.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For Non Preferred Growth hormone agents, individual has had a trial of TWO preferred GH agents (Norditropin AND Omnitrope) or preferred growth hormone agent is not FDA-approved for the prescribed diagnosis. Cont of GH tx in child is approved when doubling of pre-tx growth rate or an inc in pre-tx growth rate of 3cm/yr or more seen in the first yr of tx, for tx continuing past the 1st yr, growth remains above 2.5cm/yr (doesnt apply to child with prior hypopit). GH may be approved for Adolescents with childhood onset GHD who have completed linear growth. GH for Short bowel syndrome in individuals receiving specialized nutritional support.

# **NP Interferon for MS**

- EXTAVIA
- REBIF (WITH ALBUMIN)
- REBIF REBIDOSE
- REBIF TITRATION PACK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Members with primary progressive MS. Members with secondary progressive MS without relapsing disease. Treatment of MS with IFN beta-1a (for example, Avonex, Rebif, Plegridy) or IFN beta-1b (for example Betaseron, Extavia) in combination with glatiramer acetate (Copaxone) or in combination with natalizumab (Tysabri).
Required Medical Information	Member with a single demyelinating episode with consistent MRI findings, considered at high risk for clinically definite MS OR Member with MS with relapsing or remitting disease (RRMS) OR Member with secondary progressive MS (SPMS) with a history of superimposed relapses.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Member has been on Extavia or Rebif in the past 180 days OR member has tried therapy with ONE of the following agents: Avonex (interferon beta-1a) OR Plegridy (interferon beta-1a) OR Betaseron (interferon beta-1b) OR Tecfidera (dimethyl fumarate) OR Copaxone (glatiramer).

### **NP IVIG**

- BIVIGAM
- CARIMUNE
- CARIMUNE NF NANOFILTERED
- CUVITRU
- FLEBOGAMMA
- FLEBOGAMMA DIF
- GAMMAGARD LIQUID
- GAMMAGARD S-D (IGA < 1 MCG/ML)

- GAMMAGARD S/D
- GAMMAKED
- GAMMAPLEX
- GAMMAPLEX (WITH SORBITOL)
- HIZENTRA
- HYQVIA
- PRIVIGEN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	

PA Criteria	Criteria Details
Required Medical Information	For Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), medical records must indicate clinical presentation is not consistent with other polyneuropathies (Igm neuropathy, hereditary neuropathy, diabetic neuropathy) and ONE of the following clinical and electrodiagnostic criteria are met: proximal weakness or sensory dysfunction caused by neuropathy and nerve conduction studies confirm electrodiagnostic evidence of a demyelinating neuropathy in at least 2 limbs. OR distal muscle weakness and results of diagnostic testing meet recognized set of diagnostic criteria as established by AAN, Saperstien, or INTAC. CONT use of IG for CDIP requires clinically significant improvement in neurological symptoms as documented on physical exam AND cont need is demonstrated by documentation that attempts on an annual basis to titrate the dose or the interval of therapy result in worsening symptoms. For Multifocal Motor Neuropathy (MMN) mbr presents with asymmetric weakness that predominantly affects distal muscles AND nerve conduction studies confirm a demyelinating neuropathy is present (conduction block, slowing, or abnormal temporal dispersion in at least one nerve) OR clinical history or exam do not suggest upper motor neuron disease (no bulbar weakness, no upper motor neuron signs) and GM-1 antibody titers are elevated. OR after initial exam and electrodiagnostic testing clinical presentation suggests MMN but the dx remains uncertain. CONT use for MMN requires clinical results document an improvement in strength and function within 3 wk of start of infusion and need is demonstrated by documentation that attempts on an annual basis to titrate the dose or interval of therapy result in worsening of symptoms. To reduce the risk of GVHD, associated with interstitial pneumonia (infectious or idiopathic) and infections (CMV infections, Varicella-zoster virus infection, and recurrent bacterial infection) in allogeneic BMT recipients in the first 100 days after transplantation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	NP IG may be approved if: trial /inadequate response/ intol to ONE PF IG agent (Gammunex, Gammunex-C, Octagam) OR PF Ig is not FDA/Off-label approved or due to concomitant clinical condition(s), such as but not limited to: Renal insuff/impairmt or Non-O blood type or Severe IgA deficiency or DM/pre-DM or CVD or Hyper-prolinemia or Hypernatremia or high risk for thrombosis, such as but not limited to: a) hyperviscosity syn (such as cryoglobulinemia, monoclonal gammopathies, polyclonal hyperglobulinemia) OR b) hypercoagulable conditions or documented hypersensitivity, as manifested by severe systemic/allergic or anaphylactic rxn, to any ingred not also present in requested NP agent or other known dz state or med CI which is not also assoc with requested NP agent OR if SQ Ig only dose forms (Hizentra, Hyqvia) are designated as NP, may be approved for pts req for any of the following: difficult vein access that precludes use of any IVIG or hx of serious systemic rxn to IVIG expected to be avoided by using SCIG or hx of inconsistent serum levels of IgG with IVIG. Dermatomyositis, refractory (IVIG used as 2nd line tx of dermatomyositis. Steroids first-line tx of dermatomyositis.). MG, severe refractory. Polymyositis, routine use of IG is not recommended. IG may be considered in pts with severe polymyositis for whom other tx was unsuccessful, is intolerable or has CI. Stiff-person syn not controlled by other therapies. TSS caused by staph or strep organisms refractory to several hrs of aggressive therapy. Tx of chronic parvovirus B19 infection and severe anemia assoc with bone marrow suppression. Refractory auto-immune muccoutaneous blistering diseases including: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, epidermolysis bullosa acquisita. Tx of PI when: hx of recurrent sinopulmonary infection req antibiotic tx AND lack of, or inadequate response to immunization AND no evidence of renal (nephrotic syn) and GI (eg, protein losing enteropathy) as causes of HGG AND initial pre-

PA Criteria	Criteria Details
	initial pre-tx total serum IgG is more than 2 SD below adj mean. Tx of IgG sub-class deficiency (IgG1-4) when: One or more serum IgG subclasses are BLL of age adj lab ref range or more than 2 SD below age adj mean AND hx of recurrent sinopulmonary infect requiring abx therapy AND Lack of/inadequate response to immunization. Tx of Kawasaki Syn when: within 10 days of onset and tx for no more than 5 days. For ITP when: symptomatic thrombocytopenia or platelet count less than 20k (adult) or 30k (child). For hypogammaglobulinemia and recurrent bacterial infect assoc with B-cell chronic lymphocytic leukemia that includes both: Documented hx of recurrent bacterial infect or active infect not responding to antimicrobial therapy AND Documentation that total IgG is less than 500mg/dL.

### **NP LA Opioid**

- CONZIP
- DOLOPHINE ORAL TABLET 10 MG, 5 MG
- EXALGO ER ORAL TABLET EXTENDED RELEASE 24 HR 12 MG, 16 MG, 32 MG, 8 MG
- hydromorphone oral tablet extended release 24 hr 12 mg, 16 mg, 32 mg, 8 mg
- KADIAN
- morphine oral capsule, er multiphase 24 hr 120 mg, 30 mg, 45 mg, 60 mg, 75 mg, 90 mg
- morphine oral capsule, extend.release pellets
- MS CONTIN ORAL TABLET EXTENDED RELEASE 100 MG, 15 MG, 200 MG, 30 MG, 60 MG
- NUCYNTA ER
- OPANA ER ORAL TABLET EXTENDED

- RELEASE 12 HR 10 MG, 20 MG, 40 MG, 5 MG
- OPANA ER ORAL TABLET, ORAL ONLY, EXT. REL. 12 HR 10 MG, 15 MG, 20 MG, 30 MG, 40 MG, 5 MG, 7.5 MG
- oxymorphone oral tablet extended release 12 hr 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 5 mg, 7.5 mg
- TRAMADOL ORAL CAPSULE, ER BIPHASE 24 HR 17-83
- TRAMADOL ORAL CAPSULE, ER BIPHASE 24 HR 25-75 100 MG, 200 MG
- tramadol oral capsule, er biphase 24 hr 25-75 150 mg
- tramadol oral tablet extended release 24 hr
- tramadol oral tablet, er multiphase 24 hr 100 mg, 200 mg, 300 mg
- ULTRAM ER

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is requesting or using as an as-needed analgesic OR Individual has one of the following conditions: (a) Significant respiratory depression OR (b) Acute or severe bronchial asthma or hypercarbia OR (c) Known or suspected paralytic ileus.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

PA Criteria	Criteria Details
Other Criteria	For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure). AND Individual is not opioid naïve as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic. For continued use, Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline.

### **NP LA Opioid Abuse Deterrent**

- ARYMO ER
- BELBUCA
- BUPRENORPHINE
- BUTRANS
- EMBEDA
- HYSINGLA ER ORAL TABLET,ORAL ONLY,EXT.REL.24 HR 100 MG, 120 MG, 20 MG, 30 MG, 40 MG, 60 MG, 80 MG
- MORPHABOND ER

- XTAMPZA ER ORAL CAPSULE,SPRINKLE,ER 12HR TMPRR 13.5 MG, 18 MG, 27 MG, 36 MG, 9 MG
- ZOHYDRO ER ORAL CAPSULE, ORAL ONLY, ER 12HR 10 MG, 15 MG, 20 MG, 30 MG, 40 MG, 50 MG
- ZOHYDRO ER ORAL CAPSULE,EXTENDED RELEASE 12 HR 10 MG, 15 MG, 20 MG, 30 MG, 40 MG, 50 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is requesting or using as an as-needed analgesic OR Individual has one of the following conditions: (a) Significant respiratory depression OR (b) Acute or severe bronchial asthma or hypercarbia OR (c) Known or suspected paralytic ileus.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

PA Criteria	Criteria Details
Other Criteria	For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure). AND Individual is not opioid naïve as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic. AND If an abuse deterrent formulation is needed [such as but not limited to Embeda ER, Hysingla ER, Targiniq ER, Troxyca ER, Xtampza ER and Zohydro ER], and individual has need for abuse deterrent formulations based upon a history of substance abuse disorder OR individual's family member or household resident has active substance abuse disorder or a history of substance abuse disorder OR li is there is concern for abuse or dependence with pure opioid agents [such as but not limited to Butrans (buprenorphine transdermal patch) or Belbuca (buprenorphine buccal film)]. For continued use, Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline.

# **NP Statin**

### **Products Affected**

ALTOPREV

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has had a trial of generic statin at any dose and provider attests the member has experienced failure, contraindication, or intolerance to a generic statin. Or Individual is currently on a product that interacts with generic statin.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **NP Topical Androgens**

#### **Products Affected**

- ANDRODERM
- ANDROGEL TRANSDERMAL GEL IN METERED-DOSE PUMP 12.5 MG/ 1.25 GRAM (1 %)
- ANDROGEL TRANSDERMAL GEL IN PACKET 1 % (25 MG/2.5GRAM), 1 % (50 MG/5 GRAM)
- AXIRON
- FORTESTA
- TESTIM
- TESTOSTERONE TRANSDERMAL

#### **GEL**

- TESTOSTERONE TRANSDERMAL GEL IN METERED-DOSE PUMP 10 MG/0.5 GRAM /ACTUATION, 12.5 MG/ 1.25 GRAM (1 %)
- testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram)
- testosterone transdermal solution in metered pump w/app
- VOGELXO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older. For transgender use, individual is 16 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Individual has had a trial of androgel 1.62%. Individual has a dx of (1) primary hypogonadism (congenital or acquired) such as but not limited to: Cryptorchidism OR Bilateral torsion OR orchitis OR Vanishing testis syndrome OR Orchiectomy OR Klinefelter Syndrome OR Chemotherapy OR Toxic damage from alcohol or heavy metals OR idiopathic primary hypogonadism. Or (2) Hypogonadotropic hypogonadism (congenital or acquired), such as but not limited to: Idiopathic luteinizing hormone-releasing hormone (LHRH deficiency) OR Pituitary-hypothalamic injury. Individual is transgender AND is using for a diagnosis of gender Dysphoria or gender Identity Disorder AND Goal of treatment is female-to-male gender reassignment.

### **NP TZD**

- AVANDAMET ORAL TABLET 2-1,000 MG, 2-500 MG, 4-1,000 MG, 4-500 MG
- AVANDARYL ORAL TABLET 4-1 MG, 4-2 MG, 4-4 MG, 8-2 MG, 8-4 MG
- AVANDIA ORAL TABLET 2 MG, 4 MG, 8 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had a trial and inadequate response or intolerance to metformin OR Individual has a contraindication to metformin therapy [such as but not limited to, renal insufficiency (eGFR is less than 45mL/minute/1.73m2)] AND Individual has had a trial with ONE of the following: dipeptidyl peptidase-4 (DPP-4), glucagon-like peptide-1 (GLP-1), or a sodium-glucose co-transporter-2 (SGLT2) inhibitor.

# **Nplate**

### **Products Affected**

• NPLATE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using Nplate to normalize platelet counts. Treatment of myelodysplastic syndrome (MDS). Using for low platelet count caused by any condition other than chronic ITP.
Required Medical Information	For initial therapy, individual's degree of thrombocytopenia (platelet count less than 30,000/mm3) and clinical condition increase the risk for bleeding AND individual demonstrated an insufficient response to corticosteroids, immunoglobulins (for example, IVIg or anti-D), or splenectomy. For maintenance therapy, individual demonstrated response to therapy as evidenced by increased platelet counts, and the goal of ongoing treatment is to maintain an adequate platelet count (50,000-100,000/mm3) to decrease the risk of bleeding.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial 6 months, renewal 1 year.
Other Criteria	

# Nucala

### **Products Affected**

• NUCALA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	In the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease and known or suspected parasitic infections, the individual has a blood eosinophil count that is either greater than or equal to 150 cells/microliter at ignition of therapy OR greater than or equal 300 cells/microliter in the prior 12 months. The individual has a pretreatment forced expiratory volume in one second (FEV1) less than 80% predicted AND FEV1 reversibility of at least 12% and 200mL after albuterol (salbutamol) administration.
Age Restrictions	12 years old
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For diagnosis of severe eosinophilic asthma, individual has symptoms inadequately controlled with usage of one of the following combination controller therapies: 1) At least 12 months of high dose inhaled corticosteroid AND at least 3 months of either a long-acting beta2-agonist, leukotriene receptor antagonist or theophylline unless the individual is intolerant of, or has a medical contraindication to these agents. 2) At least 6 months of inhaled corticosteroid with daily oral glucocorticoids AND at least 3 months of either a long-acting beta2 agonist, leukotriene receptor antagonist or theophylline unless the individual is intolerant of, or has a medical contraindication to these agents. For Continuation Therapy after 12 months in individuals with documented severe eosinophilic asthma: Treatment has resulted in clinical improvement as documented by either i) Decreased utilization of rescue medications OR ii) A decreased frequency of exacerbation (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroid) OR iii) An increase in percent predicted FEV1 from pretreatment baseline OR iv) A reduction in reported asthma-related symptoms, such as, to wheezing, shortness of breath, coughing, fatigue, sleep disturbance or asthmatic symptoms upon awakening.

# Nulojix

### **Products Affected**

NULOJIX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Nuplazid**

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG, 17 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Initial therapy: Individual has a diagnosis of Parkinson's disease AND Symptoms of psychosis developed after the PD diagnosis AND Symptoms of psychosis include at least one of the following: (1) Visual hallucinations, (2) Auditory hallucination OR (3) Delusions AND Symptoms have been present for at least one month AND Individual has experienced symptoms at least once weekly. Psychiatric symptoms cannot be attributed to disorders such as schizophrenia, schizoaffective disorder, delusional disorder, or mood disorder with psychotic features, or a general medical condition including delirium. For continued therapy, the individual has had a reduction in symptoms of psychosis compared to baseline.

# Nuvigil

- armodafinil oral tablet 150 mg, 200 mg, 250 mg, 50 mgNUVIGIL ORAL TABLET 150 MG, 200
- MG, 250 MG, 50 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For Narcolepsy type 1: confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following: 1. Clear cataplexy (defined as more than one episode of generally brief) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND 2.Multiple Sleep Latency Test (MSLT) showing one of the following: a. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014)OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR 3.Cerebrospinal fluid hypocretin-1 deficiency (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay). For Narcolepsy type 2: confirmed by 1.Multiple sleep latency test (MSLT) with one of the following: a.Mean sleep latency of less than 8 minutes with and evidence of two sleep-onset rapid eye movement periods (SOREMPs) ICSD-3, 2014) OR b. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) AND 2.The absence of cataplexy AND 3.Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and Polysomnography.
Age Restrictions	
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	1 year
Other Criteria	For obstructive sleep apnea/hypopnea syndrome objectively confirmed by polysomnography (PSG) or home testing with portable monitor showing one of the following (AASM 2009): (1). Greater than 15 obstructive events (defined as apneas, hypopneas plus respiratory event related arousal) per hour of sleep OR (2) Greater than 5 obstructive events per hour of sleep and individual reports any of the following: a. Unintentional sleep episodes during wakefulness or b. Daytime sleepiness or c. Unrefreshing sleep or d. Fatigue or e. Insomnia or f. Waking up breath holding, gasping or choking or g. Bed partner describing loud snoring, breathing interruptions or both or h. Presence of comorbid conditions including hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation or type 2 diabetes mellitus. And has an Epworth Sleepiness Scale score greater than or equal to 10. For Shift-Work Sleep Disorder (SWSD) confirmed by all of the following: (1) No other medical disorder or mental disorder accounts for the symptoms AND (2)Symptoms do not meet criteria for any other sleep disorder (i.e. jet lag) AND (3) Symptoms have occurred for at least 3 months, AND (4) Individual has one of the following: a.Individual has excessive sleepiness or insomnia associated with a work period that occurs during the usual sleep phase OR b.Polysomnography demonstrates loss of a normal sleep-wake pattern (such as, disturbed chronobiological rhythmicity).

## Ocaliva

### **Products Affected**

• OCALIVA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has a diagnosis of nonalcoholic steatohepatitis (NASH), nonalcoholic fatty liver disease (NAFLD), primary sclerosing cholangitis (PSC), or biliary atresia. Individual has complete biliary obstruction.
Required Medical Information	Individual has a diagnosis of primary biliary cholangitis (PBC) as confirmed by TWO of the following (Lindor, 2009): (a) Elevated alkaline phosphatase. (b) Positive antimitochondrial antibodies (AMA) titer. (c) Liver biopsy with findings consistent with PBC.
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had a one year trial of ursodiol (Urso 250, Urso Forte) with an inadequate response as demonstrated by one of the following (FDA Ad Com, Lindor, 2009): (a) Alkaline phosphatase greater than or equal to 1.67 times the upper limit of normal OR (b) Total bilirubin greater than the upper limit of normal but less than two times the upper limit of normal) AND Individual will be utilizing Ocaliva (obeticholic acid) in combination with ursodiol (Urso 250, Urso Forte) OR has an intolerance to ursodiol (Urso 250, Urso Forte).

### **Ocrevus**

### **Products Affected**

• OCREVUS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Diagnosis of hepatitis B virus infection OR History of life- threatening infusion reaction of ocrelizumab.
Required Medical Information	Being used to treat either primary progressive multiple sclerosis (PPMS) or relapsing multiple sclerosis (RMS) in accordance with the McDonald Criteria.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Odomzo

### **Products Affected**

• ODOMZO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	

## Ofev

### **Products Affected**

• OFEV

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using in combination with Esbriet (pirfenidone). Individuals with severe hepatic impairment (child pugh class C) or end-stage liver disease.
Required Medical Information	Diagnosis of idiopathic pulmonary fibrosis (IPF) is confirmed by: Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity AND High resolution computed tomography (HRCT) with or without surgical lung biopsy. Individual has documented pulmonary function tests within prior 60 days with a Forced Vital Capacity (% FVC) greater than or equal to 50%.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Olumiant**

### **Products Affected**

• OLUMIANT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using in combination with other JAK inhibitors (such as Xeljanz), biologic disease-modifying antirheumatic drugs (DMARDs) (such as but not limited to, TNF agents, anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators) or potent immunosuppressants (such as azathioprine and cyclosporine). At initiation of therapy, absolute neutrophil count (ANC) less than 1000 cells/mm3, lymphocyte count less than 500 cells/mm3, or hemoglobin less than 8 g/dL. Tuberculosis or other active serious infections or a history of recurrent infection. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis prior to initiating Olumiant. Individual has severe hepatic impairment (Child Pugh class C) OR has a diagnosis of moderate [30-59 mL/min/1.73 m2 (KDIGO 2012)] renal impairment.
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year.

PA Criteria	Criteria Details
Other Criteria	For RA, individual has had a trial and inadequate response or intolerance to BOTH Enbrel AND Humira OR The agents tried and failed (Humira and Enbrel) are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a.) Known hypersensitivity or any active or inactive component which is not also associated with Olumiant (baricitinib) or (b.) Individual's age or (c.) Pregnant or planning or becoming pregnant or (d.) Serious infections or concurrent sepsis.

# Olysio

### **Products Affected**

• OLYSIO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using in combination with another serine protease inhibitor [such as but not limited to, paritaprevir, or asunaprevir].
Required Medical Information	A copy of the baseline quantitative hepatitis C virus (HCV) RNA test result is provided to document baseline level of viremia AND One of the following: (1) Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016, CDC 2013). OR (2) Individual is unable to delay treatment for 6 months owing to concurrent factors [such as but not limited to, advanced liver disease (Metavir fibrosis stage of F3 or F42), post-liver transplant recipients, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), coexistent liver diseases (such as nonalcoholic steatohepatitis), chronic HCV infection-associated extrahepatic manifestations (such as membranoproliferative glomerulonephritis, glomerular disease, cryoglobulinemia syndrome)] (AASLD/IDSA 2016) AND Documentation is provided for a diagnosis of chronic CHC infection, which includes a reactive HCV antibody (CDC 2013) and a subsequent positive HCV RNA result (CDC 2013). Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016).
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, Individual has had a prior trial and inadequate response to Harvoni. For GT 4, individual has had a prior trial and inadequate response to Harvoni or Epclusa. OR individual is currently on and completing a course of therapy with the requested regimen.

## Oncaspar

### **Products Affected**

ONCASPAR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	History of serious thrombosis with prior L-asparaginase therapy. History of pancreatitis with prior L-asparaginase therapy. History of serious hemorrhagic events with prior L-asparaginase therapy.
Required Medical Information	Individual is using Oncaspar as a component of a multi-agent chemotherapeutic regimen AND is using for Acute lymphoblastic lymphoma or acute lymphocytic leukemia (ALL) or Extranodal natural killer T-cell lymphoma, nasal type (ENKL).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Onfi

- ONFI ORAL SUSPENSION
- ONFI ORAL TABLET 10 MG, 20 MG, 5 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis (all ages) and if over 65 years of age or older, the physician has indicated the requested high risk medication (HRM) is not causing adverse effects OR Individual has a contraindication or has a clinical reason not to use safer alternatives (prescriber acknowledgement that medication benefits outweigh potential risks is sufficient).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Onpattro

### **Products Affected**

ONPATTRO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has TTR (transthyretin) mutation confirmed by genotyping
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Onsolis

### **Products Affected**

• ONSOLIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Treatment of acute or postoperative pain OR treatment of migraine headache pain OR treatment of non-cancer related breakthrough pain.
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain AND has tried and failed fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking Onsolis (fentanyl) for cancer related breakthrough pain.

# **Opdivo**

### **Products Affected**

• OPDIVO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Receiving therapy for an autoimmune disease or chronic condition requiring treatment with an immunosuppressant. Previous treatment with another programmed death receptor-1 (PD-1) blocking antibody agent.
Required Medical Information	Current ECOG performance status 0-2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For unresectable or metastatic melanoma: Opdivo is used as a single agent or in combination with Yervoy, as first-line therapy for untreated melanoma OR used as a single agent or in combination with Yervoy, as second-line or subsequent therapy for documented disease progression while receiving or since completing most recent therapy if PD-1 (programed death receptor -1) agent not previously used. For metastatic non-small cell lung cancer (NSCLC): Opdivo is used as a single agent AND demonstrated disease progression on or after platinum-containing chemotherapy. For RCC: used as a single AND demonstrated progression after 1 or 2 prior anti-angiogenic regimens (for example, axitinib, bevacizumb, pazopanib, sorafenib, sunitinib, etc) for the treatment of advanced or metastatic disease.

# **Opsumit**

### **Products Affected**

• OPSUMIT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is initiating therapy and has a diagnosis of clinically significant anemia
Required Medical Information	Individual has catheterization-proven diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) AND Individual has WHO Functional Class II-IV symptoms
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Oralair

### **Products Affected**

 ORALAIR SUBLINGUAL TABLET 100 INDX REACTIVITY, 300 INDX REACTIVITY

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction. Or, individual is receiving concomitant therapy with other allergen immunotherapy product. History of eosinophillic esophagitis.
Required Medical Information	For grass pollen induced allergic rhinitis, individual has a documented positive skin test OR positive in vitro testing for pollen-specific IgE antibodies for at least one of the following grass pollens: Sweet vernal, orchard, perennial rye, Timothy, or Kentucky blue grass pollen. Individual has had a trial of, and inadequate symptom control or intolerance to one (1) nasal steroid and (1) non-sedating antihistamine AND individual has a documented prescription for an auto-injectable epinephrine product.
Age Restrictions	Individual is between the ages of 10 years and 65 years old.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Treatment is initiated at least 16 weeks before the expected onset of grass pollen season and is continued throughout the season.

### **Orencia**

### **Products Affected**

• ORENCIA (WITH MALTOSE)

ML

- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SYRINGE 125 MG/ML, 50 MG/0.4 ML, 87.5 MG/0.7

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using abatacept in combination with TNF antagonists or other biologic RA therapy, such as anakinra. Tuberculosis, invasive fungal infection, other active serious infections or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis
Required Medical Information	
Age Restrictions	For RA, Patient is 18 years of age or older. For JIA, Patient is 6 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For RA, Orencia is being used to reduce signs and symptoms, induce major clinical response, inhibit the progression of structural damage, and improve physical function AND Individual has had an inadequate response to ONE non-biologic or biologic DMARD AND has had a trial of and an inadequate response or is intolerant to Humira OR Enbrel. For JIA, agent is being used to reduce signs and symptoms AND Individual has had an inadequate response to ONE non-biologic or biologic DMARD AND has had a trial of and an inadequate response or is intolerant to Humira OR Enbrel. For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Orencia or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Orencia may be allowed without trial of preferred TNF agents (Enbrel/Humira).

## **Orenitram**

### **Products Affected**

ORENITRAM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Moderate (child-Pugh Class B) or severe hepatic impairment (Child Pugh Class C). Using in combination with other treprostinil dosage forms (SQ, IV, and inhalation) unless transitioning from one dose form to another. Using in combination with other prostacyclin analogs [such as but not limited to epoprostenol (Flolan, Veletri, Ventavis (iloprost)] or prostacyclin receptor agonists [such as but not limited to Uptravi (selexipag)].
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Orfadin

### **Products Affected**

• ORFADIN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Orilissa

### **Products Affected**

• ORILISSA ORAL TABLET 150 MG, 200 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has any of the following: (a) osteoporosis (b) Individual has severe hepatic impairment [Child-Pugh class C] (c) Individual is requesting in concurrent therapy with hormonal contraceptives (d) Individual is requesting in concurrent therapy with contraindicated agents, such as but not limited to, cyclosporine or gemfibrozil.
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initial approval is 6 months, Renewal is 6 months. Requests to continue therapy beyond 24 months (2

PA Criteria	Criteria Details
Other Criteria	For initial requests, Individual is using for moderate or severe endometriosis-associated pain AND has had a trial and inadequate response or intolerance to two of the following medications or has a contraindication to all of the following medications (ACOG 2010):  (a) Nonsteroidal antiinflammatory drugs (NSAIDs) OR (b)  Combined oral contraceptives (OCs) OR (c) Oral or depot medroxyprogesterone (Provera, Depo-Provera) OR (d) Oral norethindrone. AND one of the following: (a) is naive to Orilissa (elagolix) OR (b) is using low dose (150 mg once daily), has mild (Child-Pugh class A) or no hepatic impairment, and has utilized Orilissa (elagolix) for a combined total duration of less than 24 months in their lifetime OR (c) is using high dose (200 mg twice daily) or has moderate hepatic impairment (Child-Pugh class B), and has utilized Orilissa (elagolix) for a combined total duration of less than 6 months in their lifetime. For continuation requests, Individual is using low dose (150 mg once daily) and does not have moderate hepatic impairment (Child-Pugh class B) AND has experienced a clinically significant improvement in endometriosis-associated pain.

## Orkambi

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Mutation testing indicates individual has two copies of the F508del mutation AND a copy of the CF mutation analysis test result must be provided.
Age Restrictions	Individual is 2 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Otezla

### **Products Affected**

OTEZLA

(4)-30 MG(19)

 OTEZLA STARTER ORAL TABLETS, DOSE PACK 10 MG (4)-20 MG (4)-30 MG (47), 10 MG (4)-20 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Member is unable to take biologic agent due to product warning or contraindication for any of the following: Serious infection or sepsis, Chronic or recurrent infection, Tuberculosis infection, OR Malignancy. For plaque psoriasis (Ps) involves greater than five percent (5%) body surface area (BSA) or involves less than or equal to five percent (5%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For Psoriatic Arthritis (PsA), Otezla is being used for any of the following reasons: to reduce signs or symptoms or to induce or maintain clinical response or to improve physical function. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as methotrexate, sulfasalazine, leflunomide) AND individual has had a trial and an inadequate response or is intolerant to BOTH: Humira AND Enbrel. For plaque psoriasis (Ps), Otezla is being used for any of the following reasons: to reduce signs or symptoms or to induce or maintain clinical response. Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine or methotrexate) AND individual has had a trial and an inadequate response or is intolerant to BOTH: Humira AND Enbrel. For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Otezla or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Otezla may be allowed without trial of preferred TNF agents (Enbrel/Humira).

## Oxandrin

- OXANDRIN ORAL TABLET 10 MG, 2.5 MG
- oxandrolone oral tablet 10 mg, 2.5 mg

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Carcinoma of the prostate or breast in male individuals OR Carcinoma of the breast in females with hypercalcemia. Using to enhance athletic performance or physique. Individual has a diagnosis of nephrosis (nephrotic phase of nephritis). Individual has a diagnosis of hypercalcemia.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

# **OxyContin**

- oxycodone oral tablet extended release
   12 hr
- OXYCODONE ORAL TABLET, ORAL ONLY, EXT. REL. 12 HR 10 MG, 15 MG,
- 20 MG, 30 MG, 40 MG, 60 MG, 80 MG
   OXYCONTIN ORAL TABLET, ORAL ONLY, EXT. REL. 12 HR 10 MG, 15 MG, 20 MG, 30 MG, 40 MG, 60 MG, 80 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is requesting or using as an as-needed analgesic OR Individual has one of the following conditions: (a) Significant respiratory depression OR (b) Acute or severe bronchial asthma or hypercarbia OR (c) Known or suspected paralytic ileus.
Required Medical Information	
Age Restrictions	Individual is 11 years of age or older
Prescriber Restrictions	
Coverage Duration	Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

PA Criteria	Criteria Details
Other Criteria	For initial use, Individual has one of the following: (a) Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis) OR (b) Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis) OR Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis) AND Individual has one of the following: (a) An inadequate response to ONE alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids OR (b) Alternative treatment options would otherwise be inadequate to provide sufficient management of pain OR (c) Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure). AND already receiving and tolerating a minimum daily opioid dose of at least 20mg oxycodone orally or its equivalent AND Individual is not opioid naïve as noted by the following: (a) Individual is currently using a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain OR (b) Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic. For continued use, Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline.

# **Ozurdex Implant**

### **Products Affected**

• OZURDEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### PAH - B

- epoprostenol (glycine)FLOLAN
- veletri

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnostic Criteria for PAH: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than 25mmhg, a pulmonary capillary wedge pressure (PCWP), left atrial pressure or left ventricular end diastolic pressure (LVEDP) less than or equal to 15mmhg AND a pulmonary vascular resistance (PVR) greater than 3 wood units. Criteria for Vasodilator Response: a favorable response is defined as a fall in mPAP of at least 10mmhg to an absolute mPAP of less than 40mmhg without a decrease in cardiac output, when challenged with inhaled nitric oxide, intravenous epoprostenol or intravenous adenosine.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For continuous intravenous infusion of Epoprostenol, individual must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to vasodilators AND meets one of the following patient selection criteria with New York Heart Association (NYHA) functional class III, or IV symptoms: World health Organization (WHO) Group I idiopathic pulmonary arterial hypertension including all subtypes of WHO Group I PAH or Pulmonary hypertension associated with connective tissue disorders (scleroderma, systemic sclerosis, etc.) or pulmonary hypertension associated with congenital heart defects

# **Palynziq**

### **Products Affected**

PALYNZIQ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has a confirmed prescription for an auto-injectable epinephrine agent.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	For initial requests, individual has a diagnosis of phenylketonuria (PKU) and has uncontrolled blood phenylalanine (PHE) concentrations (greater than 600 micromol/L) on existing management, including but not limited to the following: (a) Dietary phenylalanine and/or protein restriction (b) Kuvan (sapropterin dihydrochloride) agents. For continued use, Individual is showing signs of continuing improvement, as evidenced by blood PHE levels.

# **Pegylated Interferons**

### **Products Affected**

- PEGASYS
- PEGASYS CONVENIENCE PACK
- PEGASYS PROCLICK
- PEGINTRON

• PEGINTRON REDIPEN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	A copy of the baseline quantitative hepatitis C virus (HCV) RNA test result is provided to document baseline level of viremia AND One of the following: (1) Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016, CDC 2013). OR (2) Individual is unable to delay treatment for 6 months owing to concurrent factors [such as but not limited to, advanced liver disease (Metavir fibrosis stage of F3 or F42), post-liver transplant recipients, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), coexistent liver diseases (such as nonalcoholic steatohepatitis), chronic HCV infection-associated extrahepatic manifestations (such as membranoproliferative glomerulonephritis, glomerular disease, cryoglobulinemia syndrome)] (AASLD/IDSA 2016) AND Documentation is provided for a diagnosis of chronic CHC infection, which includes a reactive HCV antibody (CDC 2013) and a subsequent positive HCV RNA result (CDC 2013). Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016).
Age Restrictions	For use in combination with a protease/polymerase inhibitor and ribavirin (triple therapy), age 18 or older.
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	1 year.
Other Criteria	For Genotype 1, 2, 3, 4, 5, or 6, as part of a planned triple therapy (IFN plus RBV plus NS5B Protease Inhibitor). For Genotype 1, 2, 3, 4, 5, or 6, as part of a planned dual therapy (IFN plus RBV). For Genotype 1, 2, 3, 4, 5, or 6, monotherapy therapy when individual has contraindications or significant intolerance to HCV antiviral agents/regimens.

# Perjeta

### **Products Affected**

• PERJETA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	If administered after Herceptin (trastuzumab) is discontinued or as part of a regimen without Herceptin (trastuzumab). Concomitant use with other targeted biologic agents (including but not limited to erlotinib, cetuximab, panitumumab, bevacizumab, ziv-aflibercept and lapatinib).
Required Medical Information	Tumor(s) have been evaluated with an assay validated to predict HER2 positive (HER2+) protein overexpression. Individuals are considered HER2 positive (HER2+) as documented by one of the following, immunohistochemistry (IHC) 3+ or In Situ hybridization (ISH) positive by any of the following: Single probe average HER2 copy number greater than or equal to 6.0 signals/cell OR Dual-probe HER2/CEP 17 ratio greater than or equal to 2.0 OR Dual-probe HER2/CEP 17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For metastatic breast cancer use Perjeta will be used in combination with trastuzumab AND either docetaxel or paclitaxel. (Note If docetaxel or paclitaxel treatment is discontinued (for example, related to toxicity), treatment with Perjeta and trastuzumab may continue.) AND combination chemotherapy with Perjeta (pertuzumab) will be used as single line anti-HER2 chemotherapy for metastatic disease until progression OR individual has operable early stage, locally advanced or inflammatory breast cancer and will undergo neoadjuvant treatment (prior to surgery) of individuals with HER2-positive AND primary tumor is larger than 2cm or individual is node positive (clinically evident by palpation or imaging) AND used in combination with trastuzumab and with one of the following: docetaxel with or without carboplatin or paclitaxel AND complete surgical resection is planned if neoadjuvant therapy results in a sufficient therapeutic response AND not continued post-operatively (adjuvant) OR Individual has early stage or locally advanced breast cancer and will undergo adjuvant systemic therapy when pertuzumab is used for a maximum of 6 cycles and not used as neoadjuvant therapy and the primary tumor measures 2cm or more in diameter or individual is lymph node positive and pertuzumab is used in combination with 12 month (52 weeks) course of trastuzumab and either docetaxel with or without carboplatin or paclitaxel.

## **Pomalyst**

### **Products Affected**

 POMALYST ORAL CAPSULE 1 MG, 2 MG, 3 MG, 4 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Praluent**

- PRALUENT PEN
- PRALUENT SYRINGE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with Juxtapid or Kynamro.
Required Medical Information	Individual is at High Risk for Acute Coronary Syndrome (ACS) as identified by one of the following: (A) Heterozygous Familial Hypercholesterolemia (HeFH) with provided documentation confirming: 1.Presence of a mutation in LDLR, apolipoprotein B (ApoB), PCSK9 or ARH adaptor protein gene (LDLRAP1) gene OR 2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of gtr than 8 points OR (B) History of Clinical Atherosclerotic Cardiovascular Disease (ASCVD), including one of the following (documentation must be provided): 1.Acute coronary syndromes 2.History of myocardial infarction (MI) 3.Stable or unstable angina 4.Coronary or other arterial revascularization 5.Stroke 6.Transient ischemic attack (TIA) 7.Peripheral arterial disease presumed to be of atherosclerotic origin.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initial 3 month. Continuation 1 yr.

PA Criteria	Criteria Details
Other Criteria	For initial request, individual meets one of the following: (A) Individual is a on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher (documentation must be provided) OR (B) Individual is statin intolerant OR (C) Individual has a condition that is a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum transaminases, or pregnancy, which does not exist for the requested PCS-K9 agent (documentation must be provided). Individual also has had an adequate trial and titration of a Repatha (evolocumab) and has achieved suboptimal lipid lowering response despite at least 90 days of Repatha (evolocumab) therapy. For continuation, criteria outlined for initial Prior Authorization has been satisfied AND Documentation of LDL reduction has been provided.

# **Probuphine Implant**

### **Products Affected**

PROBUPHINE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Treatment for longer than 12 months with Probuphine. Retreatment with Probuphine after a prior 12-month treatment period. For individuals who have not achieved and sustained prolonged clinical stability while being maintained on buprenorphine 8 mg per day or less of a Subutex or Suboxone sublingual tablet or generic equivalent.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Individual has been diagnosed with opioid dependence (opioid use disorder) and individual has been treated with a stable transmucosal buprenorphine dose (of 8 mg per day or less of a sublingual Subutex or Suboxone sublingual tablet or its transmucosal buprenorphine product equivalent) for 3 months or longer without any need for supplemental dosing or adjustments and individual is currently on a maintenance dose of 8 mg per day or less of a Subutex or Suboxone sublingual tablet or its transmucosal buprenorphine product equivalent to achieve sustained prolonged clinical stability on transmucosal buprenorphine and Probuphine is used as part of a comprehensive substance use disorder treatment program to include counseling and psychosocial support.

## **Prolia**

### **Products Affected**

• PROLIA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Bone Mineral Density (BMD) and T-Score must be provided with all requests. Osteoporosis is defined as a BMD T-Score of less than or equal to -2.5. For osteoporosis treatment, risk factors for osteoporotic fracture is defined as: Hypogonadism or premature ovarian failure, Low body mass, Smoking, Rheumatoid arthritis, Alcohol intake of 3 or more drinks/day, Vitamin D deficiency, Low calcium intake, Hyperkyphosis, Parental hip fracture, Multiple falls, Medication: Anticoagulants, anticonvulsants, aromatase inhibitors, cancer chemotherapeutic drugs, gonadotropin-releasing hormone agonists, (glucocorticoid daily dosage equivalent to 5 mg or greater of prednisone for at least 3 months). For the treatment of bone loss, risk factors for osteoporotic fracture is defined as: Low body mass, Smoking, Rheumatoid arthritis, Alcohol intake of 3 or more drinks/day, Vitamin D deficiency, Low calcium intake, Hyperkyphosis, Parental hip fracture, Multiple falls, Medication: Anticoagulants, anticonvulsants, (glucocorticoid daily dosage equivalent to 5 mg or greater of prednisone for at least 3 months).
Age Restrictions	For Osteoporosis 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For osteoporosis treatment, member has had at least ONE osteoporotic (minimal trauma) fracture OR has two or more risk factors for osteoporotic fracture OR Individual has failed or is intolerant to other available osteoporosis therapies (such as, bisphosphonates). For treatment of bone loss, member has had at least ONE osteoporotic (minimal trauma) fracture OR has one or more risk factors for osteoporotic fracture.

### **Promacta**

### **Products Affected**

• PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using Promacta to normalize platelet counts. Use in individuals with ITP whose degree of thrombocytopenia and clinical condition (for example, platelet count greater than 30 x 109/L or active bleeding) do not increase the risk of bleeding. Use in individuals with chronic hepatitis C whose degree of thrombocytopenia does not prevent the initiation of peginterferon therapy or limits the ability to maintain an optimal peginterferon-based therapy. Used in individuals with chronic hepatitis C who are no longer on a peginterferon and ribavirin based regimen. Used concomitantly with other thrombopoietin receptor agonists such as romiplostim (Nplate). Used in individuals taking in combination with direct-acting antiviral agents used without concomitant use of a peginterferon agent for treatment of thrombocytopenia associated with chronic hepatitis C infection.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For initial therapy: 1) Diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) AND individual has platelet count of less than 30 x 109/L or active bleeding (ASH, 2011. Hicks et al., 2014) AND has had a prior trial and insufficient response to one of the following: a) corticosteroids or b) immunoglobulins [for example, intravenous, anti-D] or c) splenectomy. OR, 2) Diagnosis of severe aplastic anemia AND individual has a platelet count of less than or equal to 30 x 109/L (Olnes et al., 2012.Desmond et al., 2014) AND individual has had a prior trial and insufficient response to an immunosuppressive therapy [such as, anti-thymocte globulin (ATG)]. For maintenance therapy, individual has demonstrated a response to therapy as evidenced by increased platelet counts AND to maintain an adequate platelet count (50 - 200 x 109/L) to decrease the risk of bleeding.

# **Protopic**

- PROTOPIC
- tacrolimus topical

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For Protopic (tacrolimus) 0.03 percent, individual is 2 years of age and older. For Protopic (tacrolimus) 0.1 percent, individual is 16 years of age and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual had a trial of and inadequate response or intolerance to one topical prescription strength corticosteroid.

## **Purixan**

### **Products Affected**

PURIXAN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# quinine

- QUALAQUIN
- quinine sulfate

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Treatment or prevention for nocturnal recumbancy leg muscle cramps or related conditions such as but not limited to: Leg cramps, muscle cramps, myoclonus, Periodic Movements of Sleep, Periodic Limb Movements of Sleep (PLMS), Restless Leg Syndrome (RLS), severe hepatic impairment (Child-Pugh C), known prolongation of the QT interval, initial treatment of severe or complicated P. falciparum malaria, prevention of malaria, individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency, individuals with myasthenia gravis, or individuals with optic neuritis.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has been diagnosed with uncomplicated malaria caused by one of the following: Plasmodium falciparum known or suspected to be resistant to chloroquine (CDC 2013) OR chloroquine-resistant Plasmodium vivax (CDC 2013) OR an unidentified plasmodial species known or suspected to be resistant to chloroquine (CDC 2013).

# Ragwitek

### **Products Affected**

RAGWITEK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Severe, unstable or uncontrolled asthma. History of any severe systemic allergic reaction. History of eosinophilic esophagitis. Or, individual is receiving concomitant therapy with other allergen immunotherapy product.
Required Medical Information	For short ragweed pollen induced allergic rhinitis, individual has a documented positive skin test OR positive in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. Individual has had a trial of, and inadequate symptom control or intolerance to (1) nasal steroid and (1) non-sedating antihistamine AND individual has a documented prescription for an auto-injectable epinephrine product.
Age Restrictions	Individual is between the ages of 18 years and 65 years old.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Treatment is initiated at least 12 weeks before the expected onset of ragweed pollen season and is continued throughout the season.

## Ravicti

### **Products Affected**

RAVICTI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using for the management of acute hyperammonemia. Using to treat N-acetylglutamate synthase deficiency (NAGS).
Required Medical Information	
Age Restrictions	2 months of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Reclast

- RECLAST
- zoledronic acid-mannitol-water

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For Paget's disease of bone in men and women, treatment is indicated with elevations in serum alkaline phosphatase of two times or higher than the upper limit of the age-specific normal reference range, or those who are symptomatic, or those at risk for complications from their disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Regranex

### **Products Affected**

• REGRANEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	Individual is using as adjunctive therapy with good ulcer care practices including, but not limited to sharp debridement of the ulcer

### **RELISTOR**

- RELISTOR ORAL
- RELISTOR SUBCUTANEOUS KIT
- RELISTOR SUBCUTANEOUS SOLUTION
- RELISTOR SUBCUTANEOUS SYRINGE 12 MG/0.6 ML, 8 MG/0.4 ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has a known or suspected mechanical gastrointestinal obstruction.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual must have a previous trial of or insufficient response to polyethylene glycol (generic MiraLax) (AGA 2013) AND a trial and inadequate response or intolerance to a preferred agent (Movantik/Amitiza) OR the preferred agent (Movantik/Amitiza) is not acceptable due to concomitant clinical situations, warnings or contraindications, such as but not limited to the following: (1) individual is taking a diphenylheptane opioid (e.g., methadone), where effectiveness has not been established in the treatment of OIC (Amitiza) OR (2) individual has disruption to the blood-brain barrier and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik) OR (3) individual is taking strong CYP3A4 inhibitors and may be at increased risk for opioid withdrawal and/or reduced analgesia (Movantik).

## Remicade

- INFLECTRA
- REMICADE
- RENFLEXIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Tuberculosis, invasive fungal infection, other active serious infections or a history of recurrent infection. Individuals who have not had a tuberculin skin test or CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating infliximab. Using in combination with other TNF antagonists, abatacept, anakinra, tofacitinib or tocilizumab.
Required Medical Information	For chronic moderate to severe plaque psoriasis: Greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).
Age Restrictions	For Crohn's Disease or Ulcerative colitis, 6 yr of age or older. For all other indications 18 yr of age.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For RA, agent is being used to reduce signs/symptoms OR induce/maintain clinical response OR inhibit the progression of structural damage OR improve physical function AND Infliximab is given in combination with methotrexate or with another immunosuppressive agent if the individual is intolerant to methotrexate AND individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE nonbiologic DMARD. For Crohn's Disease, individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressive drugs) and infliximab is being used to reduce signs/symptoms OR induce/maintain clinical remission OR individual has fistulizing Crohn's disease with draining enterocutaneous or rectovaginal fistulas, of at least 3 months duration OR individual has fistulizing or moderately to severely active Crohn's disease and has responded to previous therapy with infliximab. For moderately to severely active Ulcerative Colitis, agent is being used to reduce signs/symptoms OR induce/maintain clinical remission and mucosal healing AND individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressive drugs). For Ankylosing Spondylitis individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as NSAIDs, or nonbiologic DMARDs). For Psoriatic Arthritis, agent is being used to reduce signs/symptoms OR induce/maintain clinical response OR inhibit the progression of structural damage OR improve physical function AND individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as nonbiologic DMARD). For chronic plaque psoriasis, agent is being used to reduce signs/symptoms OR induce/maintain clinical response AND individual has fa

PA Criteria	Criteria Details
	methotrexate, acetretin, or cyclosporine). For Refractory Wegener's Granulomatosis, individual is using in combination with ONE corticosteroid. For JIA, agent is being used to reduce signs/symptoms OR induce/maintain clinical response AND individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE nonbiologic DMARD. For chronic, recurrent, treatment-refractory or vision-threatening, non-infectious uveitis, individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as corticosteroids or immunosuppressive drugs [for example, azathioprine, cyclosporine, or methotrexate]).

## Remodulin

### **Products Affected**

REMODULIN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnostic Criteria for PAH: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than or equal to 25mmhg, a pulmonary capillary wedge pressure (PCWP), left atrial pressure or left ventricular end diastolic pressure (LVEDP) less than or equal to 15mmhg AND a pulmonary vascular resistance (PVR) greater than 3 wood units. Criteria for Vasodilator Response: a favorable response is defined as a fall in mPAP of at least 10mmhg to an absolute mPAP of less than 40mmhg without a decrease in cardiac output, when challenged with inhaled nitric oxide, intravenous epoprostenol or intravenous adenosine.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For Remodulin patient must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to one vasodilator AND meets one of the following patient selection criteria with New York Heart Association (NYHA) functional class II, III, or IV symptoms: World health Organization (WHO) Group I idiopathic pulmonary arterial hypertension including all subtypes of WHO Group I PAH or Pulmonary hypertension associated with connective tissue disorders (scleroderma, systemic sclerosis, etc.) or pulmonary hypertension associated with congenital heart defects. For Continuous intravenous infusion of Remodulin the individual must also be able document the inability to tolerate treatment by subcutaneous infusion.

## Repatha

- REPATHA PUSHTRONEX
- REPATHA SURECLICK
- REPATHA SYRINGE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with Juxtapid or Kynamro.
Required Medical Information	Individual is at High Risk for Acute Coronary Syndrome (ACS) as identified by one of the following: A. Homozygous Familial Hypercholesterolemia (HoFH) with provided documentation confirming: 1.Presence of two (2) mutant alleles at the LDLR, apoB, PCSK9 or ARH adaptor gene locus OR 2.untreated LDL-C concentration greater than 500 mg/dL (13 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) AND one of the following: i.Cutaneous or tendonous xanthoma before age of 10 years OR ii.Untreated LDL-C levels consistent with heterozygous familial hypercholesterolemia in both parents (greater than190 mg/dL) OR B. Heterozygous Familial Hypercholesterolemia (HeFH) with provided documentation confirming: 1.Presence of a mutation in LDLR, apolipoprotein B (ApoB), PCSK9 or ARH adaptor protein gene (LDLRAP1) gene OR 2. World Health Organization (WHO)/Dutch Lipid Network Criteria with score of gtr than 8 points OR C. History of Clinical Atherosclerotic Cardiovascular Disease (ASCVD), including one of the following (documentation must be provided): 1.Acute coronary syndromes 2.History of myocardial infarction (MI) 3.Stable or unstable angina 4.Coronary or other arterial revascularization 5.Stroke 6.Transient ischemic attack (TIA) 7.Peripheral arterial disease presumed to be of atherosclerotic origin.
Age Restrictions	For Dx HeFH, 18 years of age or older. For Dx HoFH, 13 years of age or older.
Prescriber Restrictions	
Coverage Duration	Initial 3 month. Continuation 1 yr.

PA Criteria	Criteria Details
Other Criteria	For initial HoFH request, individual meets the following: (A) Individual is a on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher (documentation must be provided) OR (B) Individual is statin intolerant OR (C) Individual has a condition that is a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum transaminases, or pregnancy, which does not exist for the requested PCS-K9 agent (documentation must be provided) AND Individual is on ezetimibe (applies to individuals on statin therapy only) with documentation. For initial HeFH or ASCVD requests, individual meets the following: (A) Individual is a on high intensity statin therapy, or statin therapy at the maximum tolerated dose, where high intensity statin is defined as atorvastatin 40 mg or higher OR rosuvastatin 20 mg or higher (documentation must be provided) OR (B) Individual is statin intolerant OR (C) Individual has a condition that is a contraindication for statin therapy including active liver disease, unexplained persistent elevation of serum transaminases, or pregnancy, which does not exist for the requested PCS-K9 agent (documentation must be provided). For continuation, criteria outlined for initial Prior Authorization has been satisfied AND Documentation of LDL reduction has been provided.

## **Restasis**

- RESTASIS
- RESTASIS MULTIDOSE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documentation is provided indicating an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods (AAO, 2013): (a) Tear break-up time (less than 10 seconds) OR (b) Ocular surface dye staining using fluorescein, rose bengal, or lissamine green dyes OR (c) Schirmer test (aqueous tear production of less than or equal to 10 mm of strip wetting in 5 minutes) OR (d) Fluorescein clearance test/tear function index OR (e)Tear osmolarity (indicating tear film instability) OR (f) Tear lactoferrin concentrations in the lacrimal gland (decreased).
Age Restrictions	16 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	Individual is using to treat moderate to severe dry eye disease (AAO 2013) AND Individual has had a trial and inadequate response or intolerance to Xiidra (lifitegrast) OR Individual has a known hypersensitivity to any ingredient in the preferred agent (Xiidra) which is not also present in the requested non-preferred agent.

# **Retisert Implant**

### **Products Affected**

RETISERT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Revatio

- REVATIO INTRAVENOUS
- REVATIO ORAL SUSPENSION FOR **RECONSTITUTION**
- REVATIO ORAL TABLET

- sildenafil (antihypertensive) intravenoussildenafil (antihypertensive) oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use in combination with phosphodiesterase-5 (PDE5) inhibitors [such as but not limited to, Viagra (sildenafil)]. Use in combination with organic nitrates, such as but not limited to, isosoribide mono/dinitrate or nitroglycerin. Use in combination with guanylate cyclase stimulators [such as but not limited to, Adempas (riociguat)]. Use in individuals requesting for the treatment of erectile dysfunction. Use in individuals with severe hepatic impairment (Child-Pugh Class C). Use in individual has a diagnosis of pulmonary veno-occlusive disease (PVOD). Use in individual has a known hereditary degenerative retinal disorder (such as but not limited to, retinitis pigmentosa).
Required Medical Information	Catheterization-proven diagnosis of Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO Group I) and WHO Functional Class II-IV symptoms.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For sildenafil INJ, individual is temporarily unable to take oral dose forms and requires continued therapy.

## Revlimid

### **Products Affected**

 REVLIMID ORAL CAPSULE 10 MG, 15 MG, 2.5 MG, 20 MG, 25 MG, 5 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Rexulti

### **Products Affected**

 REXULTI ORAL TABLET 0.25 MG, 0.5 MG, 1 MG, 2 MG, 3 MG, 4 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	

## Rubraca

### **Products Affected**

• RUBRACA ORAL TABLET 200 MG, 250 MG, 300 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has deleterious BRCA mutation (verified by diagnostic testing)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Ruconest**

### **Products Affected**

• RUCONEST

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is using for prophylaxis or in individuals with laryngeal attacks.
Required Medical Information	Hereditary Angioedema (HAE) Type I/II is confirmed by a C4 level below the lower limit of normal as defined by the laboratory performing the test AND ONE of the following (a or b): a. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test OR b.C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test. AND Individual has a history of moderate or severe attacks (for example, airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion). HAE Type III was confirmed by: C1 inhibitor (C1-INH) antigenic level is normal as defined by the laboratory performing the test AND C4 level is normal as defined by the laboratory performing the test.
Age Restrictions	13 years and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Rydapt

### **Products Affected**

RYDAPT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has been treated previously for acute myeloid leukemia (AML).
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Sabril

- SABRIL
- vigabatrin
- vigadrone

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For infantile spasm 1 month to 2yr old. For seizure 10 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Samsca

### **Products Affected**

• SAMSCA ORAL TABLET 15 MG, 30 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has an acute, urgent need to raise serum sodium OR is unable to sense/appropriately respond to thirst OR is anuric. Diagnosis of hypovolemic hyponatremia. Individual has underlying liver disease, including cirrhosis OR is currently receiving a strong CYP3A inhibitor (such as clarithromycin, ketoconazole, itraconazole, ritonavir., indinavir., nelfinavir, saquinavir, nefazodone and telithromycin).
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **SANCUSO**

### **Products Affected**

• SANCUSO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had a trial of and inadequate response or intolerance to EITHER generic ondansetron or oral granisetron OR individual is unable to take oral medications.

## Sandostatin IR

- octreotide acetate
- SANDOSTATIN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has (A) diagnosis of carcinoid tumors for any of the following: Metastatic carcinoid tumors OR Carcinoid syndrome to suppress or inhibit severe diarrhea and flushing episodes associated with the disease OR Prophylactic administration prior to biopsy in an individual with a suspected functioning carcinoid tumor OR Prophylactic administration prior to induction of anesthesia in an individual with a functional carcinoid tumor OR Prophylactic administration to a surgical procedure in an individual with a functional carcinoid tumor. OR (B) Diagnosis of Bleeding gastroesophageal varices when GE varices are associated with liver disease AND octreotide acetate is used in combination with endoscopic therapy or alone if endoscopic therapy is not available. OR (C) Chemotherapy or radiation-induced diarrhea that is unresponsive to conventional antidiarrheal medications (for example, diphenoxylate and atropine or loperamide) OR (D) Malignant bowel obstruction to manage GI symptoms (such as nausea, vomiting or pain). Or supplemental treatment with shortacting octreotide acetate (Sandostatin)is approved for rapid relief of symptoms or for breakthrough symptoms in individuals taking longacting octreotide acetate.

### **Sandostatin LAR**

#### **Products Affected**

SANDOSTATIN LAR DEPOT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has (A) diagnosis of carcinoid tumors for any of the following: Metastatic carcinoid tumors OR Carcinoid syndrome to suppress or inhibit severe diarrhea and flushing episodes associated with the disease OR Prophylactic administration prior to biopsy in an individual with a suspected functioning carcinoid tumor OR Prophylactic administration prior to induction of anesthesia in an individual with a functional carcinoid tumor OR Prophylactic administration to a surgical procedure in an individual with a functional carcinoid tumor. OR (B) Diagnosis of Bleeding gastroesophageal varices when GE varices are associated with liver disease AND octreotide acetate is used in combination with endoscopic therapy or alone if endoscopic therapy is not available. OR (C) Chemotherapy or radiation-induced diarrhea that is unresponsive to conventional antidiarrheal medications (for example, diphenoxylate and atropine or loperamide) OR (D) Malignant bowel obstruction to manage GI symptoms (such as nausea, vomiting or pain).

### **Seroquel Line**

- quetiapine oral tablet extended release
   24 hr 150 mg, 200 mg, 300 mg, 400 mg,
   50 mg
- SERÖQUEL ORAL TABLET 100 MG, 200 MG, 25 MG, 300 MG, 400 MG, 50
- MG
   SEROQUEL XR ORAL TABLET
  EXTENDED RELEASE 24 HR 150 MG,
  200 MG, 300 MG, 400 MG, 50 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For schizophrenia, 13 years of age or older. For bipolar disorder, 10 years of age or older. For MDD, 18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For schizophrenia/bipolar use, the individual has had a trial of one of the following generic oral atypical antipsychotic: Risperidone, Olanzapine, Quetiapine fumarate, Paliperidone or Ziprasidone.

# Signifor IR

#### **Products Affected**

• SIGNIFOR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has a diagnosis of severe hepatic impairment (Child-Pugh C)
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Signifor LAR

#### **Products Affected**

SIGNIFOR LAR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Siklos**

#### **Products Affected**

• SIKLOS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	Individual has a diagnosis of sickle cell anemia with recurrent moderate to severe painful crises AND is unable to swallow the oral tablet dose form due to a clinical condition such as but not limited to the following: (a) Dysphagia or (b) Individual's age.

### **SIMPONI**

#### **Products Affected**

• SIMPONI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use of golimumab in combination with other TNF antagonists, abatacept, tofacitinib or anakinra. Tuberculosis, invasive fungal infections, other active serious infections, or a history of recurrent infections. Individuals who have not had a TST or a CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating Simponi (golimumab).
Required Medical Information	
Age Restrictions	Individual is 18 years or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For RA, agent is being used to reduce signs/symptoms OR induce/maintain clinical response OR improve physical function AND individual is taking in combination with methotrexate OR with another immunosuppressive agent if the individual is intolerant to methotrexate AND individual has failed to respond to, is intolerant to of, or has a medical contraindication to ONE nonbiologic DMARD AND member has had a trial of and an inadequate response or is intolerant to BOTH: Humira AND Enbrel. For Psoriatic Arthritis, agent is being used to reduce signs/symptoms OR induce/maintain clinical response OR improve physical function AND individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as non-biologic DMARDs) AND individual has had a trial of and an inadequate response or is intolerant to BOTH: Humira AND Enbrel. For Ankylosing Spondylitis, agent is being used to reduce signs/symptoms AND member has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (e.g. NSAIDs or nonbiologic DMARDs) AND member has had a trial of and an inadequate response or is intolerant to BOTH: Humira AND Enbrel. For UC agent is being used to reduce signs/symptoms OR induce/maintain clinical remission and mucosal healing AND individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as 6-mercaptopurine, azathioprine, oral aminosalicylates, or oral corticosteroids) OR demonstrated dependence on corticosteroids AND individual has had a trial of and an inadequate response or is intolerant to Humira. For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Simponi or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serio
	preferred TNF agents (Enbrel/Humira).

### **Sirturo**

#### **Products Affected**

• SIRTURO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Latent infection due to Mycobacterium tuberculosis OR Drug- sensitive tuberculosis OR Extra-pulmonary tuberculosis OR Infections caused by non-tuberculosis mycobacteria.
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of pulmonary multi-drug resistant tuberculosis AND is unable to use an effective regimen for treatment AND the individual is using Sirturo (bedaquiline) with at least 3 drugs to which the multi-drug resistant tuberculosis isolate is susceptible in vitro OR with at least 4 drugs to which the multi-drug resistant tuberculosis isolate is likely to be susceptible if in vitro testing results are unavailable.

### **Sivextro**

- SIVEXTRO INTRAVENOUS
- SIVEXTRO ORAL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Treatment of gram-negative infections.
Required Medical Information	Individual has been diagnosed with acute bacterial skin and skin structure infection (ABSSSI) defined as one of the following (FDA, 2013): Cellulitis/erysipelas OR Wound infection OR Major cutaneous abscess. AND Individual has a minimum total lesion surface area of approximately 75 cm squared (FDA, 2013) AND Individual has at least 1 regional or 1 systemic sign of infection as defined by: Lymphadenopathy OR temperature greater than or equal to 38 degrees Celsius OR White blood cell count greater than or equal to 10,000 per microliter OR White blood cell count less than 4000 per microliter OR Greater than 10% of immature neutrophils. AND Infection is caused by methicillin-resistant Staphylococcus aureus [MRSA].
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 days
Other Criteria	Individual has had a trial and inadequate response or intolerance to of or has contraindications to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: TMP/SMX, doxycycline, vancomycin, daptomycin, televancin, clindamycin) (IDSA 2014) OR Individual started treatment with intravenous antibiotic(s) in the hospital and requires continued outpatient therapy for an organism susceptible to Sivextro (tedizolid).

### Solaraze

- diclofenac sodium topical gel 3 %SOLARAZE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Dx of Actinic Keratosis
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Somatuline Depot**

#### **Products Affected**

 SOMATULINE DEPOT SUBCUTANEOUS SYRINGE 120 MG/0.5 ML, 60 MG/0.2 ML, 90 MG/0.3 ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Somavert**

#### **Products Affected**

SOMAVERT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Dx of acromegaly AND member has had an inadequate response to surgery and/or radiation OR Surgery and/or radiation therapy are not an option (such as but not limited to, individual is an in appropriate candidate for surgical or radiation based therapy
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Sovaldi

#### **Products Affected**

• SOVALDI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has severe renal impairment (CrCl less than 30 mL/min), end stage renal disease, or requires dialysis (AASLD/IDSA 2014). Individual is using in combination with Daklinza (daclatasvir) and a known NS5A polymorphism is present.
Required Medical Information	A copy of baseline quantitative HCV RNA test results is provided to document baseline level of viremia AND One of the following: (1) Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016, CDC 2013). OR (2) Individual is unable to delay treatment for 6 months owing to concurrent factors [such as but not limited to, advanced liver disease (Metavir fibrosis stage of F3 or F42), post-liver transplant recipients, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), coexistent liver diseases (such as nonalcoholic steatohepatitis), chronic HCV infection-associated extrahepatic manifestations (such as membranoproliferative glomerulonephritis, glomerular disease, cryoglobulinemia syndrome)] (AASLD/IDSA 2016) AND Documentation is provided for a diagnosis of chronic CHC infection, which includes a reactive HCV antibody (CDC 2013) and a subsequent positive HCV RNA result (CDC 2013). Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016).
Age Restrictions	Individual is 18 years of age or older.
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, Individual has had a prior trial and inadequate response to Harvoni. For GT 4, individual has had a prior trial and inadequate response to Harvoni or Epclusa. OR individual is currently on and completing a course of therapy with the requested regimen.

# **Spritam**

#### **Products Affected**

 SPRITAM ORAL TABLET FOR SUSPENSION 1,000 MG, 250 MG, 500 MG, 750 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has a diagnosis of partial onset seizures OR primary generalized tonic-clonic seizures AND weighs more than 20 kg.
Age Restrictions	Partial onset seizures: 4 years old. Juvenile myoclonic epilepsy: 12 years old. Primary generalized tonic-clonic seizures: 6 years old.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Sprycel

#### **Products Affected**

• SPRYCEL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Stelara

- STELARA INTRAVENOUS
- STELARA SUBCUTANEOUS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Known to have reversible posterior leukoencephalopathy syndrome (RPLS) while on tx with Stelara. Individual has not had a tuberculin skin test (TST) or a positive Centers for Disease Control (CDC) and Prevention-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Stelara (ustekinumab).
Required Medical Information	Diagnosis of moderate to severe plaque psoriasis with either of the following: Patient has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).
Age Restrictions	Individual is 18 years of age or older. For Plaque Psoriasis, age 12 and older.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For a dx of chronic plaque psoriasis, agent is used for any of the following reasons: To reduce signs/symptoms or To induce/maintain clinical response AND individual has failed to respond to, is intolerant of, or has a medical contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND member has had a trial of and an inadequate response or is intolerant to BOTH: Humira and Enbrel. For a dx of psoriatic arthritis, individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE conventional therapy (such as nonbiologic DMARDS) AND Agent is used for any of the following reasons: To reduce signs/symptoms or To induce/maintain clinical response or To inhibit the progression of structural damage or To improve physical function AND individual has had a trial of and an inadequate response or is intolerant to BOTH: Humira and Enbrel. For dx of Crohns disease, individual has failed to respond to, has lost response to, is intolerant of, or has a medical contraindication to either of the following: Conventional drug therapy, such as aminosalicylate (5-ASA) products (for example, mesalamine, sulfasalazine) or an immunomodulator drug (for example, azathioprine [AZA], 6-mercaptopurine [6-MP], or methotrexate [MTX]) or has demonstrated dependence on systemic corticosteroids or individual has had a trial and inadequate response or intolerance to Humira. For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Stelara or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with
	documented left ventricular dysfunction, Stelara may be allowed without trial of preferred TNF agents (Enbrel/Humira).

# Stivarga

#### **Products Affected**

• STIVARGA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Strattera**

#### **Products Affected**

atomoxetine oral capsule 10 mg, 100 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg
STRATTERA ORAL CAPSULE 10 MG,

80 MG

100 MG, 18 MG, 25 MG, 40 MG, 60 MG,

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For dx of ADHD/ADD, Individual has had a trial of ONE generic stimulant medication unless either of the following apply: (1) patient or family member has a history of substance diversion or abuse OR (2) patient has diagnosis of anxiety or a tic disorder (e.g. tourettes syndrome).
Age Restrictions	age 6 and up
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Strensiq**

#### **Products Affected**

• STRENSIQ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Total serum alkaline phosphatase is below the lower limit of normal for the individual's age and gender at diagnosis and Plasma pyridoxal 5'-phosphate levels are greater than the upper limit of normal at the time of diagnosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial 3 mon. Continuation 1 year
Other Criteria	For initial treatment of perinatal/infantile or juvenile onset hypophosphatasia, individual has onset of symptoms occurred prior to 6 months of age and has one or more of the following: (a) Radiographic evidence of poor bone mineralization such as flared and frayed metaphyses, severe/ generalized osteopenia, or widened growth plates or (b) Genetic test results that confirm infantile HPP or (c) one or more of the following: (1) History or presence of nontraumatic postnatal fracture healing or (2) History of elevated serum calcium or (3) Functional craniosynostosis with decreased head circumference growth or (4) Nephrocalcinosis or (5) Rachitic chest deformity or (6) Respiratory compromise or (7) Vitamin B6-responsive seizures or (8) Failure to thrive. For Continuation of Therapy: The individual has demonstrated clinical improvement in symptoms following asfotase alfa therapy.

### Subsys

#### **Products Affected**

• SUBSYS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using for the treatment of acute or postoperative pain. Using for treatment of migraine headache pain. Using for non-cancer related breakthrough pain.
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of active cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain (provide diagnosis) AND has tried and failed fentanyl citrate lozenge (generic Actiq) AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking Subsys (fentanyl) for cancer related breakthrough pain.

# Supprelin LA

#### **Products Affected**

• SUPPRELIN LA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has precocious puberty defined as: Beginning of secondary sexual characteristics before age 8 in girls and age 9 in boys.

### **Sutent**

#### **Products Affected**

• SUTENT ORAL CAPSULE 12.5 MG, 25 MG, 37.5 MG, 50 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Sylatron**

- SYLATRON
- SYLATRON 4-PACK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Member is being treated for melanoma with microscopic or gross nodal involvement AND Treatment is initiated within 84 days after definitive surgical resection.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Sylvant**

#### **Products Affected**

• SYLVANT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual does not have a concurrent clinically significant infection (for example, Hepatitis B or C) AND No concurrent lymphoma.
Required Medical Information	Individual is negative for human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Symdeko

#### **Products Affected**

• SYMDEKO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	12 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	Individual has a diagnosis of cystic fibrosis (CF) AND has a confirmed mutation-positive result in the cystic fibrosis transmembrane conductance regulator (CFTR) gene and the mutation type is provided and responsive to Symdeko.

# **Symlin**

- SYMLINPEN 120
- SYMLINPEN 60

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	May not be approved if individual has any of the following: receiving drugs that stimulate gastric motility (i.e. metoclopramide), diagnosis of severe gastroparesis, hypoglycemia unawareness or recent hypoglycemia requiring assistance within past 6 months
Required Medical Information	Type 1 or type 2 diabetes AND taking mealtime insulin therapy AND failed to achieve glucose control AND HBA1C is less than or equal to 9.
Age Restrictions	18 or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Synagis**

#### **Products Affected**

• SYNAGIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Administration of more than 5 doses of palivizumab in one RSV season including Florida. Immunoprophylaxis for RSV for children who reach ages 24 months prior to the commencement of the RSV season. Treatment in children or infants with known RSV disease.
Required Medical Information	Immunoprophylaxis for respiratory syncytial virus (RSV) for the prevention of serious lower respiratory tract disease in infants and young children who are at high risk, when the following are met: A. Maximum of Five (5) doses of palivizumab within the RSV season which begins during the first year of life with any of the following clinical presentations: Born before 29 weeks 0 days gestation (up to and including 28 weeks, 6 days) and younger than 12 months of age at the start of the RSV season OR Chronic lung disease (CLD) of prematurity (defined as birth at less than 32 weeks, 0 days gestation and a requirement for greater than 21% oxygen for at least 28 days after birth) OR Hemodynamically significant congenital heart disease (CHD) (for example, but not limited to, infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension OR infants with anatomic pulmonary abnormalities (i.e., tracheal ring) or a neuromuscular condition that impairs the ability to clear secretions from the upper airway because of ineffective cough. B. Maximum of five (5) doses of palivizumab for children younger than 24 months of age with any of the following clinical presentations during the RSV season: Profoundly immunocompromised, such as severe combined immunodeficiency, advanced acquired immunodeficiency syndrome undergoing organ or hematopoietic stem cell transplant, or an absolute lymphocyte count of less than 100 cell/mm3 OR undergoing cardiac transplantation.

PA Criteria	Criteria Details
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	5 months
Other Criteria	C. An additional dose of palivizumab may be allowed for children who undergo cardiopulmonary bypass for surgical procedures. If cardiac or pulmonary hemodynamic support remains unchanged after surgery or if any other medically necessary criteria are present (for example, prematurity). D. A second season of palivizumab prophylaxis may be approved for preterm infants born at less than 32 weeks, 0 days gestation who required at least 28 days of oxygen after birth and who continue to require medical intervention within 6 months of the start of the second RSV season (for example, supplemental oxygen, chronic systemic corticosteroid therapy, or diuretics). E. An infant with cystic fibrosis in the first year of life with clinical evidence of CLD and/or nutritional compromise, defined as weight for length less than tenth percentile. A second season may be considered for children with severe lung disease (history of hospitalization, abnormal chest x-ray or CT scan) or weight for length less than tenth percentile.

# **Synarel Nasal Solution**

#### **Products Affected**

SYNAREL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Precocious puberty, defined as the beginning of secondary sexual maturation characteristics before age 8 in girls and before age 9 in boys.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Endometriosis: 6 months, all other indications: 1 year
Other Criteria	For gender dysphoria in adolescents: a) Fulfills the DSM V criteria for gender dysphoria, AND b) Has experienced puberty to at least Tanner stage, 2 AND c) Has (early) pubertal changes that have resulted in an increase of their gender dysphoria, AND d) Does not suffer from a psychiatric comorbidity that interferes with the diagnostic work-up or treatment, AND e) Has psychological and social support during treatment, AND f) Demonstrates knowledge and understanding of the expected outcomes of GnRH analog treatment.

# Synribo

#### **Products Affected**

SYNRIBO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Tafinlar**

#### **Products Affected**

• TAFINLAR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Tafinlar may not be approved for the treatment of individuals with wild type BRAF melanoma.
Required Medical Information	Documentation of BRAF V600E or V600K mutation.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	

# **Tagrisso**

#### **Products Affected**

• TAGRISSO ORAL TABLET 40 MG, 80 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	EGFR (epidermal growth factor receptor) T790M mutation is present and documentation is provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Takhzyro**

#### **Products Affected**

TAKHZYRO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	12 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	1.Using for prophylaxis against acute attacks of hereditary angioedema (HAE) for either: of the following: a. Short term prophylaxis prior to surgery, dental procedures or intubation OR b. Long term prophylaxis and individual has failed, or is intolerant to, or has contraindication (such as pregnant, or breastfeeding) to 17 alpha-alkylated androgens (e.g., danazol) or antifibrinolytic agents (e.g., aminocaproic acid) AND 2.Diagnosis is confirmed by C4 level below the lower limit of normal as defined by lab test and any of the following: a. C1 inhibitor antigenic level below the lower limit or normal as defined by lab test OR b. C1 inhibitor functional level below the lower limit of normal as defined by lab test OR c. Presence of a known HAE causing C1-INH mutation AND 3. Individual has a history of moderate or severe attacks (such as airway swelling, severe abdominal pain, facial swelling, nausea and vomiting, painful facial distortion).

### **Taltz**

- TALTZ AUTOINJECTOR
- TALTZ AUTOINJECTOR (2 PACK)
- TALTZ AUTOINJECTOR (3 PACK)
- TALTZ SYRINGE

- TALTZ SYRINGE (2 PACK)TALTZ SYRINGE (3 PACK)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Use of Taltz (ixekizumab) in combination with other immunosuppressive therapy or phototherapy. Use of Taltz (ixekizumab) in combination with other biologic drugs (such as adalimumab, brodalumab, certolizumab pegol, etanercept, infliximab, secukinumab, or ustekinumab). Individuals with Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC)-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Taltz (ixekizumab).
Required Medical Information	Diagnosis of moderate to severe plaque psoriasis with either of the following: Individual has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For a dx of moderate to severe plaque psoriasis, agent is used for any of the following reasons: To reduce signs/symptoms or To induce/maintain clinical response AND individual has failed to respond to, is intolerant of, or has a medical contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND member has tried and failed BOTH: Humira and Enbrel. Or (Humira/Enbrel) are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Cosentyx (secukinumab) or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR The individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction.

### **Tarceva**

#### **Products Affected**

• TARCEVA ORAL TABLET 100 MG, 150 MG, 25 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For NSCLC tumors that have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, a copy of the test results must be provided
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Targretin**

- bexarotene
- TARGRETIN ORAL
- TARGRETIN TOPICAL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Tasigna**

#### **Products Affected**

• TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Tasmar**

- TASMAR
- tolcapone

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Tazorac**

- tazarotene
- TAZORAC

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	May not be approved for cosmetic purposes such as, but not limited to the following: Photoaging, Wrinkles, Hyperpigmentation, Sun damage, or Melasma.
Required Medical Information	For psoriasis, individual has up to 20% of body surface area involvement.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For psoriasis, individual has had a prior trial and inadequate response to either of the following (AAD 2009): Any two (2) topical corticosteroids or any one (1) topical corticosteroids plus calcipotriene. For psoriasis use greater than 1 year, efficacy must be documented for continued use. Documentation may include chart notes, consultation notes.

# **Tecentriq**

#### **Products Affected**

• TECENTRIQ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has received treatment with another PD-1 agent (for example, nivolumab or pembrolizumab) and Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For locally advanced or metastatic urothelial carcinoma, disease has progressed during or following platinum-containing chemotherapy (for example, cisplatin) or has progressed within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy and has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. For metastatic non-small cell lung cancer (NSCLC) disease has progressed during or following platinum-containing chemotherapy (for example, cisplatin) and when anaplastic lymphoma kinase (ALK) or epidermal growth factor receptor (EGFR) genomic tumor aberrations are present, must have demonstrated disease progression on U.S. Food and Drug Administration (FDA) approved therapy and has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.

## **Tecfidera**

#### **Products Affected**

• TECFIDERA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using in combination with other immunomodulatory products (such as Aubagio, Gilenya, Tysabri, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy or Betaseron).
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Technivie**

#### **Products Affected**

• TECHNIVIE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	A copy of the baseline quantitative hepatitis C virus (HCV) RNA test result is provided to document baseline level of viremia AND One of the following: (1) Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016, CDC 2013). OR (2) Individual is unable to delay treatment for 6 months owing to concurrent factors [such as but not limited to, advanced liver disease (Metavir fibrosis stage of F3 or F42), post-liver transplant recipients, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), coexistent liver diseases (such as nonalcoholic steatohepatitis), chronic HCV infection-associated extrahepatic manifestations (such as membranoproliferative glomerulonephritis, glomerular disease, cryoglobulinemia syndrome)] (AASLD/IDSA 2016) AND Documentation is provided for a diagnosis of chronic CHC infection, which includes a reactive HCV antibody (CDC 2013) and a subsequent positive HCV RNA result (CDC 2013). Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016).
Age Restrictions	18 years of age or older
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. Individual has had a trial of Harvoni or Epclusa OR Individual is currently on and completing a course of therapy with the requested regimen.

## **Testosterone Inj**

- AVEED
- DEPO-TESTOSTERONE
- testosterone cypionate
- testosterone enanthate

- testosterone intramuscular
- testosterone propionate

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For initial use, Individual has a dx of (1) primary hypogonadism (congenital or acquired) such as but not limited to: Cryptorchidism OR Bilateral torsion OR Vanishing testis syndrome OR orchitis OR Orchiectomy OR Klinefelter Syndrome OR Chemotherapy OR Toxic damage from alcohol or heavy metals OR idiopathic primary hypogonadism. Or (2) Hypogonadotropic hypogonadism (congenital or acquired), such as but not limited to: Idiopathic luteinizing hormone-releasing hormone (LHRH deficiency) OR Pituitary-hypothalamic injury. OR (3) treatment of delayed puberty when ALL the criteria below are met: Individual is using to stimulate puberty and Documentation is provided indicating few to no signs of puberty. Or (4) treatment of breast cancer when the following are met: Female 1-5 years post-menopause and Individual is using secondarily for advanced inoperable metastatic (skeletal) breast cancer OR Premenopausal female who has benefited from oophorectomy and is considered to have a hormone responsive tumor. Or (5) treatment of HIV-infected male adults with low testosterone and HIV-associated weight loss and wasting. Or (6) for transgender individuals who meet ALL the following criteria: Individual has a diagnosis of gender dysphoria or gender identity disorder and goal of treatment is female-to-male gender reassignment. For Continuation of Testosterone Inj agents, (a) Individual met all diagnostic criteria for initial therapy and (b) Individual has had serum testosterone level measured in the previous 180 days and (c) Individual has obtained clinical benefits as noted by symptom improvement.

## **Thalomid**

#### **Products Affected**

• THALOMID ORAL CAPSULE 100 MG, 150 MG, 200 MG, 50 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Thiola

#### **Products Affected**

• THIOLA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Tibsovo**

#### **Products Affected**

• TIBSOVO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documented susceptible isocitrate dehydrogenase-1 (IDH1) (written or verbal attestation is acceptable)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Topamax**

- QUDEXY XR ORAL CAPSULE, SPRINKLE, ER 24HR 100 MG, 150 MG, 200 MG, 25 MG, 50 MG
- TOPAMAX ORAL CAPSULE, SPRINKLE
- TOPAMAX ORAL TABLET 100 MG, 200
   MG, 25 MG, 50 MG
- TOPIRAGEN ORAL TABLET 100 MG,

- 200 MG, 25 MG, 50 MG
- topiramate oral capsule, sprinkle
- TOPIRAMATE ORAL CAPSULE, SPRINKLE, ER 24HR 100 MG, 150 MG, 200 MG, 25 MG, 50 MG
- topiramate oral tablet 100 mg, 200 mg, 25 mg, 50 mg
- TROKENDI XR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For migraine headache prophylaxis, 12 years of age and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Topical Acne Antibiotic**

- VELTIN
- ZIANA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For dx of Acne, Individual has had a prior trial and inadequate response to the following: (1) One preferred generic topical tretinoin agent AND (2) One preferred generic erythromycin/benzoyl peroxide combination agent OR (3) One preferred generic clindamycin/benzoyl peroxide combination agent.

### **Topical Androgens**

- ANDROGEL TRANSDERMAL GEL IN METERED-DOSE PUMP 20.25 MG/1.25 GRAM (1.62 %)
- ANDROGEL TRANSDERMAL GEL IN PACKET 1.62 % (20.25 MG/1.25 GRAM), 1.62 % (40.5 MG/2.5 GRAM)
- testosterone transdermal gel in metereddose pump 20.25 mg/1.25 gram (1.62 %)
- testosterone transdermal gel in packet 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older. For transgender use, individual is 16 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a dx of (1) primary hypogonadism (congenital or acquired) such as but not limited to: Cryptorchidism OR Bilateral torsion OR orchitis OR Vanishing testis syndrome OR Orchiectomy OR Klinefelter Syndrome OR Chemotherapy OR Toxic damage from alcohol or heavy metals OR idiopathic primary hypogonadism. Or (2) Hypogonadotropic hypogonadism (congenital or acquired), such as but not limited to: Idiopathic luteinizing hormone-releasing hormone (LHRH deficiency) OR Pituitary-hypothalamic injury. Individual is transgender AND is using for a diagnosis of gender Dysphoria or gender Identity Disorder AND Goal of treatment is female-to-male gender reassignment.

# **Topical Onychomycosis**

- JUBLIA
- KERYDIN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has a confirmed fungal infection (i.e. physical exam).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had a trial of and inadequate response or intolerance to oral itraconazole and terbinafine. Or has a, contraindication, drug interaction or concomitant clinical condition (such as but not limited history of liver disease or concerns over hepatotoxicity, history of CHF) which make use of oral itraconazole and terbinafine unacceptable OR Individual has used requested medication within the previous 6 months.

## **Topical Tretinoin Agents**

- ATRALIN
- avita topical cream
- AVITA TOPICAL GEL
- RETIN-A
- RETIN-A MICRO
- RETIN-A MICRO PUMP

- TRETIN-X
- TRETIN-X CREAM KIT
- tretinoin
- tretinoin (emollient)
- tretinoin microspheres

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Topical tretinoin agents may not be approved for cosmetic purposes such as, but not limited to the following: Photoaging, Wrinkles, Hyperpigmentation, Sun damage, Melasma.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Torisel**

- temsirolimus
- TORISEL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For advanced renal cell carcinoma, individual is using for either of the following (A or B): (A) As first-line therapy as a single agent (monotherapy) for (either i or ii): (i) Relapsed metastatic disease or (ii) Surgically unresectable stage IV renal carcinoma in individuals with a poor prognosis as manifested by having at least 3 of the following (1 through 6): 1. Lactate dehydrogenase greater than 1.5 times the upper limit of normal or 2. Hemoglobin less than the lower limit of normal or 3. Corrected calcium level greater than 10mg/dL (2.5mmol/liter) or 4. Interval of less than a year from original diagnosis to the start of systemic therapy or 5. Karnofsky performance status less than or equal to 70 or ECOG performance score of 2 - 4 or 6. Greater than or equal to 2 sites of metastases. OR (B) For subsequent (second-line) therapy as a single agent (monotherapy) for relapsed metastatic or for surgically unresectable stage IV disease.

### **Tracleer**

- TRACLEER ORAL TABLET
- TRACLEER ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is concomitantly taking cyclosporine A or glyburide. Individual has a diagnosis of moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment or in the treatment of congestive heart failure with left ventricular dysfunction.
Required Medical Information	Catheterization-proven diagnosis of Pulmonary Arterial Hypertension (WHO Group I), and WHO Functional Class II-IV symptoms.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Transmucosal Fentanyl Citrate**

#### **Products Affected**

• fentanyl citrate

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using for the treatment of acute or postoperative pain. Using for treatment of migraine headache pain Using for non-cancer related breakthrough pain.
Required Medical Information	
Age Restrictions	Individual is 16 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has a diagnosis of active cancer with breakthrough cancer (such as, metastatic or locally invasive cancer for which the individual is currently seeking treatment) with breakthrough cancer pain AND Individual is already receiving opioid therapy and is TOLERANT to opioid therapy as defined as receiving around the clock medicine consisting of one of the following: At least 60mg morphine per day, OR At least 25mcg/hr transdermal fentanyl/hour, OR At least 30mg of oxycodone daily, OR At least 8mg of oral hydromorphone daily, OR At least 25mg of oral oxymorphone daily, OR An equianalgesic dose of another opioid for a week or longer. Individual will also continue around the clock opioids when taking transmucosal fentanyl Citrate for cancer related breakthrough pain.

### **Trelstar Line**

#### **Products Affected**

TRELSTAR DEPOT

• TRELSTAR INTRAMUSCULAR ML, 3.75 MG/2 SUSPENSION FOR RECONSTITUTION • TRELSTAR LA

SYRINGE 11.25 MG/2 ML, 22.5 MG/2 ML, 3.75 MG/2 ML

TRELSTAR INTRAMUSCULAR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7, or prostate specific antigen (PSA) value of 10-20 ng/mL) OR higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery OR Following radical prostatectomy as adjuvant therapy when lymph node metastases are present OR Locally advanced disease OR Other advanced, recurrent, or metastatic disease.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Tremfya**

#### **Products Affected**

• TREMFYA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using in combination with other immunosuppressive therapy (such as other biologic drugs or phototherapy). Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections. Individual has not had a tuberculin skin test or a Centers for Disease Control and Prevention-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Tremfya.
Required Medical Information	Diagnosis of moderate to severe plaque psoriasis with either of the following: Patient has greater than 5% of body surface area with plaque psoriasis OR Less than or equal to 5% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For a dx of chronic plaque psoriasis, agent is used for any of the following reasons: To reduce signs/symptoms or To induce/maintain clinical response AND individual has failed to respond to, is intolerant of, or has a medical contraindication to phototherapy or any ONE systemic therapy (for example acitretin, methotrexate, cyclosporine) AND member has had a trial of and an inadequate response or is intolerant to BOTH: Humira and Enbrel. For any of the above indications, if the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Tremfya or (b) Individuals age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Tremfya may be allowed without trial of preferred TNF agents (Enbrel/Humira).

# **Triptodur**

#### **Products Affected**

• TRIPTODUR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Precocious puberty, defined as beginning of secondary sexual characteristics before age 8 in girls and before age 9 in boys.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Tykerb**

#### **Products Affected**

• TYKERB

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Cancer has been confirmed HER2 positive
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Tysabri

#### **Products Affected**

• TYSABRI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using for Types of MS other than relapsing forms. Currently responsive to and tolerating another treatment for MS or CD. Current or prior history of progressive multifocal leukoencephalopathy (PML). Medical condition which significantly compromises the immune system including HIV infection or AIDS, leukemia, lymphoma or organ transplantation. Receiving chronic antineoplastics or immunosuppressants (for example, azathioprine). Receiving any other immune system modifying drugs such as interferon beta-1 (for example, Avonex). Positive test results for anti- John Cunningham virus (JCV) antibodies
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual is using as monotherapy for relapsing forms of multiple sclerosis (MS) who have had an inadequate response to, or are unable to tolerate, alternative treatments for MS. For diagnosis of Crohns disease, individual is enrolled in and met all conditions of the CD or MS Touch Prescribing Program.

### **Tyvaso**

- TYVASO
- TYVASO INSTITUTIONAL START KIT
- TYVASO REFILL KIT
- TYVASO STARTER KIT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnostic Criteria for PAH: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than or equal to 25mmhg, a pulmonary capillary wedge pressure (PCWP), left atrial pressure or left ventricular end diastolic pressure (LVEDP) less than or equal to 15mmhg AND a pulmonary vascular resistance (PVR) greater than 3 wood units. Criteria for Vasodilator Response: a favorable response is defined as a fall in mPAP of at least 10mmhg to an absolute mPAP of less than 40mmhg without a decrease in cardiac output, when challenged with inhaled nitric oxide, intravenous epoprostenol or intravenous adenosine.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For Tyvaso, patient must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to vasodilators AND meets one of the following patient selection criteria with New York Heart Association (NYHA) functional class III, or IV symptoms: World health Organization (WHO) Group I idiopathic pulmonary arterial hypertension including all subtypes of WHO Group I PAH or Pulmonary hypertension associated with connective tissue disorders (scleroderma, systemic sclerosis, etc.) or pulmonary hypertension associated with congenital heart defects.

## **Tyzeka**

#### **Products Affected**

• TYZEKA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	chronic hepatitis B with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.
Age Restrictions	Patient is 16 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Uptravi**

- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLETS, DOSE PACK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has a diagnosis of severe hepatic impairment (Child-Pugh Class C). In combination with prostacyclin analogs [such as but not limited to treprostinil (Orenitram, Remodulin, Tyvaso), Epoprostenol (Flolan, Veletri), Ventavis (iliprost)]
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has catheterization-proven diagnosis of pulmonary arterial hypertension (PAH) [World Health Organization (WHO) Group 1) AND individual has WHO functional class II-IV symptoms.

### **Valchlor**

#### **Products Affected**

VALCHLOR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Vancocin

#### **Products Affected**

FIRVANQ

mg

- VANCOCIN ORAL CAPSULE 125 MG, 250 MG
- vancomycin oral capsule 125 mg, 250

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual is being treated for enterocolitis caused by Staphylococcal aureus including methicillin-resistant strains. Individual is being treated for clostridium difficile AND individual has had a trial and inadequate response or intolerance to oral metronidazole for mild to moderate Clostridium difficile infection. OR individual is being treated for a severe or severe, complicated Clostridium difficile infection.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	14 days
Other Criteria	

### **Vectibix**

#### **Products Affected**

VECTIBIX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has received prior treatment with cetuximab (Erbitux) [Note: a course of cetuximab discontinued because of an adverse reaction is not considered prior treatment] OR Vectibix is used in combination with other anti-VEGF agents (e.g., bevacizumab) OR Vectibix is being used for more than one line (course) of therapy.
Required Medical Information	KRAS gene mutation testing is documented and the tumor is determined to be KRAS wild-type.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Used as a single agent or as part of combination therapy for stage IV colon, rectal, colorectal, small bowel or anal adenocarcinoma.

### Velcade

- BORTEZOMIB
- VELCADE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Vemlidy

#### **Products Affected**

• VEMLIDY

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has end stage renal disease (estimated creatinine clearance below 15 mL/min). Individual has decompensated (Child-Pugh B or C) hepatic impairment
Required Medical Information	
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Venclexta**

- VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Ventavis**

#### **Products Affected**

• VENTAVIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnostic Criteria for PAH: right heart catheterization which shows a mean pulmonary artery pressure (mPAP) greater than or equal to 25mmhg, a pulmonary capillary wedge pressure (PCWP), left atrial pressure or left ventricular end diastolic pressure (LVEDP) less than or equal to 15mmhg AND a pulmonary vascular resistance (PVR) greater than 3 wood units. Criteria for Vasodilator Response: a favorable response is defined as a fall in mPAP of at least 10mmhg to an absolute mPAP of less than 40mmhg without a decrease in cardiac output, when challenged with inhaled nitric oxide, intravenous epoprostenol or intravenous adenosine.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For Ventavis, patient must meet all of the following: meets diagnostic criteria for PAH AND demonstrates an unfavorable acute response to vasodilators AND meets one of the following patient selection criteria with New York Heart Association (NYHA) functional class III, or IV symptoms: World health Organization (WHO) Group I idiopathic pulmonary arterial hypertension including all subtypes of WHO Group I PAH or Pulmonary hypertension associated with connective tissue disorders (scleroderma, systemic sclerosis, etc.) or pulmonary hypertension associated with congenital heart defects.

## Verzenio

#### **Products Affected**

VERZENIO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Vfend

- VFEND
- voriconazole oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Transitioning from inpatient treatment with IV antifungal to an outpatient setting.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Vibativ**

#### **Products Affected**

VIBATIV

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 day supply/One time only
Other Criteria	Individual has started therapy in an inpatient setting and requires continued outpatient therapy for an organism susceptible to VIBATIV (telavancin). For hospital-acquired or ventilator-associated bacterial pneumonia (HABP or VABP), Individual has had a trial and an inadequate response or intolerance to or has a contraindication to at least one alternative antibiotic (such as but not limited to, intravenous vancomycin) (IDSA 2011, ATS/IDSA 2005). For complicated skin and skin structure infections (cSSSI), Individual has had an inadequate response to at least one alternative therapy (such as but not limited to, intravenous vancomycin) (IDSA 2014, 2011).

## **VIBERZI**

#### **Products Affected**

VIBERZI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has a history of severe constipation or sequelae from constipation OR Biliary duct obstruction or sphincter of Oddi dysfunction OR History of pancreatitis or structural disease of the pancreas OR Excessive alcohol intake (more than 3 alcoholic beverages per day) OR Severe hepatic impairment (Child-Pugh Class C).
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 Year
Other Criteria	Individual is using for the treatment of irritable bowel syndrome with diarrhea (IBS-D) AND has had a trial and inadequate response or intolerance to two of the following medications or has a contraindication to all of the following medications: 1. Loperamide OR 2. Antispasmodics (such as dicyclomine) OR 3. Tricyclic antidepressants (AGA 2014).

## **Victrelis**

#### **Products Affected**

VICTRELIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using in combination with another serine NS3/4A protease inhibitor, a NS5B polymerase inhibitor or NS5A inhibitor. Individual has received previous treatment for hepatitis C virus (HCV) with one of the following: An interferon-based triple therapy regimen, which includes ribavirin and an oral direct-acting antiviral [such as but not limited to, Incivek (telaprevir), Victrelis (boceprevir), Olysio (simeprevir), or Sovaldi (sofosbuvir)] OR a therapy regimen containing a NS5A inhibitor [such as but not limited to, Harvoni (ledipasvir/sofosbuvir) or ombitasvir)] OR a therapy regimen containing a serine NS3/4A protease inhibitor [such as but not limited to, Incivek (telaprevir), Victrelis (boceprevir), Olysio (simeprevir), or asunaprevir] OR a therapy regimen containing a NS5B polymerase inhibitor [such as but not limited to Sovaldi (sofosbuvir) or dasabuvir].
Required Medical Information	Documentation must be provided for a diagnosis of Hep C genotype 1 AND a copy of the baseline quantitative HCV RNA test result is provided to document baseline level of viremia AND using in combination with peginterferon alfa and ribavirin AND individual has compensated liver disease (with or without cirrhosis) AND individual will receive treatment with peginterferon alfa and ribavirin for 4 weeks (treatment weeks 1-4) prior to starting therapy with Victrelis. Documentation may include but is not limited to chart notes, prescription claims records, prescription receipts and laboratory data.
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. Individual has had a prior trial of and inadequate response to Harvoni. Individual will have access to sufficient quantity to complete an entire course of therapy.

## Vidaza

- azacitidine
- VIDAZA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Viekira

- VIEKIRA PAK
- VIEKIRA XR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual is requesting in concurrent therapy with alfuzosin, carbamazepine, phenytoin, phenobarbital, gemfibrozil, rifampin, ergot derivatives, ethinyl estradiol-containing agents, St. Johns Wort, lovastatin, simvastatin, pimozide, efavirenz, Revatio (sildenafil), triazolam, and oral midazolam. Individual is using in combination with another NS3/4A protease inhibitor [such as but not limited to Olysio (simeprevir). Individual is using in combination with another non-nucleoside NS5B polymerase inhibitor. Individual is using in combination with another NS5A inhibitor (such as but not limited to, Harvoni [ledipasvir/sofosbuvir]. Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of a serine NS3/4A protease inhibitor [such as but not limited to, Olysio (simeprevir), or paritaprevir] (AASLD/IDSA 2014). Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of ombitasvir. Individual is requesting the regimen for re-treatment and either failed to achieve a SVR (defined as a lower limit HCV RNA of 25 IU/mL) or relapsed after achieving a SVR during a prior successfully completed treatment regimen consisting of a nonnucleoside NS5B polymerase inhibitor, such as dasabuvir or a regimen containing a nucleotide NS5B polymerase inhibitor, such as Sovaldi or Harvoni (AASLD/IDSA 2014).

PA Criteria	Criteria Details
Required Medical Information	A copy of the baseline quantitative hepatitis C virus (HCV) RNA test result is provided to document baseline level of viremia AND One of the following: (1) Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016, CDC 2013). OR (2) Individual is unable to delay treatment for 6 months owing to concurrent factors [such as but not limited to, advanced liver disease (Metavir fibrosis stage of F3 or F42), post-liver transplant recipients, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), coexistent liver diseases (such as nonalcoholic steatohepatitis), chronic HCV infection-associated extrahepatic manifestations (such as membranoproliferative glomerulonephritis, glomerular disease, cryoglobulinemia syndrome)] (AASLD/IDSA 2016) AND Documentation is provided for a diagnosis of chronic CHC infection, which includes a reactive HCV antibody (CDC 2013) and a subsequent positive HCV RNA result (CDC 2013). Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. Individual has had a prior trial and inadequate response to Harvoni OR individual is currently on and completing a course of therapy with the requested regimen.

## **Vimizim**

#### **Products Affected**

VIMIZIM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Confirmed diagnosis of Morquio A syndrome by documented reduced fibroblast or leukocyte N-acetylgalactosamine-6-sulfatase (GALNS) enzyme activity or by genetic testing and Documented clinical signs and symptoms of Morquio A syndrome (for example, knee deformity, corneal opacity or pectus carinatum).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Virazole

- ribavirin inhalation
- VIRAZOLE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual is hospitalized and will receive treatment in an inpatient setting.

## **Vivitrol**

#### **Products Affected**

VIVITROL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For alcohol dependence, Individual is able to abstain from alcohol for at least 7 days in an outpatient setting prior to treatment initiation AND is not actively drinking at the time of initial injectable naltrexone (Vivitrol) administration AND actively participates in a comprehensive rehabilitation program that includes psychosocial support AND Individual is NOT currently on opioid analgesics OR not currently on opioid agonist for the treatment of opioid dependence (opioid use disorder) (for example buprenorphine and methadone) OR physiologically dependent on opioids OR currently in acute opioid withdrawal. Individual also does NOT have: a positive urine screen for opioids OR a failed naloxone challenge test OR acute hepatitis OR liver failure OR previous hypersensitivity to naltrexone, 75:25 polylactide-co-glycolide (PLG), carboxymethylcellulose or any other component of the diluent. For Opioid dependence, individual has successfully completed an opioid detoxification program AND has been opioid-free (including buprenorphine and methadone) for at least 7 days prior to initiating treatment with naltrexone (Vivitrol) injection AND actively participates in a comprehensive rehabilitation program that includes psychosocial support AND is NOT currently on opioid analgesics for pain management OR currently in acute opioid withdrawal. Individual also does NOT have a positive urine screen for opioids OR a failed naloxone challenge test OR acute hepatitis OR liver failure OR previous hypersensitivity to naltrexone, 75:25 polylactide-co-glycolide (PLG), carboxymethylcellulose or any other component of the diluent.
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Vosevi

#### **Products Affected**

VOSEVI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has severe renal impairment (eGFR less than 30 mL/min/1.73m2), end stage renal disease, or requires dialysis OR Individual has moderate or severe hepatic impairment (Child-Pugh B or C).
Required Medical Information	Copy of the baseline quantitative HCV RNA test result is provided to document baseline level of viremia AND Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016, CDC 2013). Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016). Individual has compensated liver disease (with or without cirrhosis).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.

PA Criteria	Criteria Details
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. For Genotype 1, 1a Individual has had a trial of and inadequate response to Harvoni OR Individual is currently on and completing a course of therapy with Vosevi OR has one of the following: (1) Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Harvoni which is not also in Vosevi OR (2) concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens OR (3) Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor or a Hepatitis C regimen containing sofosbuvir without an NS5A inhibitor. For Genotype 4 Individual has had a trial of and inadequate response to Harvoni or Epclusa OR Individual is currently on and completing a course of therapy with Vosevi OR has one of the following: (1) Documented hypersensitivity, as manifested by a severe allergic reaction to any ingredient in Harvoni or Epclusa which is not also in Vosevi OR (2) concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with the preferred regimen or regimens OR (3) Individual failed to achieve a sustained viral response (SVR) or relapsed after achieving a SVR during a prior successfully completed Hepatitis C regimen containing an NS5A inhibitor or a Hepatitis C regimen containing sofosbuvir without an NS5A inhibitor.

## **VOTRIENT**

#### **Products Affected**

VOTRIENT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Vraylar

- VRAYLAR ORAL CAPSULE
- VRAYLAR ORAL CAPSULE, DOSE PACK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Vytorin**

#### **Products Affected**

- ezetimibe-simvastatin
- VYTORIN 10-10
- VYTORIN 10-20
- VYTORIN 10-40

• VYTORIN 10-80

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Individual has had a trial of one generic statin (at any dose) AND Crestor (rosuvastatin) (at any dose) and provider attests the member has experienced failure, contraindication, or intolerance to statin therapy OR Individual is currently on an agent that interacts with both preferred generic and Crestor (rosuvastatin).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Xalkori

#### **Products Affected**

XALKORI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Xeljanz

- XELJANZ
- XELJANZ XR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Using in combination with a biologic disease-modifying antirheumatic drug (DMARDs) (such as but not limited to, TNF agents, anti-CD20 monoclonal antibodies, IL-1R antagonists, selective co-stimulation modulators) or potent immunosuppressants such as azathioprine and cyclosporine. At initiation of therapy, absolute neutrophil count (ANC) less than 1000 cells/mm3, lymphocyte count less than 500 cells/mm3, or hemoglobin less than 9 g/dL. Tuberculosis or other active serious infections or a history of recurrent infections. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC)-recommended equivalent to evaluate for latent tuberculosis prior to initiating Xeljanz. Individual has severe hepatic impairment (Child Pugh class C).
Required Medical Information	
Age Restrictions	18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	Individual is using to reduce sings/symptoms or induce/maintain clinical response or improve physical function AND had an inadequate response to, is intolerant of, or has a contraindication methotrexate and individual has had a trial of and an inadequate response or is intolerant to BOTH: Humira and Enbrel OR the TNF agent (Enbrel/Humira) tried and failed are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Xeljanz or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR mbr has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Xeljanz may be allowed without trial of preferred TNF agents (Enbrel/Humira).

### **XENAZINE**

- tetrabenazine oral tablet 12.5 mg, 25 mg
  XENAZINE ORAL TABLET 12.5 MG, 25 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Xermelo

#### **Products Affected**

• XERMELO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initial: 3 months. Continuation: 1 year
Other Criteria	For initial therapy: Individual is using in combination with somtostatin analog (SSA) therapy (such as but not limited to, lanreotide(Somatuline Depot), cotreotide (Sandostatin)) AND individual has had an inadequate response on a stable dose of SSA monotherapy for at least 3 months. For continuation therapy: Individual has previously met the initiation criteria AND if clinically significant improvements are confirmed after 12 weeks pf treatment with Xermelo (telotristat ethyl) when added to SSA therapy

# Xgeva

#### **Products Affected**

• XGEVA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Skeletally mature adolescent is defined by at least one mature long bone [for example, closed epiphyseal growth plate of the humerus]. Hypercalcemia of malignancy is defined as an albumin corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L).

## Xiaflex

#### **Products Affected**

• XIAFLEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Repeat injection of a previously treated cord within one year of a prior course for treating Dupuytren's contracture.
Required Medical Information	For Peyronie disease, stable disease as define by symptoms (that is, penile curvature and pain) for at least 6 months and Penile curvature greater than or equal to 30 and less than or equal to 90 degrees and Intact erectile function with or without use of medications and Palpable penile plaque. For Dupuytren's contracture, there is documented impairment to the individual's functional activities which measures either: 20 degrees or more at the metacarpophalangeal (MP) joint or 20 degrees or more at the proximal interphalangeal (PIP) joint.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## Xifaxan

#### **Products Affected**

• XIFAXAN ORAL TABLET 200 MG, 550 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	For HE and IBS, 18 years of age or older. For TD, 12 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For Xifaxan 200mg, travelers diarrhea (TD) caused by noninvasive strains of Escherichia coli AND Individual has already been started on Xifaxan and needs to complete treatment OR Individual has had a trial and inadequate response or intolerance to one of the following medications or has contraindications to all of the following medications (CDC, 2012): (1) Generic Fluoroquinolone OR (2) Azithromycin.

## Xiidra

#### **Products Affected**

• XIIDRA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Documentation is provided indicating an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods (AAO, 2013): (a) Tear break-up time (less than 10 seconds) OR (b) Ocular surface dye staining using fluorescein, rose bengal, or lissamine green dyes OR (c) Schirmer test (aqueous tear production of less than or equal to 10 mm of strip wetting in 5 minutes) OR (d) Fluorescein clearance test/tear function index OR (e)Tear osmolarity (indicating tear film instability) OR (f) Tear lactoferrin concentrations in the lacrimal gland (decreased).
Age Restrictions	17 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	Individual is using to treat moderate to severe dry eye disease (AAO 2013).

## Xolair

#### **Products Affected**

XOLAIR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Mbr has Moderate Persistent to Severe Persistent Asthma AND has a positive skin test or in vitro reactivity to a perennial aeroallergen, AND Mbr has an FEV1 less than 80% predicted AND Mbr IgE level is equal to or greater than 30 IU/ml. Severe asthma as defined by the National Heart, Lung, and Blood Institute: Severe Persistent Asthma: symptoms throughout the day, extremely limited normal activity. Nocturnal symptoms are frequent, FEV1 or PEF is less than or equal to 60% predicted. Moderate Persistent Asthma as defined by the National Heart, Lung, and Blood Institute: Daily symptoms, daily use of inhaled short-acting beta2-agonist, somewhat limited activity, Nocturnal symptoms occur greater than 1 time per week, FEV1 or PEF is greater than 60% and less then 80% predicted, FEV1 FVC is reduced 5 percent or exacerbations requiring oral systemic corticosteroids use for more than or equal to 2 times per year.
Age Restrictions	Patient is 12 years of age or older for urticaria and 6 years of age or older for moderate to severe persistent asthma
Prescriber Restrictions	
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	For moderate to severe persistent asthma, Mbr symptoms are inadequately controlled after a minimum of 3 months with combination controller therapy (medium to high doses of inhaled corticosteroids plus long acting beta-2 agonists or Leukotriene modifiers), or cannot tolerate these medications. Continued treatment beyond 12 months is allowed when treatment has resulted in clinical improvement as documented by one or more of the following: Decreased utilization of rescue medications OR Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids) OR Increase in percent predicted FEV1 from pretreatment baseline OR Reduction in reported asthma-related symptoms, such as, but not limited to, wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening. For chronic idiopathic urticaria, individual is refractory to prior treatment of ONE potent antihistamine at maximal FDA approved dosage.

## Xtandi

#### **Products Affected**

XTANDI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has had a previous trial and inadequate response or intolerance to Zytiga (abiraterone) OR Individual has visceral metastases.

## Xuriden

#### **Products Affected**

• XURIDEN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Xyrem**

#### **Products Affected**

• XYREM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For initial tx of Narcolepsy type 1 (narcolepsy with cataplexy) confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and at least one of the following: (1) Clear cataplexy (defined as more than one episode of generally brief [less than 2 min]) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness) AND (2) Multiple Sleep Latency Test (MSLT) showing one of the following: (a) MSLT of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014) or (b) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG) OR (3) Cerebrospinal fluid hypocretin-1 deficiency (less than 110 pg/mL or less than one-third of the normative values with the same standardized assay).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initial Request 3 months, Renewal is 6 months.

PA Criteria	Criteria Details
Other Criteria	For initial tx, of Narcolepsy type 2 (narcolepsy without cataplexy) confirmed by the following: (1) Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months AND (2) MSLT showing one of the following: (a) MSLT of less than 8 minutes with evidence of two SOREMPs (ICSD-3, 2014) or (b) At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight PSG AND (3) absence of cataplexy AND (4) Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and PSG. AND (5) Mbr has had a previous trial of and inadequate response or intolerance to TWO of the following medications: (i) Modafinil or (ii) Nuvigil (armodafinil) AND (B) One of the following stimulants: (i) Methylphenidate (ii) Dextroamphetamine or (iii) Amphetamine/dextroamphetamine salt immediate-release OR (6) Trials of wakefulness promoting agents and stimulant agents are not acceptable due to concomitant clinical situations including but not limited to the following: (1) Cardiovascular disease or (2) Drug interactions. For Renewal of Narcolepsy type I or II, Xyrem (sodium oxybate) use has resulted in a reduction in frequency of cataplexy attacks OR use has resulted in a reduction in excessive daytime sleepiness (EDS) as measured by improvement in Epworth Sleepiness Scale (ESS) measurements or Maintenance of Wakefulness Test (MWT). For continuation, use has resulted in a reduction in frequency of cataplexy attacks compared to baseline OR use has resulted in a reduction in excessive daytime sleepiness (EDS) as measured by improvement in Epworth Sleepiness Scale (ESS) measurements or Maintenance of Wakefulness Test (MWT) compared to baseline

### Yervoy

#### **Products Affected**

YERVOY

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has autoimmune disease which requires treatment with immunosuppressant drugs.
Required Medical Information	Individual has unresectable or metastatic melanoma AND individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Used in combination with nivolumab (Opdivo) as: (a) First-line therapy or (b) Second-line or subsequent therapy for disease progression if nivolumab was not previously used or Ipilimumab is used as a single agent for one of the following: (a) First line therapy as a single course of 4 treatments or (b) Second-line or subsequent lines of therapy as a single course of 4 treatments or (c) Retreatment, consisting of a 4-dose limit, for an individual who had no significant systemic toxicity during prior ipilimumab therapy, and whose disease progressed after being stable for greater than 6 months following completion of a prior course of ipilimumab, and for whom no intervening therapy has been administered. OR used for the adjuvant treatment of cutaneous melanoma in individuals with pathologic involvement of regional lymph nodes of more than 1 millimeter who have undergone complete resection, including lymphadenetomy.

### Yonsa

#### **Products Affected**

YONSA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year.
Other Criteria	

# Zaltrap

#### **Products Affected**

• ZALTRAP

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Diagnosis of metastatic anal adenocarcinoma or metastatic appendicle adenocarcinoma or metastatic small bowel adenocarcinoma or metastatic colorectal cancer AND used in combination with an irinotecan based regimen AND individual is resistant to or has disease progression following treatment with an oxaliplatin containing regimen AND Zaltrap will be used in a single line of therapy.

### Zavesca

#### **Products Affected**

- miglustat ZAVESCA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	May not be approved for use in conjunction with Cerdelga (eliglustat) or enzyme replacement therapy (ERT) agents (Cerezyme, Elelyso or Vpriv). Severe Type 1 Gaucher disease (hemoglobin less than 9 g/dL, platelet count less than 50,000 mm3 or those at risk developing new bone complications) (Weinreb et al. 2005). Individual has severe renal impairment (less than 30 mL/min/1.73 m2). Individual has mild, moderate or severe hepatic impairment or cirrhosis.
Required Medical Information	Presence of type 1 (non-neuropathic) Gaucher disease is confirmed by either of the following (Weinreb et al. 2004, Wang et al. 2011): Glucocerebrosidase activity in the white blood cells or skin fibroblasts less than or equal to 30% of normal activity, OR genotype testing indicating mutation of two alleles of the glucocerebrosidase genome. And patient has clinically significant manifestations of Type 1 gauchers disease including any of the following: skeletal disease (demonstrated by radiologic evidence of ANY of the following (Weineb et al. 2004):: avascular necrosis, erlenmeyer flask deformity, lytic disease, marrow infiltration, osteopenia, osteosclerosis, pathological fracture, joint deterioration or replacement) OR patient presents with at least 2 of the following (Weinreb et al. 2004, Mistry et al. 2015): clinically significant hepatomegaly as confirmed by medical imaging (such as but limited to, volumetric MRI), clinically significant splenomegaly as confirmed by medical imaging (such as but limited to, volumetric MRI), hgb less than or equal to 11.5 grams per dl for females or 12.5 grams per deciliter for males or 1 gram per deciliter below lower limit for normal for age and sex, platelet counts less than or equal to 120,000 mm3.
Age Restrictions	Individual is 18 years of age or older
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	1 year
Other Criteria	Enzyme replacement therapy with Cerezyme, ELELYSO or VPRIV is not a therapeutic option for reasons such as but limited to any of the following (Label, Weinreb et al. 2005): (a) Medically unmanageable hypersensitivity or (b) Development of therapy-limiting inhibitory antibodies or (c) Poor peripheral or central venous access.

# Zejula

#### **Products Affected**

• ZEJULA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	In the last 8 weeks, the individual has had a complete or partial response to a platinum-based chemotherapy.

### Zelboraf

#### **Products Affected**

• ZELBORAF

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individuals with wild-type BRAF melanoma.
Required Medical Information	Individual has BRAF mutation and a copy of the BRAF test results must be provided.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Zepatier

#### **Products Affected**

• ZEPATIER

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	A copy of the baseline quantitative hepatitis C virus (HCV) RNA test result is provided to document baseline level of viremia AND One of the following: (1) Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a positive HCV RNA test result at least 6 months following either a baseline positive HCV RNA result or reactive HCV antibody test (AASLD/IDSA 2016, CDC 2013). OR (2) Individual is unable to delay treatment for 6 months owing to concurrent factors [such as but not limited to, advanced liver disease (Metavir fibrosis stage of F3 or F42), post-liver transplant recipients, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), coexistent liver diseases (such as nonalcoholic steatohepatitis), chronic HCV infection-associated extrahepatic manifestations (such as membranoproliferative glomerulonephritis, glomerular disease, cryoglobulinemia syndrome)] (AASLD/IDSA 2016) AND Documentation is provided for a diagnosis of chronic CHC infection, which includes a reactive HCV antibody (CDC 2013) and a subsequent positive HCV RNA result (CDC 2013). Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016). If Genotype 1a subtype is present, a copy of the baseline NS5A resistant-associated polymorphism test result is provided.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, Individual has had a prior trial and inadequate response to Harvoni. For GT 4, individual has had a prior trial and inadequate response to Harvoni or Epclusa. OR individual is currently on and completing a course of therapy with the requested regimen.

### Zinbryta

#### **Products Affected**

ZINBRYTA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Members with primary progressive MS. Members with secondary progressive MS. Individuals with hepatic disease, hepatic impairment and autoimmune conditions involving the liver.
Required Medical Information	
Age Restrictions	18 years of age and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# Zinplava

#### **Products Affected**

• ZINPLAVA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual has confirmed Clostridium difficile infection when the following are met: (a) Passage of three or more loose stools within 24 hours or less AND (b) Positive stool test for toxigenic Clostridium difficile from a stool sample collected not more than 7 days prior to scheduled infusion AND (c) currently receiving antibacterial therapy for Clostridium difficile infection AND (d) Individual is at high risk of Clostridium difficile infection recurrence meeting any one of the following: (1) Individual 65 years of age or older, with a history of Clostridium difficile infection in the past 6 months or (2) Immunocompromised state or (3) Severe Clostridium difficile infection at presentation or (4) Clostridium difficile ribotype 027.

### Zolinza

#### **Products Affected**

• ZOLINZA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Zometa**

#### **Products Affected**

- ZOLEDRONIC AC-MANNITOL-0.9NACL
- zoledronic acid
- ZOMETA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Bone metastases documented on imaging or bone pain associated with imaging-documented metastases from breast, prostate, lung, kidney, thyroid, or other solid tumors.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For Breast cancer, prevention of bone loss secondary to adjuvant hormone therapy OR for early stage, premenopausal breast cancer, prevention of bone loss secondary to ovarian dysfunction induced by adjuvant chemotherapy therapy OR glucocorticoidinduced osteoporosis (OP) in men and women who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5mg or greater of prednisone and who are expected to remain on glucocorticoids for at least 12 months OR OP treatment to increase bone mass in men OR OP treatment and prevention in postmenopausal women OR Paget's disease of bone in men and women indicated with elevation in serum alkaline phosphatase of 2 times or higher than the upper limit of the agespecific normal reference range or those who are symptomatic or at risk for complication from their disease.

# Zurampic

#### **Products Affected**

• ZURAMPIC

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Individual has severe renal impairment (creatinine clearance less than 30mL/min), end stage renal disease, is on dialysis or is a kidney transplant recipient. Individual has Lesch-Nyhan syndrome or tumor lysis syndrome.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Individual remains symptomatic (such as, but not limited to joint pain, swelling, limited range of motion, erythema) despite use of xanthine oxidase inhibitor

# **Z**ydelig

#### **Products Affected**

• ZYDELIG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### Zykadia

#### **Products Affected**

ZYKADIA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

# **Zytiga**

#### **Products Affected**

• ZYTIGA ORAL TABLET 250 MG, 500 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

### **Zyvox**

#### **Products Affected**

- linezolid oral suspension for reconstitution
- linezolid oral tablet
- ZYVOX ORAL SUSPENSION FOR

RECONSTITUTION
• ZYVOX ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Confirmed vancomycin-resistant enterococcus faecium (VRE) infection. Confirmed methicillin-resistant S. aureus (MRSA) infection AND individual has had a trial and inadequate response or intolerance to or has contraindications to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: vancomycin, TMP-SMX, clindamycin, doxycycline, tetracycline (Based on 2011 IDSA MRSA guideline recommendations)). Individual started treatment with Zyvox in the hospital and requires continued outpatient therapy. Isolates of MRSA have a vancomycin minimum inhibitory concentration (MIC) of greater than 2.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 days
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