

## 2019 Simply Prior Authorization Document

# Abraxane

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### Products Affected

- ABRAXANE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 persistent or recurrent ovarian cancer (epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer) when the individual is using either as a single agent or agent is being used in combination with carboplatin in a platinum-sensitive individual with confirmed taxane (that is solvent-based paclitaxel or docetaxel) hypersensitivity.

# Abstral

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## Products Affected

- ABSTRAL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Treatment of acute or postoperative pain OR treatment of migraine headache pain OR treatment of non-cancer related breakthrough pain.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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
- ACTEMRA ACTPEN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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/mm <sup>3</sup> , platelet count below 100,000/mm <sup>3</sup> , or ALT or AST above 1.5 times the upper limit of normal.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 clinically significant infection (for example, Hepatitis</p>
	<p>B or Hepatitis C) and has no concurrent lymphoma. For Giant Cell Arteritis, agent is used in combination with a tapering course of corticosteroids (such as, prednisone) OR being used as a single agent after discontinuing corticosteroids.</p>

# Actimmune

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## Products Affected

- ACTIMMUNE

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

# Actiq

## Products Affected

- ACTIQ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Treatment of acute or postoperative pain OR treatment of migraine headache pain OR treatment of non-cancer related breakthrough pain
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 16 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- ADCETRIS

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 maintenance therapy for 1 yr following high dose therapy and autologous stem cell rescue for relapsed or refractory dx those who are brentuximab vedotin naive and have Deauville score less than 5 OR Using as single agent, palliative treatment option for relapsed or refractory dx in adults older than 60 yrs. 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 CD30+ non-Hodgkins Lymphoma with either one of the following: cutaneous anaplastic large cell lymphoma OR cutaneous T-cell lymphoma, including mycosis fungoides/Sezary syndrome which is relapsed, refractory or as first line therapy for advanced disease presentation (for example, folliculotropic, large cell transformation or extracutaneous disease) OR relapsed or refractory disease after at least one prior multi-agent chemotherapy regimen for treatment of ANY if the following: a) systemic anaplastic large cell lymphoma b) T-cell lymphoma (excluding cutaneous T-cell lymphoma) c) Lymphomatoid papulosis that is symptomatic or characterized by extensive cutaneous lesions d) as a single-agent for adult T-cell leukemia/lymphoma after high dose therapy and autologous stem cell rescue OR e) adjuvant systemic therapy for breast implant-associated anaplastic large cell lymphoma for either of the following: residual, localized disease (confined to capsule/implant/breast) following partial excision or capsulectomy OR extended disease (stage II-IV).</p>



# Adcirca

## Products Affected

- ADCIRCA
- ALYQ
- *tadalafil (antihypertensive)*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	Catheterization-proven diagnosis of Pulmonary Arterial Hypertension World Health Organization (WHO) Group 1. Individual has WHO functional class II- IV symptoms.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Addyi

## Products Affected

- ADDYI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years old
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	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

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## Products Affected

- ADEMPAS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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)]. Individual has a diagnosis of severe hepatic impairment (Child-Pugh class C). Individual is on dialysis or has creatinine clearance less than 15 ml/min. Individual has a diagnosis of pulmonary veno-occlusive disease (PVOD), or pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	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 endarterectomy OR Inoperable (via pulmonary endarterectomy) CTEPH.

# AFINITOR

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## Products Affected

- AFINITOR
- AFINITOR DISPERZ

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

# 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), 8 UNIT (90)/ 12 UNIT (90)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Individual has had a physical examination including detailed medical history to identify potential lung disease.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- AIMOVIG AUTOINJECTOR (2 PACK)
- AIMOVIG AUTOINJECTOR  
SUBCUTANEOUS AUTO-INJECTOR 140  
MG/ML, 70 MG/ML

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



PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>

# Ajovy

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## Products Affected

- AJOVY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months, Maintenance: 1 Year
<b>Other Criteria</b>	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 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) AND (II) Individual is using for migraine prophylaxis. For Renewal requests: Individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month AND Individual has obtained clinical benefit deemed significant by individual or prescriber.

# Aldurazyme

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## Products Affected

- ALDURAZYME

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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).</p>

# Alecensa

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## Products Affected

- ALECENSA

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

# Alimta

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## Products Affected

- ALIMTA

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

# Aliqopa

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## Products Affected

- ALIQOPA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 1 year. Continuation 6 months.
<b>Other Criteria</b>	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

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## Products Affected

- ALOXI
- *palonosetron intravenous solution 0.25 mg/2 ml*
- *palonosetron intravenous syringe*

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



# Alpha1-Proteinase Inhibitor

## Products Affected

- ARALAST
- ARALAST NP
- GLASSIA
- PROLASTIN
- PROLASTIN-C
- ZEMAIRA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Alpha 1 proteinase inhibitors may not be approved for individuals with IgA antibodies.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Alunbrig

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## Products Affected

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

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

# Amphetamine Salts

## Products Affected

- *dextroamphetamine-amphetamine oral capsule, extended release 24hr* 30 mg, 5 mg, 7.5 mg
- *dextroamphetamine-amphetamine oral tablet 10 mg, 12.5 mg, 15 mg, 20 mg,*

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

# Amphetamine Salts - B

## Products Affected

- ADDERALL ORAL TABLET 10 MG, 12.5 MG, 15 MG, 20 MG, 30 MG, 5 MG, 7.5 MG
- ADDERALL XR
- MYDAYIS

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

# Ampyra

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## Products Affected

- AMPYRA
- *dalfampridine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Member has a history of seizures, OR moderate or severe renal impairment (defined as creatinine clearance less than or equal to 50 mL/min)
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval 12 weeks, renewal 1 year
<b>Other Criteria</b>	

# Anadrol 50

## Products Affected

- ANADROL-50

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	For Delayed puberty: age 14 years of age or older. For all other: 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year
<b>Other Criteria</b>	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

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## Products Affected

- APOKYN

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



# Aranesp

## Products Affected

- ARANESP (IN POLYSORBATE)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	<p>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 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 myelosuppressive chemotherapy and anemia can be managed by transfusion. 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. Pre-operative use for patients who are willing to donate autologous blood.</p>

PA Criteria	Criteria Details
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	8wk.
<b>Other Criteria</b>	

# Arcalyst

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## Products Affected

- ARCALYST

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

# Arzerra

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## Products Affected

- ARZERRA

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

# AUBAGIO

## Products Affected

- AUBAGIO

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

# Auryxia

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## Products Affected

- AURYXIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has a diagnosis of an iron overload syndrome (for example, hemochromatosis) or has a diagnosis of iron deficiency anemia associated with chronic kidney disease (CKD) stages 3, 4, or 5 and is not on dialysis [Not Part D].
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Austedo

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## Products Affected

- AUSTEDO

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For initial requests, Individual has a diagnosis of chorea associated with Huntington's disease. Has a diagnosis of Tardive dyskinesia confirmed by the following DSM-5 AND (a.) At least 60 days of stable (drug, dose) 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 drugs 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. For continuation requests, Individual has experienced an improvement in symptoms deemed to be clinically significant by the provider (verbal attestation).</p>



# AVASTIN

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## Products Affected

- AVASTIN
- MVASI

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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, 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, is being used in combination with both platinum based therapies with a taxane or pemetrexed for the first-line tx 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, is being used as first-line therapy in combination with paclitaxel or paclitaxel protein bound. For Metastatic Clear Cell Renal Carcinoma (RCC), 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 or for relapsed or medically unresectable stage IV non-clear cell RCC (including papillary RCC and hereditary leiomyomatosis and RCC (HLRCC) in combination with erlotinib or everolimus. 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</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>or recurrent ependymoma that has failed radiation therapy, Anaplastic glioma, High-grade glioma, Recurrent, Glioblastoma, OR Glioblastoma multiforme. For recurrent, metastatic epithelial ovarian cancer, fallopian tube cancer, or recurrent primary peritoneal cancer, 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 OR approved for maintenance therapy when all of the following are met: previously used as first line combination chemotherapy regimen and used as a single agent and used until disease progression. For malignant mesothelioma, in combination with cisplatin or carboplatin and pemetrexed. 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.</p>

# Balversa

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## Products Affected

- BALVERSA ORAL TABLET 3 MG, 4 MG, 5 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has confirmed (written or verbal attestation) disease susceptible to genetic alterations.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Banzel

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## Products Affected

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

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

# Baraclude

## Products Affected

- BARACLUDE
- *entecavir*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has a diagnosis of Chronic Hepatitis B virus (HBV) infection and has not been previously treated with lamivudine (AASLD 2016) OR is using as prophylaxis for hepatitis B reactivation in the setting of immune suppression (AGA 2015) or in combination with hepatitis C direct-acting antiviral therapy (AASLD 2017) OR Individual is post liver-transplantation and using in combination with Hepatitis B immunoglobulin (HBIG) for hepatitis B virus recurrence prophylaxis (EASL 2017).
<b>Age Restrictions</b>	2 years of age and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Bavencio

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## Products Affected

- BAVENCIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 for metastatic merkel cell carcinoma and locally advanced or metastatic urothelial carcinoma.
<b>Age Restrictions</b>	12 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>For metastatic merkel cell carcinoma, Bavencio is used when individual has not received treatment with another PD-1 (programed death receptor -1) agent (for example, Opdivo or Keytruda) and is not receiving treatment with a systemic immunosuppressant. For locally advanced or metastatic urothelial carcinoma, Bavencio is used as a single agent and individual has not received treatment with another PD-1 agent (for example, Opdivo or Keytruda) and is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant and individual meets ONE of the following criteria: has demonstrated disease progression on or after platinum-containing chemotherapy or has demonstrated disease progression within 12 months of receiving neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.</p>



# Beleodaq

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## Products Affected

- BELEODAQ

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

# Benlysta

## Products Affected

- BENLYSTA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Berinert

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## Products Affected

- BERINERT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Prophylaxis for HAE attacks.
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	Individual is 5 years or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- BLINCYTO

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

# Bosulif

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## Products Affected

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

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

# Botox-Myobloc-Dysport

## Products Affected

- BOTOX
- DYSPORT
- MYOBLOC
- XEOMIN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Botulinum toxin is considered cosmetic as a treatment of skin wrinkles or other cosmetic indications and is not approvable.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	1 year, chronic migrains 6months
<b>Other Criteria</b>	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

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## Products Affected

- BRAFTOVI ORAL CAPSULE 50 MG, 75 MG

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

# Briviact

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 16 years of age or older. For oral tablets and solution, Individual is 4 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Buphenyl

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## Products Affected

- BUPHENYL
- *sodium phenylbutyrate*

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

# Cabometyx

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## Products Affected

- CABOMETYX

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

# Calquence

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## Products Affected

- CALQUENCE

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

# Caprelsa

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## Products Affected

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

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

# Carbaglu

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## Products Affected

- CARBAGLU

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

# Cayston

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## Products Affected

- CAYSTON

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



# Celebrex

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## Products Affected

- CELEBREX
- *celecoxib*

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

# Cequa

## Products Affected

- CEQUA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has an abnormal result or response to one or more of the following dry eye disease diagnostic/assessment methods (AAO, 2018): 1) Tear break-up time (less than 10 seconds) or 2) Ocular surface dye staining using fluorescein, rose bengal, or lissamine green dyes or 3) Schirmer test (aqueous tear production of less than or equal to 10 mm of strip wetting in 5 minutes) or 4) Fluorescein clearance test/tear function index or 5) Tear osmolality (indicating tear film instability) or 6) Tear lactoferrin concentrations in the lacrimal gland (decreased) or 7) Matrix metalloproteinase-9 (MMP-9) test.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual using for moderate to severe dry eye AND has had a trial and inadequate response or intolerance to Xiidra OR has a known hypersensitivity to any ingredient to Xiidra (preferred agent) which is not also present in the requested non-preferred agent

# Cerdelga

## Products Affected

- CERDELGA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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 ultra-rapid 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.
<b>Required Medical Information</b>	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 mm <sup>3</sup> OR (C) individual is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as confirmed by a FDA-approved genotype test.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Chantix

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## Products Affected

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

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

# Chenodal

## Products Affected

- CHENODAL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has large or nonfloatable stones OR has calcified (radiopaque) or radiolucent bile pigment stones OR has preexisting hepatic impairment OR has known hepatocyte dysfunction or bile ductal abnormalities (such as but not limited to intrahepatic cholestasis, primary biliary cirrhosis, or sclerosing cholangitis) OR has a gallbladder confirmed as nonvisualizing after two consecutive single doses of dye OR has gallstone complications or compelling reasons for gallbladder surgery (such as but not limited to unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary gastrointestinal fistula).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	2 years. Requests to continue therapy beyond 24 months (2 years) should not be approved.
<b>Other Criteria</b>	Individual is using for gallstone dissolution AND has a well-opacifying gallbladder with radiolucent stones AND has an increased surgical risk due to systemic disease or advanced age. For continuation, Repeat imaging studies show partial (or complete) dissolution of gallstone(s) AND Documentation has been provided.

# Cholbam

## Products Affected

- CHOLBAM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Used to treat extrahepatic manifestations (such as but not limited to neurologic symptoms) of SED-associated-BASDs or PDs.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial therapy: 3 months. Continuation therapy: 1 year
<b>Other Criteria</b>	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.

# Chorionic Gonadotropin

## Products Affected

- *chorionic gonadotropin, human* SOLN 5,000 UNIT
- *novarel intramuscular recon soln 10,000 unit* • *pregnyl*
- NOVAREL INTRAMUSCULAR RECON

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Use in the following: Infertility treatments (Including use with IVF, ART), Obesity, Weight loss, Stimulation of spermatogenesis in males, Treatment of anovulation in females with infertility, Ovulation induction in females.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Individual is using for Pre-pubertal cryptorchidism not caused by anatomical obstruction in males OR Hypogonadotropic hypogonadism from pituitary deficiency in males.



# Cialis BPH

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## Products Affected

- CIALIS ORAL TABLET 2.5 MG, 5 MG

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

# Cimzia

## Products Affected

- CIMZIA
- CIMZIA POWDER FOR RECONST
- CIMZIA STARTER KIT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Individual has chronic moderate to severe (that is, extensive or disabling) 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).
<b>Age Restrictions</b>	Individual is 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For plaque psoriasis, agent is being used to either reduce signs/symptoms OR induce/maintain clinical response AND individual has had a trial of and inadequate response or intolerance to BOTH Enbrel and Humira. For Crohn's Disease, agent is being used to reduce signs/symptoms OR induce/maintain clinical response. Individual 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 Individual 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. Individual has failed to respond to, is intolerant of, or has a medical contraindication to ONE nonbiologic DMARDs AND Individual 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. Individual 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. Individual 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 trail and an inadequate response or is intolerant to BOTH: Humira AND Enbrel. For dx of non-radiographic axial spondyloarthritis (nr-axSpA), individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAID or nonbiologic DMARDS (such as sulfasalazine)] (ACR 2015).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</p>
	<p>the following: (a) Known hypersensitivity or any active or inactive component which is not also associated with Cimzia or (b) Individuals age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis.</p>

# Cinqair

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## Products Affected

- CINQAIR

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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</p>

# Cinryze

## Products Affected

- CINRYZE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	6 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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-alpha-alkylated androgens or antifibrinolytic agents.

# Cometriq

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## 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)

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

# Copaxone

## Products Affected

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



# Copiktra

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## Products Affected

- COPIKTRA

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

# Corlanor

## Products Affected

- CORLANOR ORAL SOLUTION
- CORLANOR ORAL TABLET

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has a heart rate maintained exclusively by a pacemaker. Individual has severe hypotension (blood pressure less than 90/50 mmHg). Individual has severe hepatic impairment (Child-Pugh Class C).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	(A) Individual is using for the treatment of New York Heart Association (NYHA) class II, III or IV heart failure symptoms. OR (B) Individual is using for the treatment of New York Heart Association (NYHA) class II, III, or IV heart failure symptoms due to dilated cardiomyopathy AND has a left ventricular ejection fraction less than or equal to 45% AND is in normal sinus rhythm AND If initiating treatment with Corlanor, individual has an elevated resting heart rate.

# Cosentyx

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Using Cosentyx in combination with other biologic drugs such as Enbrel (etanercept), Humira (adalimumab), certolizumab pegol (Cimzia), Remicade (infliximab), ixekizumab (Taltz), 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.
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 Enbrel OR 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 tumor necrosis factor (TNF) antagonist AND Individual has had a trial of and an inadequate response or is intolerant to Enbrel OR 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 nonbiologic DMARDs or TNF antagonist) AND Individual has had a trial of and an inadequate response or is intolerant to Enbrel OR 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).</p>

# Cotellic

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## Products Affected

- COTELLIC

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

# Cresemba

## Products Affected

- CRESEMBA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual initiated treatment in an inpatient setting and requires continued treatment of invasive aspergilliosis or mucormycosis in an outpatient setting. For invasive aspergilliosis 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).

# Crinone

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## Products Affected

- CRINONE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Progesterone supplementation or replacement as part of an Assisted Reproductive Technology ("ART") treatment for infertile women with progesterone deficiency, Progesterone supplementation/deficiency.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Cyramza

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## Products Affected

- CYRAMZA

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



# D.H.E Inj

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## Products Affected

- D.H.E.45
- *dihydroergotamine injection*

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

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>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 a.-c): (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 a.-d.): (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).</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For cluster headache episodes in adults meeting the following International Headache Society diagnostic criteria: At least five or more attacks (must also meet criteria a.-d.): (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 approved: For Status migrainosus or rebound withdrawal type of headaches OR As alternative to narcotic therapy for severe migraine or cluster headaches OR individual is unresponsive to prior use of triptans for severe migraine or cluster headache.</p>

# DAKLINZA

**Products Affected**

- DAKLINZA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and a reactive HCV antibody, and a subsequent positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND 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).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, 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 OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni (ledipasvir/sofosbuvir) which is not also in Daklinza OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with 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 OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni or Epclusa which is not also in Daklinza OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni or Epclusa.</p>

# Daliresp

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## Products Affected

- DALIRESP

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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)
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual is currently or will be concomitantly using with a long-acting bronchodilator.

# Darzalex

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## Products Affected

- DARZALEX

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

# Daurismo

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## Products Affected

- DAURISMO ORAL TABLET 100 MG, 25 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 75 years old or older OR has comorbidities that preclude use of intensive induction chemotherapy.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	



# Desoxyn

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## Products Affected

- DESOXYN
- *methamphetamine*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 6 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

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

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

# Dificid

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## Products Affected

- DIFICID

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has had a trial and inadequate response or intolerance to or has a contraindication to a course of oral vancomycin.
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	

# Doptelet

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## Products Affected

- DOPELET
- DOPELET (10 TAB PACK)
- DOPELET (15 TAB PACK)
- DOPELET (30 TAB PACK)

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

# Doxil

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## Products Affected

- DOXIL
- *doxorubicin, peg-liposomal*
- *lipodox*
- *lipodox 50*

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

# 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 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 m <sup>2</sup> )] AND Individual has had a trial and inadequate response or intolerance to Januvia (sitagliptin) or Tradjenta (linagliptin).

# Duavee

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## Products Affected

- DUAVEE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Age 18 through age 75
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Duexis

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## Products Affected

- DUEXIS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	Individual has had a trial and inadequate response or intolerance to one (1) oral generic prescription Non-Steroidal Anti-Inflammatory Drugs (NSAID) AND has had a trial and inadequate response or intolerance to one (1) of the following (Lanza 2009): (a.) Generic proton pump inhibitor (PPI) OR (b.) Generic misoprostol OR(c.) Generic histamine-2 receptor antagonist (H2RA) AND Individual has had an adequate response (pain relief and appropriate gastro protection) with a trial of ibuprofen and famotidine used at the same time AND Documentation has been provided for why the combination agent is clinically necessary and not for convenience.



# Duobrii

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## Products Affected

- DUOBRII

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	Individual has a diagnosis of plaque psoriasis AND Documentation (verbal or written) has been provided for why the combination agent is clinically necessary and not for convenience.

# Duopa

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## Products Affected

- DUOPA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 levodopa-carbidopa, a Dopamine agonist [such as, but limited to Apokyn (apomorphine), Mirapex (pramipexole), Requip (ropinirole) and Neupro (rotigotine)], a catechol-O-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

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## Products Affected

- DUPIXENT SUBCUTANEOUS SYRINGE  
200 MG/1.14 ML, 300 MG/2 ML

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>

# Duragesic Patch

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## Products Affected

- DURAGESIC
- *fentanyl*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 OR (c) 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. For continued use, Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline.</p>

# Duzallo

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## Products Affected

- DUZALLO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation provided for why Duzallo (lesinurad and allopurinol) combination agent is clinically necessary (written or verbal attestation is acceptable).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.

# Egrifta

## Products Affected

- EGRIFTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	For initial requests, individual has a body mass index (BMI) is greater than 20 kg/m <sup>2</sup> 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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 6 months, renewal 1 year.



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	

# Elaprase

## Products Affected

- ELAPRASE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 pathologic iduronate 2-sulfatase gene mutation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- ELIDEL
- *pimecrolimus*

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

# ELIGARD\_GNRH

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## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, 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 Other advanced, recurrent, or metastatic disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Elitek

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## Products Affected

- ELITEK

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has a diagnosis of glucose-6-phosphate dehydrogenase (G6PD) deficiency.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	Individual has been diagnosed with leukemia, lymphoma or other hematologic malignancy with risk factors for tumor lysis syndrome AND Individual is receiving chemotherapy.

# Elzonris

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## Products Affected

- ELZONRIS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has a current Eastern Cooperative Oncology Group (ECOG) status of 0-1.
<b>Age Restrictions</b>	2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Emflaza

## Products Affected

- EMFLAZA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	One of the following: (1) 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. Or (2) Documentation has been provided regarding the presence of clinically significant neuropsychiatric side effects while on prednisone (such as but not limited to aggression) AND Neuropsychiatric side effects are likely to be the direct result of prednisone use.
<b>Age Restrictions</b>	Individual is 2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>For initial treatment of Duchenne Muscular Dystrophy (DMD) AND Individual has had a 6 month trial of oral prednisone (AAN 2016, DrugPoints B, IIa). Request for continuation of therapy when one of the following: (1) when approved due to excess weight gain with prednisone, individual has experienced a return to baseline growth curve expectations or remained on the same growth curve that was in effect when Emflaza was initiated (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) Or (2) When approved due to neuropsychiatric side effects while on prednisone, individual has shown improvement in neuropsychiatric symptoms.</p>



# Emgality

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## Products Affected

- EMGALITY PEN
- EMGALITY SYRINGE SUBCUTANEOUS  
SYRINGE 120 MG/ML, 300 MG/3 ML (100  
MG/ML X 3)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months, Maintenance: 1 Year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For Initial requests of migraine prophylaxis: (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 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) AND (II) Individual is using for migraine prophylaxis. For Renewal requests: (I) For Migraine Prophylaxis: (a) Individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month AND (b) has obtained clinical benefit deemed significant by individual or prescriber. (II) For treatment of Episodic Cluster HA: (a) Individual has a reduction in the overall number of cluster headache periods AND (b) has obtained clinical benefit deemed significant by individual or prescriber.</p>

# Empliciti

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## Products Affected

- EMPLICITI

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

# Emsam

## Products Affected

- EMSAM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Individual has no known contraindications to the use of a monoamine oxidase inhibitor (MAOI).
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Enbrel

## Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS RECON SOLN
- ENBREL SUBCUTANEOUS SYRINGE 25 MG/0.5 ML (0.5), 50 MG/ML (1 ML)
- ENBREL SURECLICK

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Etanercept 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 infections or history of recurrent infections. Individual who have not had a tuberculin skin test or a CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating etanercept.
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year except for Initial high dose tx chronic plaque psoriasis 12 wk

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>

# Entresto

## Products Affected

- ENTRESTO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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 m <sup>2</sup> ).
<b>Required Medical Information</b>	Individual has a left ventricular ejection fraction less than or equal to 40%.
<b>Age Restrictions</b>	Individual is 18 years or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Entyvio

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## Products Affected

- ENTYVIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 6 years or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year



PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 is not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:</p> <ul style="list-style-type: none"> <li>(a) Known hypersensitivity or any active or inactive component which is not also associated with Entyvio or</li> <li>(b) Individual's age or</li> <li>(c) Pregnant or planning or becoming pregnant or</li> <li>(d) Serious infections or concurrent sepsis OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, (c) Malignancy [such as, but not limited to, solid or hematologic cancers excluding superficial skin cancers (such as basal and squamous cell)], or (d) tuberculosis infection. Entyvio may be allowed without trial of preferred TNF agents (Humira).</li> </ul>

# Epclusa

## Products Affected

- EPCLUSA
- *sofosbuvir-velpatasvir*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and a reactive HCV antibody, and a subsequent positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND 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).
<b>Age Restrictions</b>	Individual is 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

# Epidiolex

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## Products Affected

- EPIDIOLEX

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

# Epogen and Procrit

## Products Affected

- EPOGEN
- PROCIT
- RETACRIT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	<p>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.</p> <p>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. Anemia in cancer patients receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. 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 patients who are willing to donate autologous blood.</p>

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	8wk.
<b>Other Criteria</b>	<p>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.</p>

# Eraxis

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## Products Affected

- ERAXIS(WATER DILUENT)

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

# Erbitux

## Products Affected

- ERBITUX

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Erbitux is used in combination with other anti-VEGF agents (e.g., bevacizumab). Erbitux is used in more than one line of therapy.
<b>Required Medical Information</b>	For stage IV, kras wild type colon, rectal, colorectal, small bowel, appendix, 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Erivedge

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## Products Affected

- ERIVEDGE

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



# Erleada

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## Products Affected

- ERLEADA

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

# Erwinase

## Products Affected

- ERWINAZE

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

# Esbriet

## Products Affected

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

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

# Ethyol

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## Products Affected

- *amifostine crystalline*
- ETHYOL

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

# Evekeo

## Products Affected

- *amphetamine sulfate oral tablet 10 mg, 5 mg* MG, 20 MG, 5 MG
- EVEKEO ORAL TABLET 10 MG, 5 MG
- EVEKEO ODT ORAL TABLET,DISINTEGRATING 10 MG, 15

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	3 years of age or older for attention deficit hyperactivity disorder (ADHD). 6 years of age or older for narcolepsy.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Evenity

## Products Affected

- EVENITY SUBCUTANEOUS SYRINGE 105 MG/1.17 ML, 210MG/2.34ML (105MG/1.17MLX2)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual is using Evenity (romosozumab-aqqg) in combination with any of the following: Prolia (denosumab), Bisphosphonates, Evista (raloxifene), Miacalcin/Fortical (calcitonin nasal spray), Reclast (zoledronic acid), Forteo (teriparatide), Tymlos (abaloparatide).
<b>Required Medical Information</b>	Osteoporosis is defined as a BMD T-Score in the spine, femoral neck, total hip or distal 1/3 of the radius 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Individual meets one of the following: (A) Individual has been refractory to 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. 5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate. Individual has utilized Evenity (romosozumab-aqqg) for a total duration of less than 12 months in their lifetime.</p>

# Exjade

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## Products Affected

- *deferasirox*
- EXJADE

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



# Exondys 51

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## Products Affected

- EXONDYS 51

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has a confirmed genetic mutation of the DMD gene that is amenable to exon 51 skipping
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For initial use in the treatment of Duchenne muscular dystrophy (DMD), individual is ambulatory (with or without needing an assistive device, such as a cane or walker). For continued therapy following each 12 month period post initiation of therapy, the initial therapy has been met AND the individual remains ambulatory (with or without needing an assistive device, such as a cane or walker).

# Eylea

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## Products Affected

- EYLEA

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

# Fabrazyme

## Products Affected

- FABRAZYME

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 8 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

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

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

# Fasenra

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## Products Affected

- FASENRA PEN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Evidence of asthma is demonstrated by the following (NAEPP, 2008): (a) pretreatment forced expiratory volume in 1 second (FEV1) less than 80% predicted AND (b) FEV1 reversibility of at least 12% and 200 milliliters after albuterol administration.
<b>Age Restrictions</b>	12 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For Initial use, individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting beta2 -agonists, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS, 2013) AND has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid or temporary increase in the individual's usual maintenance dosage of oral corticosteroids (ERS/ATS, 2013) AND has a blood eosinophil count (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 300 cells/microliter (300 cells/mm<sup>3</sup>) at initiation of therapy. For Continuation use, treatment has resulted in clinical improvement as confirmed by one or more of the following: (a) decreased utilization of rescue medications OR (b) decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic corticosteroids) OR (c) increase in percent predicted FEV1 from pretreatment baseline OR (d) reduction in reported asthma-related symptoms, such as asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing.</p>

# Faslodex

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## Products Affected

- FASLODEX
- *fulvestrant*

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

# Fentora

## Products Affected

- FENTANYL CITRATE BUCCAL TABLET, MCG, 600 MCG, 800 MCG EFFERVESCENT
- FENTORA BUCCAL TABLET, EFFERVESCENT 100 MCG, 200 MCG, 400

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Using for treatment of acute or postoperative pain OR migraine headache pain OR non-cancer related pain.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- FERRIPROX

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

# Fetzima

## Products Affected

- FETZIMA ORAL CAPSULE,EXT REL 24HR 80 MG DOSE PACK
- FETZIMA ORAL CAPSULE,EXTENDED RELEASE 24 HR 120 MG, 20 MG, 40 MG,

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	May not be approved for treatment of fibromyalgia
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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
- *icatibant*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Prophylaxis for HAE attacks.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 Icatibant for acute HAE attacks.

# Firdapse

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## Products Affected

- FIRDAPSE
- RUZURGI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	History of seizures or Using in combination with compounded form of 3,4 diaminopyridine
<b>Required Medical Information</b>	Diagnosis is confirmed by one of the following: Presence of anti-P/Q type voltage-gated calcium channel (VGCC) antibodies or Characteristic electrodiagnostic findings.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For initial requests, individual has diagnosis of Lambert Eaton myasthenic syndrome. Continued treatment with Firdapse may be approved when there is objective evidence that the individual achieved and sustained meaningful improvement in muscle strength.

# Firmagon

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, 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 Used for progressive castration-naïve disease or for castration-recurrent disease OR Other advanced, recurrent, or metastatic disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Flector Patch

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## Products Affected

- DICLOFENAC EPOLAMINE
- FLECTOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual is not using Forteo (teriparatide) in combination with any of the following: Prolia (denosumab), Bisphosphonates, Evista (raloxifene), Miacalcin/Fortical (calcitonin nasal spray), Recalst (zoledronic acid), or Tymlos (abaloparatide).
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	2 years. Requests to continue therapy beyond 24 months (2 years) should not be approved.
<b>Other Criteria</b>	Individual has one of the following: (A) Individual has been refractory to 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. 5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate.



# Fusilev

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## Products Affected

- FUSILEV
- KHAPZORY
- *levoleucovorin calcium*

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

# GamaSTAN

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## Products Affected

- GAMASTAN
- GAMASTAN S/D

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p> <p>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, non-immune individuals will receive a vaccine containing the measles virus greater than or equal to 6 months after 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 contraindication or an initial exposure greater than 72 hours) or no evidence of measles immunity in particular pregnant woman or severely immunocompromised individuals. For post-exposure prophylaxis of varicella infection in susceptible individuals (such as, immunocompromised) AND varicella-zoster immune globulin (human) (VZIG) and immune globulin intravenous (IGIV) are not available. For post-exposure prophylaxis administered within 72 hours of exposure to a confirmed case of rubella to modify to suppress symptoms (label, CDC 2001) AND</p>
	<p>mbr is in the early stages (first trimester) of pregnancy, and will not consider terminating the pregnancy under any circumstance.</p>

# Gamifant

## Products Affected

- GAMIFANT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has a diagnosis of active primary active primary hemophagocytic lymphohistiocytosis (HLH) as confirmed (written or verbal attestation is acceptable) by one of the following: 1) A genetic mutation known to cause HLH or 2) A family history consistent with primary HLH or 3) Individual meets five of the following criteria: Fever, Splenomegaly, Cytopenias affecting 2 of 3 lineages in the peripheral blood (HGB less than 9g/dL (or less than 10g/dL in infants), platelets less than $100 \times 10^9/L$ , neutrophils less than $1 \times 10^9/L$ ), Hypertriglyceridemia (fasting TG greater than or equal to 265mg/dL) and/or hypofibrinogenemia (fibrinogen less than or equal to 1.5g/L), Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy, Low or absent NK-cell activity, Ferritin greater than or equal to 500 mcg/L, Soluble CD25 greater than or equal to 2400U/mL
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual is using in combination with dexamethasone AND has had an inadequate response to, is intolerant of or has a contraindication to conventional therapy (such as etoposide, dexamethasone or cyclosporine).

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November 2019

# Gattex

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## Products Affected

- GATTEX 30-VIAL
- GATTEX ONE-VIAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For diagnosis of Short Bowel Syndrome (SBS) individual 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

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## Products Affected

- CEREZYME
- ELELYSO
- VPRIV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	<p>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 2 or more 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 mm<sup>3</sup>. [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 mm<sup>3</sup> 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 ophthalmoscopy, 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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	



# Gazyva

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## Products Affected

- GAZYVA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year
<b>Other Criteria</b>	Gazyva may be approved for the treatment of follicular lymphoma when used as a component of ONE of the following combination therapies regimens and as monotherapy for up to 24 months or until disease progression, following the listed combination therapy regimens: cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP regimen) or cyclophosphamide, vincristine, and prednisone (CVP regimen) or bendamustine.

# Gilenya

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## Products Affected

- GILENYA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent use with other MS disease modifying agents (such as, Aubagio, Tecfidera, Tysabri, Copaxone/Glutopa, 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.

PA Criteria	Criteria Details
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Gilotrif

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## Products Affected

- GILOTRIF

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Test results confirmed for individuals with metastatic non-small cell lung cancer (NSCLC) with non-resistant epidermal growth factor receptor (EGFR) mutation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Gleevec

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## Products Affected

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

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

# Gleostine

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## Products Affected

- GLEOSTINE

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

# Granix

## Products Affected

- GRANIX

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	Prognostic factors predictive of clinical deterioration: Expected prolonged (greater than 10 day) and profound (less than 0.1 x 10 <sup>9</sup> /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 1500/mm <sup>3</sup> ), 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is between the ages of 5 years and 65 years old.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	12 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- HALAVEN

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation is provided for a diagnosis of chronic Hepatitis C virus (CHC) infection, which includes Genotype and a reactive HCV antibody, and a subsequent positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND 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).
<b>Age Restrictions</b>	12 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

# Hepsera

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## Products Affected

- *adefovir*
- HEPSERA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	12 years of age and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has had a previous trial and inadequate response or intolerance to or has a contraindication to an alternative antiviral agent with a higher genetic barrier to resistance for Hepatitis B [such as entecavir or tenofovir] (AASLD 2016).

# Hetlioz

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## Products Affected

- HETLIOZ

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

# Horizant

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## Products Affected

- HORIZANT ORAL TABLET EXTENDED RELEASE 300 MG, 600 MG

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

# HP Acthar

## Products Affected

- ACTHAR
- ACTHAR H.P.

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	For West Syndrome, infant and children less than 2 years of age.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 month
<b>Other Criteria</b>	



# HRM Age

## Products Affected

- *amitriptyline*
- *amitriptyline-chlordiazepoxide*
- *amoxapine*
- ANAFRANIL
- *clomipramine*
- *desipramine*
- *doxepin oral*
- *imipramine hcl*
- *imipramine pamoate*
- NEMBUTAL SODIUM
- NORPRAMIN
- *nortriptyline oral capsule*
- NORTRIPTYLINE ORAL SOLUTION
- PAMELOR
- *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*
- *protriptyline*
- SURMONTIL
- TOFRANIL
- TOFRANIL-PM
- *trimipramine*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge this is a high risk medication (HRM) (as identified by American Geriatric Society) for individuals greater than 65 and medication benefits outweigh potential risk for this individual.
<b>Age Restrictions</b>	Individuals that are 64 years of age or younger are NOT subject to the prior authorization requirements. Prior Authorization applies to individuals that are 65 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# HRM Age AU

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## Products Affected

- ACTIVELLA
- ALAGESIC LQ
- ALLZITAL
- ALORA
- *amabelz*
- AMBIEN
- AMBIEN CR
- AMRIX
- AMYTAL
- ANGELIQ
- ANTIVERT
- *arbinoxa*
- ARMOUR THYROID
- *ascomp with codeine*
- BENTYL ORAL
- *benztropine oral*
- BONJESTA
- BUPAP
- BUTALBITAL COMPOUND
- *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
- CAPACET
- *carbinoxamine maleate*
- *carisoprodol*
- *carisoprodol-asa-codeine*
- *carisoprodol-aspirin*
- CENESTIN
- *chlordiazepoxide-clidinium*
- *chlorpropamide oral tablet 100 mg, 250 mg*
- *chlorzoxazone oral tablet 375 mg, 500 mg, 750 mg*
- *clemastine oral syrup*
- *clemastine oral tablet 2.68 mg*
- CLIMARA
- CLIMARA PRO
- *codeine-butalbital-asa-caff*
- COMBIPATCH
- COMFORT PAC-CYCLOBENZAPRINE
- COMPLETE ALLERGY MEDICINE
- *cyclobenzaprine*
- *cyproheptadine*
- DEMEROL (PF)
- DEMEROL INJECTION
- DEMEROL ORAL
- *dexchlorpheniramine maleate*
- DIABETA ORAL TABLET 1.25 MG, 2.5 MG, 5 MG
- DICLEGIS
- *dicyclomine oral*
- *digitek oral tablet 250 mcg (0.25 mg)*
- *digox oral tablet 250 mcg (0.25 mg)*
- *digoxin injection solution*
- *digoxin oral tablet 250 mcg (0.25 mg)*
- *diphenhydramine hcl oral*
- *diphenoxylate-atropine*
- *dipyridamole oral*
- *disopyramide phosphate*
- DIVIGEL
- DOTTI
- *doxylamine-pyridoxine (vit b6)*
- DYTUSS
- EDLUAR
- ELESTRIN
- ENJUVIA
- *ergoloid*
- ESGIC
- ESTRACE ORAL
- ESTRADERM
- *estradiol oral*
- *estradiol transdermal patch semiweekly*
- *estradiol transdermal patch weekly*
- *estradiol-norethindrone acet*
- ESTRASORB
- ESTROGEL

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November 2019

- *estropipate*
- *eszopiclone*
- 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 ORAL
- *indomethacin*
- *indomethacin sodium*
- INTERMEZZO
- *jevantique lo*
- *jinteli*
- KARBINAL ER
- *ketorolac injection cartridge*
- *ketorolac injection solution*
- *ketorolac injection syringe 30 mg/ml*
- *ketorolac intramuscular*
- *ketorolac oral*
- LANOXIN INJECTION
- LANOXIN ORAL TABLET 187.5 MCG (0.1875 MG), 250 MCG (0.25 MG)
- LIBRAX (WITH CLIDINIUM)
- LOMOTIL
- *lopreeza oral tablet 0.5-0.1 mg*
- LOPREEZA ORAL TABLET 1-0.5 MG
- LORZONE
- LUNESTA
- 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*
- *meprobamate*
- METAXALL
- *metaxalone*
- *methocarbamol*
- *methyldopa*
- *methyldopa-hydrochlorothiazide*
- *methyldopate*
- MIMVEY
- *mimvey lo*
- MINIVELLE
- MOTOFEN
- *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*
- NORGESIC FORTE
- NORPACE
- NORPACE CR
- *np thyroid oral tablet 120 mg, 15 mg*
- NP THYROID ORAL TABLET 30 MG, 60 MG, 90 MG
- OGEN 2.5
- ORBIVAN
- ORBIVAN CF
- *orphenadrine citrate*
- ORPHENADRINE COMPOUND
- ORPHENADRINE COMPOUND-DS

Y0114\_19\_36674\_I\_011

November 2019

- *orphenadrine-asa-caffeine*
- ORPHENGESIC FORTE
- PALGIC
- *pentazocine-naloxone*
- PERSANTINE
- *phenadoz*
- PHENERGAN INJECTION
- *phenergan rectal*
- PHRENILIN FORTE(WITH CAFFEINE)
- PREFEST
- PREMARIN ORAL
- PREMPHASE
- PREMPRO
- PROCARDIA
- *promethazine*
- *promethazine vc*
- *promethazine-phenylephrine*
- *promethegan*
- *propantheline*
- REPAN
- *reserpine*
- ROBAXIN
- ROBAXIN-750
- RYCLORA
- RYVENT
- SECONAL SODIUM
- SILENOR
- SKELAXIN
- SOMA
- SONATA ORAL CAPSULE 10 MG, 5 MG
- TALWIN
- *tencon*
- TENEX
- *thyroid (pork)*
- *ticlopidine*
- *trihexyphenidyl*
- VANATOL LQ
- VANATOL S
- VISTARIL
- VIVELLE-DOT
- *zaleplon oral capsule 10 mg, 5 mg*
- ZEBUTAL
- *zolpidem*
- ZOLPIMIST

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge this is a high risk medication (HRM) (as identified by American Geriatric Society) for individuals greater than 65 and medication benefits outweigh potential risk for this individual.
<b>Age Restrictions</b>	Individuals that are 64 years of age or younger are NOT subject to the prior authorization requirements. Prior Authorization applies to individuals that are 65 years of age or older.
<b>Prescriber Restrictions</b>	

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Human Growth Hormone

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## Products Affected

- NORDITROPIN FLEXPRO
- NORDITROPIN NORDIFLEX
- OMNITROPE

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	<p>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</p>

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For idiopathic GHD, has signs/sym of GHD, GV 2 SD below age-appropriate mean or ht 2.25 SD below age-appropriate mean and A subnormal (SubNL) response (less than 10ng/ml) to 2GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml) OR 2 other 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 than 10 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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	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

## Products Affected

- HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML, 40 MG/0.8 ML (6 PACK)
- HUMIRA PEN
- HUMIRA PEN CROHNS-UC-HS START
- HUMIRA PEN PSOR-UEVITS-ADOL HS
- HUMIRA SUBCUTANEOUS SYRINGE KIT 10 MG/0.2 ML, 20 MG/0.4 ML, 40 MG/0.8 ML
- HUMIRA(CF) PEDI CROHNS STARTER SUBCUTANEOUS SYRINGE KIT 80 MG/0.8 ML, 80 MG/0.8 ML-40 MG/0.4 ML
- HUMIRA(CF) PEN
- HUMIRA(CF) PEN CROHNS-UC-HS
- HUMIRA(CF) PEN PSOR-UV-ADOL HS
- HUMIRA(CF) SUBCUTANEOUS SYRINGE KIT 10 MG/0.1 ML, 20 MG/0.2 ML, 40 MG/0.4 ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Using adalimumab in combination with other TNF agents, Abatacept, tofacitinib, or Kineret (anakinra). Tuberculosis, invasive fungal infection, or other active serious infections or a history of recurrent infections. Individuals who have not had a tuberculin skin test or CDC-recommended equivalent to evaluate for latent tuberculosis prior to initiating adalimumab.
<b>Required Medical Information</b>	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 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.
<b>Age Restrictions</b>	Patient is 18 years of age or older for all indications except JIA, non-infectious Uveitis, Hidradenitis Suppurativa (HS) and Crohns disease. Patient must be at least 2 years old for JIA and non-infectious uveitis. Patient must be at least 6 years of age for Crohns disease. Patient must be at least 12 years old for HS.
<b>Prescriber Restrictions</b>	

PA Criteria	Criteria Details
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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 nonbiologic 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 nonbiologic 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, systemic corticosteroids, or immunosuppressive drugs). For</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	uveitis, individual has chronic, recurrent, treatment-refractory or vision-threatening disease and has failed to respond to, is intolerant 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).

# Humulin U500

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## Products Affected

- HUMULIN R U-500 (CONC) INSULIN
- HUMULIN R U-500 (CONC) KWIKPEN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	For use as a continuous subcutaneous infusion.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	Individual has a diagnosis of diabetes mellitus AND requires more than 200 units of insulin per day.

# Ibrance

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## Products Affected

- IBRANCE

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

# Iclusig

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## Products Affected

- ICLUSIG ORAL TABLET 15 MG, 45 MG

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

# Idhifa

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## Products Affected

- IDHIFA ORAL TABLET 100 MG, 50 MG

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



# Ilaris

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## Products Affected

- ILARIS (PF)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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 Ilaris (canakinumab). Using Ilaris in combination with other biologic disease-modifying antirheumatic drugs (DMARDs), such as, tumor necrosis factor (TNF) antagonists, IL-1R antagonists, Janus kinase inhibitors (for example, tofacitinib citrate), or IL-6 receptor antagonists.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	For cryopyrin-associated periodic syndromes age 4 years and older and for systemic juvenile idiopathic arthritis 2 years of age and older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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) AND may be used alone or in combination with corticosteroids, methotrexate or 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.</p>

# Ilumya

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## Products Affected

- ILUMYA

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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).</p>

# Imbruvica

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## Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG, 560 MG

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

# Imfinzi

## Products Affected

- IMFINZI

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	For locally advanced or metastatic urothelial carcinoma, Inoperable or metastatic transitional-cell urothelial carcinoma histologically or cytologically confirmed. For locally advanced, unresectable non-small cell lung cancer, histologically or cytologically confirmed stage III and current Eastern Cooperative Oncology Group performance status 0-2.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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. For locally advanced, unresectable non-small cell lung cancer (NSCLC), disease has not progressed after definitive chemoradioation and disease has progressed or individual has reached a maximum of 12 months of treatment.

# Incivek

## Products Affected

- INCIVEK

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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].
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 18 years of age or older
<b>Prescriber Restrictions</b>	

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	12 weeks
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 INITIATION PACK
- INGREZZA ORAL CAPSULE 40 MG, 80 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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)
<b>Required Medical Information</b>	Tardive dyskinesia confirmed by the following (DSM-5): A) At least 60 days of stable (drug, dose) 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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Requests for continuation of therapy may be approved for individuals who meet the following criteria: Individual has experienced an improvement in symptoms deemed to be clinically significant by the provider.

# Inlyta

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## Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

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

# Inrebic

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## Products Affected

- INREBIC

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

# Interferons for MS

## Products Affected

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

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

# Intuniv

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## Products Affected

- *guanfacine oral tablet extended release*  
24 hr
- INTUNIV ER

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

# Istodax

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## Products Affected

- ISTODAX
- ROMIDEPSIN

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

# ITRACONAZOLE

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## Products Affected

- *itraconazole oral capsule*
- SPORANOX ORAL CAPSULE
- SPORANOX PULSEPAK

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	For fingernail/toenail onychomycosis 12 weeks. For all other indications 1 year.
<b>Other Criteria</b>	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

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## Products Affected

- GAMUNEX
- GAMUNEX-C
- OCTAGAM

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

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), medical records show clinical presentation not consistent with other polyneuropathies AND a) proximal weakness or sensory dysfunction caused by neuropathy and nerve conduction studies confirm electrodiagnostic evidence of demyelinating neuropathy in at least 2 limbs OR b) distal muscle weakness and results of diagnostic testing meet recognized set of diagnostic criteria as established by AAN, Saperstien or INTAC. Cont use for CIDP, shows improvement in neurological sx as documented on physical exam AND cont need demonstrated by documentation that annual attempts to titrate dose or interval of therapy results in worsening sx. Multifocal Motor Neuropathy (MMN) presents with asymmetric weakness that mainly affects distal muscles AND nerve conduction studies confirm demyelinating neuropathy is present (conduction block, slowing or abnormal temporal dispersion in at least one nerve) OR clinical hx nor exam suggest upper motor neuron DZ (no bulbar weakness nor upper motor neuron signs) and GM-1 antibody titers are elevated OR after initial exam and electrodiagnostic testing clinical presentation suggests MMN but dx remains uncertain. Cont use for MMN, clinical results document improvement in strength and fx within 3wks of start of infusion and need is demonstrated by documentation that annual attempts to titrate the dose or interval of therapy results in worsening of sx. Dermatomyositis confirmed by presence of skin lesions OR For polymyositis, AND both dx must have at least 4 of the following: weakness in trunk or proximal extremities, elevated serum creatinine kinase or aldolase level, muscle pain not otherwise explained, characteristic electromyography finds, presence of anti-Jo-1 antibody, arthralgia/arthritis without joint destruction, evidence of systemic inflammation or inflammatory myositis seen on muscle biopsy.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>To reduce risk of GvHD with interstitial pneumonia and infections in allogeneic bone marrow transplant pts in the first 100dys post-transplant. Hx and physical exam characteristic of Myasthenia Gravis AND presence of antibodies (AB) against at least 1 neuromuscular junction protein OR characteristic findings on repetitive nerve stimulation or single-fiber electromyography. Stiff-person syndrome not controlled by other therapies. TSS caused by staph or strep refractory to several hrs of aggressive therapy. Tx of chronic parvovirus B19 infection and severe anemia assoc with bone marrow suppression. Refractory auto-immune mucocutaneous blistering DZs: pemphigus vulgaris, pemphigoid 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/inadequate response to immunization AND no evidence of renal (nephrotic syndrome) and GI as causes of hypogammaglobulinemia (HGG) AND initial pre-tx total serum IgG 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 IgG sub-class deficiency (IgG1, IgG2, IgG3, IgG4) when 1 or more serum IgG subclasses are below lower limit of age adj lab ref range or more than 2 SD below age adj mean AND hx of recurrent sinopulmonary infection requiring antibiotic therapy AND lack of/inadequate response to immunization. Tx of Kawasaki Synd when within 10dys of onset and tx for no more than 5dys. For ITP when symptomatic thrombocytopenia (TCP) or platelet count less than 20,000 (adult)/30,000 (child). For HGG and recurrent bacterial infect assoc with B-cell chronic lymphocytic leukemia that includes both Documented hx of recurrent bacterial infect or active infect unresponsive to antimicrobial therapy AND Documentation that total IgG is less than 500mg/dL. Tx of severe hyperbilirubinemia.</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	For antenatal alloimmune TCP: AB to paternal platelet antigen found in maternal serum AND previously affected pregnancy, family hx of maternofetal alloimmune TCP OR fetal blood sample shows TCP. For autoimmune neutropenia, active infection is excluded as the cause. For ELS: has muscle weakness, characteristic electromyography and presence of AB directed against voltage-gated calcium channels.

# Ixempra

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## Products Affected

- IXEMPRA

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

# Jadenu

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## Products Affected

- JADENU
- JADENU SPRINKLE

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

# Jakafi

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## Products Affected

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

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

# Jetrea

## Products Affected

- JETREA (PF)

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



# Jevtana

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## Products Affected

- JEVTANA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has had an adequate trial and titration of Repatha and achieved suboptimal lipid lowering response.

# Jynarque

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## Products Affected

- JYNARQUE ORAL TABLET 15 MG, 30 MG
- JYNARQUE ORAL TABLETS, SEQUENTIAL

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

# Kadcyla

## Products Affected

- KADCYLA

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

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## Products Affected

- KALBITOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Prophylaxis for HAE attacks.
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	12 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Using Kalydeco (ivacaftor) monotherapy, without concurrent use of lumacaftor, for the F508del mutation in the CFTR gene.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Kanuma

## Products Affected

- KANUMA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial request: 6 months, Maintenance: 1 year
<b>Other Criteria</b>	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

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## Products Affected

- KEVEYIS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 3 months, renewal 1 year
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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/mm <sup>3</sup> , platelet count less than 150,000/mm <sup>3</sup> , 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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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).</p>

# Keytruda

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## Products Affected

- KEYTRUDA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Current ECOG (Eastern Cooperative Oncology Group) performance status of 0-2.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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. For first line tx of metastatic nonsquamous NSCLC, used in combination with pemetrexed and carboplatin, cytologically confirmed stage IIIb or IV NSCLC and No sensitizing EGFR mutations ALK translocations. For tx of unresectable or metastatic solid tumors (dMMR/MSIH only), used as a single agent. For malignant pleural mesothelioma, individual ineligible for platinum-based chemotherapy toxicity, defined as one of the following: a) ECOG performance status equal to 1 b) Glomerular filtration rate less than 60mL/min c) hearing loss (measured at audiometry) of 25 dB at two contiguous frequencies or d) Grade 2 or greater peripheral neuropathy.</p>

# Kineret

## Products Affected

- KINERET

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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)].
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	For RA, individual is 18 years of age or older. For SJIA, individual is 2 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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).</p>

# Kisqali

## Products Affected

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

# Korlym

## Products Affected

- KORLYM

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

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November 2019



# Krystexxa

## Products Affected

- KRYSTEXXA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has asymptomatic hyperuricemia. Individual has a known glucose-6-phosphate dehydrogenase (G6PD) deficiency.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 8 weeks, 1 year for continuation
<b>Other Criteria</b>	

# KYNAMRO

## Products Affected

- KYNAMRO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has had an adequate trial and titration of Repatha and achieved suboptimal lipid lowering response.

# Kyprolis

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## Products Affected

- KYPROLIS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year
<b>Other Criteria</b>	For the treatment of Waldenstrom's macroglobulinemia 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

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## Products Affected

- LARTRUVO

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 curative treatment option and Individual's current Eastern Cooperative Oncology Group (ECOG) performance status is 0-2.</p> <p>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 after at least 8 cycles with doxorubicin or earlier discontinuation of doxorubicin due to toxicity, and then if so chosen, continuing olaratumab as monotherapy in the absence of unacceptable toxicities until disease progression and Radiotherapy or surgery is not a treatment option and Individual's current Eastern Cooperative Oncology Group (ECOG) performance status is 0-2.</p>

# Latuda

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## Products Affected

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

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

# Lazanda

## Products Affected

- LAZANDA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Treatment of acute or postoperative pain, migraine headache pain OR non-cancer related breakthrough pain
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- LEMTRADA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual with primary progressive MS. Individual with secondary progressive MS.
<b>Required Medical Information</b>	Individual is Human immunodeficiency virus (HIV) negative.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## 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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Letairis

## Products Affected

- *ambrisentan*
- LETAIRIS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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/severe anemia. Using in combination with other endothelin receptor antagonist (ERA) agents, such as but not limited to Opsumit (macitentan) or Tracleer (bosentan).
<b>Required Medical Information</b>	Individual has catheterization-proven diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) AND individual has WHO Functional Class II-IV symptoms.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Leukine

## Products Affected

- LEUKINE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 $0.1 \times 10^9/L$ ) 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 $1500/mm^3$ ), 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
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

PA Criteria	Criteria Details
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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 myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm<sup>3</sup> 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).</p>

# Libtayo

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## Products Affected

- LIBTAYO

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

# Lidocaine Topical

## Products Affected

- *lidocaine hcl mucous membrane jelly*
- *lidocaine hcl mucous membrane solution*  
2 %, 4 % (40 mg/ml)
- *lidocaine hcl topical*
- *lidocaine topical ointment*
- *lidocaine viscous*
- XYLOCAINE JELLY
- XYLOCAINE MUCOUS MEMBRANE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	Individual is using for local analgesia OR Individual is using for relief of pain and itching due to minor cuts, minor scrapes, minor skin irritations, minor burns, and insect bites.

# Lidoderm Patch

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## Products Affected

- *lidocaine topical adhesive patch, medicated*
- LIDODERM
- ZTLIDO

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



# Liptruzet

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## Products Affected

- LIPTRUZET

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

# Lonsurf

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## Products Affected

- LONSURF

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

# Lorbrena

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## Products Affected

- LORBRENA ORAL TABLET 100 MG, 25 MG

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

# Lotronex

## Products Affected

- *alosetron*
- LOTRONEX

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual is a Female with Severe diarrhea-predominant Irritable Bowel Syndrome (IBS) defined as including diarrhea and 1 or 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.
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- LUCENTIS

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

# Lumizyme

## Products Affected

- LUMIZYME

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For infantile-onset Pompe disease, dx 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. 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 ability to walk 40 meters on a 6-minute walk test (assistive devices permitted) AND muscle weakness in the lower extremities.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Lumoxiti

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## Products Affected

- LUMOXITI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individuals with severe renal impairment (CrCl less than 29 mL/min).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Lupaneta

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## Products Affected

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

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



# Lupron Depot

## Products Affected

- 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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, 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 Other advanced, recurrent, or metastatic disease.</p> <p>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.</p>
<b>Age Restrictions</b>	

PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year, except for Endometriosis:6months, Uterine Fibroids:3months
<b>Other Criteria</b>	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

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## Products Affected

- *leuprolide*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, 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 Other advanced, recurrent, or metastatic disease.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Lynparza

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## Products Affected

- LYNPARZA ORAL CAPSULE
- LYNPARZA ORAL TABLET

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

# Lyrica

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## Products Affected

- LYRICA ORAL CAPSULE 100 MG, 150 MG, 200 MG, 225 MG, 25 MG, 300 MG, 50 MG, 75 MG
- LYRICA ORAL SOLUTION
- *pregabalin oral capsule 100 mg, 150 mg, 200 mg, 225 mg, 25 mg, 300 mg, 50 mg, 75 mg*
- *pregabalin oral solution*

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 ((AAACE 2015, ADA 2017)) (2) Tricyclic antidepressants (such as, amitriptyline, clomipramine, desipramine, nortriptyline) (AAACE 2015, AAFP 2010, ADA 2017, NICE 2013) OR (3) Gabapentin (AAACE 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) 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).</p>

# Lyrice CR

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## Products Affected

- LYRICA CR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has had a prior trial of immediate-release form of Lyrica (pregabalin) AND Documentation (verbal or written) has been provided which defines the following: (a.) The inadequate response to Lyrica (pregabalin) AND (b.) The medical reason extended release Lyrica CR is clinically necessary, and the same medical reason and clinical reason benefits are not expected with Lyrica.

# Makena

## Products Affected

- *hydroxyprogest(pf)(preg presv)*
  - HYDROXYPROGESTERONE CAP(PPRES)
  - *hydroxyprogesterone caproate*
  - MAKENA
- MAKENA (PF)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Women with multiple gestations.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	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.



# Mavenclad

## Products Affected

- MAVENCLAD (10 TABLET PACK)
- MAVENCLAD (4 TABLET PACK)
- MAVENCLAD (5 TABLET PACK)
- MAVENCLAD (6 TABLET PACK)
- MAVENCLAD (7 TABLET PACK)
- MAVENCLAD (8 TABLET PACK)
- MAVENCLAD (9 TABLET PACK)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Mayzent, Tecfidera, Tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, or Betaseron). Individual with clinically isolated syndrome (CIS) OR human immunodeficiency virus (HIV) infection. Individual with an active acute or chronic infection at the initiation of therapy OR moderate to severe renal impairment (creatinine clearance less than 60 mL/min) OR moderate to severe hepatic impairment (Child-Pugh class B or C) OR has completed two treatment courses (two years) of Mavenclad therapy.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	Individual has a diagnosis of relapsing multiple sclerosis (RMS), including relapsing-remitting disease and active secondary progressive disease AND has had a trial and inadequate response or intolerance to at least one alternative drug indicated for the treatment of multiple sclerosis.

# Mavyret

## Products Affected

- MAVYRET

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a genotype and a reactive HCV antibody, and a subsequent positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND 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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

# Mayzent

## Products Affected

- MAYZENT ORAL TABLET 0.25 MG, 2 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent use with other MS disease modifying agents (such as Aubagio, Gilenya, Mavenclad, Tecfidera, Tysabri, Lemtrada, Ocrevus, Copaxone/Glatopa, Extavia, Rebif, Avonex, Plegridy, or Betaseron). Individual who has been tested for CYP2C9 genotype and is homozygous for CYP2C9*3 (ie, CYP2C9*3/*3 genotype). Individual has had a recent (within the past 6 months) occurrence of one of the following: Myocardial infarction or Unstable angina or Stroke or Transient ischemic attack (TIA) or Decompensated heart failure requiring hospitalization or Class III/IV heart failure. 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 an active acute or chronic infection at the initiation of therapy.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Megace Suspension HRM

## Products Affected

- 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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual is using for the treatment of anorexia, cachexia, or unexplained weight loss in individuals with HIV/AIDS. Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] for individuals greater than 65 and medication benefits outweigh potential risk for this individual
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Megace Tabs HRM

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## Products Affected

- *megestrol oral tablet*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] for individuals greater than 65 and medication benefits outweigh potential risk for this individual.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Mekinist

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## Products Affected

- MEKINIST ORAL TABLET 0.5 MG, 2 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	BRAF V600E or V600K mutation results must be confirmed.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year
<b>Other Criteria</b>	

# Mektovi

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## Products Affected

- MEKTOVI

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

# Mepron

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## Products Affected

- *atovaquone*
- MEPRON

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



# Mepsevii

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## Products Affected

- MEPSEVII

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

# Mesnex

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## Products Affected

- *mesna*
- MESNEX

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

# Methoxsalen

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## Products Affected

- 8-MOP
- *methoxsalen*
- OXSORALEN ULTRA

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

# Methylphenidate

## Products Affected

- ADHANSIA XR
- 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, 72 mg*
- QUILLICHEW ER ORAL TABLET,CHEW,IR-ER.BIPHASIC24HR 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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual is using for Attention Deficit Hyperactivity Disorder/Attention Deficit Disorder (ADHD/ADD) or Narcolepsy.
<b>Age Restrictions</b>	6 years of age and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Mircera

## Products Affected

- MIRCERA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	12 weeks.
<b>Other Criteria</b>	

# Modafinil

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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.</p>
<b>Age Restrictions</b>	

PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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).</p>



# Mozobil

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## Products Affected

- MOZOBIL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	3 months
<b>Other Criteria</b>	Individual may use a maximum of up to four consecutive doses of plerixafor (Mozobil) injections per cycle for up to 2 cycles.

# Mulpleta

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## Products Affected

- MULPLETA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Used to normalize platelet counts in those with chronic liver disease
<b>Required Medical Information</b>	Individual has a platelet count of less than 50 X 10 <sup>9</sup> /L
<b>Age Restrictions</b>	18 years of age
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Myalept

## Products Affected

- MYALEPT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual is using for the treatment of complications of partial lipodystrophy. Individual is using for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH). Individual is using for the treatment of HIV-related lipodystrophy. Individual is using for treatment in patients with general obesity or metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of congenital or acquired generalized lipodystrophy
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Mylotarg

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## Products Affected

- MYLOTARG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Relapsed or refractory CD33-positive AML: 2 years and older. For newly diagnosed CD33-positive AML: 18 years and older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Myozyme

## Products Affected

- MYOZYME

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	For the treatment of non-infantile onset (late-onset) Pompe disease.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Naglazyme

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## Products Affected

- NAGLAZYME

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

# 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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	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.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has a diagnosis of moderate to severe dementia of the Alzheimer's type.

# Namzarin

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## Products Affected

- NAMZARIC

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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 calcium-sensing 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).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Diagnosis of chronic (duration of greater than or equal to 18 months, mannstadt et, al 2013) hypoparathyroidism.

# Nerlynx

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## Products Affected

- NERLYNX

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

# Neulasta

## Products Affected

- FULPHILA
- NEULASTA
- UDENYCA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 $0.1 \times 10$ 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 1500mm <sup>3</sup> ), 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

PA Criteria	Criteria Details
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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 use after accidental or intentional total body radiation of myelosuppressive doses (greater than 2 Grays [Gy]) (such as Hematopoietic Syndrome of Acute Radiation Syndrome). For myelodysplastic syndromes (MDS) with severe neutropenia (absolute neutrophil count (ANC) less than or equal to 500 mm<sup>3</sup> 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.</p>

# Neupogen

## Products Affected

- NEUPOGEN
- NIVESTYM
- ZARXIO

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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 <math>0.1 \times 10^9/L</math>) 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 <math>1500/mm^3</math>), 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</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	

PA Criteria	Criteria Details
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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 mm<sup>3</sup> 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 myelosuppressive 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 is delayed or has failed. To</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	mobilize progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT). Use as an alternate or adjunct to donor leukocyte infusions (DLI) in individuals with leukemic relapse after an allogeneic hematopoietic stem cell transplant.

# Neupro

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## Products Affected

- NEUPRO

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

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## Products Affected

- NEXAVAR

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

# Ninlaro

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## Products Affected

- NINLARO

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

# Nityr

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## Products Affected

- NITYR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual's plasma tyrosine level is maintained below 500 micromol/L to reduce risk of ocular symptoms, developmental delay, or hyperkeratotic plaques.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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.

# Nothera

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## Products Affected

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

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

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## Products Affected

- NOXAFIL ORAL
- POSACONAZOLE

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

# NP Human Growth Hormone

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## Products Affected

- 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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	<p>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</p>

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For idiopathic GHD, has signs/sym of GHD, GV 2 SD below age-appropriate mean or ht 2.25 SD below age-appropriate mean and A subnormal (SubNL) response (less than 10ng/ml) to 2 GH stim tests OR Neonates with hypoglycemia and clinical/hormone evidence of hypopit and low GH (less than 10ng/ml) OR 2 other 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 than 10 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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	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. 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

## Products Affected

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

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

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## Products Affected

- BIVIGAM
- CARIMUNE
- CARIMUNE NF NANOFILTERED
- CUTAQUIG
- CUVITRU
- FLEBOGAMMA
- FLEBOGAMMA DIF
- GAMMAGARD LIQUID
- GAMMAGARD S-D (IGA < 1 MCG/ML)
- GAMMAGARD S/D
- GAMMAKED
- GAMMAPLEX
- GAMMAPLEX (WITH SORBITOL)
- HIZENTRA
- HYQVIA
- PANZYGA
- PRIVIGEN
- XEMBIFY

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

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), medical records show clinical presentation not consistent with other polyneuropathies AND a) 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 b) distal muscle weakness and results of diagnostic testing meet recognized set of diagnostic criteria as established by AAN, Saperstien or INTAC. CONT use for CIDP shows improvement in neurological sx as documented on physical exam AND cont need demonstrated by documentation that annual attempts to titrate dose or the interval of therapy result in worsening sx. Multifocal Motor Neuropathy (MMN) presents with asymmetric weakness that mainly affects distal muscles AND nerve conduction studies confirm demyelinating neuropathy is present (conduction block, slowing, or abnormal temporal dispersion in at least one nerve) OR clinical hx nor exam suggest upper motor neuron DZ (no bulbar weakness, nor upper motor neuron signs) and GM-1 antibody (AB) titers are elevated OR after initial exam and electrodiagnostic testing clinical presentation suggests MMN but dx remains uncertain. CONT use for MMN: clinical results document an improvement in strength and fx within 3wks of start of infusion and need is demonstrated by documentation that annual attempts to titrate the dose or interval of therapy results in worsening sx. Dermatomyositis confirmed by presence of skin lesions OR For polymyositis, AND both dx must have at least 4 of the following: weakness in trunk/proximal extremities, elevated serum creatinine kinase or aldolase level, muscle pain not otherwise explained, characteristic electromyography finds, presence of anti-Jo-1 antibody, arthralgia/arthritis without joint destruction, evidence of systemic inflammation or inflammatory myositis seen on muscle biopsy.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>NP IG may be approved if trial/inadeq response/intol to 1 PF IG (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, Non-O blood type, Severe IgA def, DM/pre-DM, CVD, Hyper-prolinemia, Hypernatremia, hi-risk of thrombosis (such as but not limited to hyperviscosity syn OR hypercoagulable cond), documented hypersensitivity 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 not also assoc with requested NP agent. OR if SCIG-only dose forms (Hizentra, Hyqvia) are designated as NP, may be approved for 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. To reduce risk of GvHD with interstitial PNA and infect in allogeneic BMT pts in the first 100dys post-transplant. Hx and physical exam characteristic of myasthenia gravis AND presence of AB against at least 1 neuromuscular or single-fiber electromyography. Stiff-person syn not controlled by other therapies. TSS caused by staph/strep refractory to several hrs of aggressive therapy. Tx of chronic parvovirus B19 and severe anemia assoc with bone marrow suppression. Refractory auto-immune mucocutaneous blistering DZs: pemphigus vulgaris or foliaceus, bullous pemphigoid, mucous membrane pemphigoid, epidermolysis bullosa acquisita. Tx of PI when hx of recurrent sinopulmonary infection req abx tx AND lack of/inadeq response to immunization AND no evidence of renal and GI as causes of HGG AND initial pre-tx total serum IgG is BLL 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 IgG sub-class deficiency (IgG1-4) when 1 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</p>

PA Criteria	Criteria Details
	<p>requiring abx therapy AND lack of/inadeq response to immunization. Tx of Kawasaki Syn when within 10dys of onset and tx for no more than 5dys. For ITP when symptomatic thrombocytopenia (TCP) or platelet count less than 20k (adult)/30k (child). For HGG and recurrent bacterial infect assoc with B-cell CLL that includes both Documented hx of recurrent bacterial infect or active infect unresponsive to antimicrobial therapy AND Documentation that total IgG is less than 500mg/dL. Tx of severe hyperbilirubinemia. For antenatal alloimmune TCP: AB to paternal platelet antigen found in maternal serum AND previously affected pregnancy, family hx of maternofetal alloimmune TCP OR fetal blood sample shows TCP. For autoimmune neutropenia, active infect is excluded as the cause. For ELS: has muscle weakness, characteristic electromyography and presence of AB directed against voltage-gated Ca-channels.</p>

# NP LA Opioid

## Products Affected

- CONZIP
- DOLOPHINE
- EXALGO ER
- *hydromorphone oral tablet extended release 24 hr*
- KADIAN
- *morphine oral capsule, er multiphase 24 hr*
- *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
- *oxymorphone oral tablet extended release 12 hr*
- *tramadol oral capsule, er biphasic 24 hr 17-83*
- *tramadol oral capsule, er biphasic 24 hr 25-75*
- *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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 for initial therapy, 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.</p>



# NP LA Opioid Abuse Deterrent

## Products Affected

- ARYMO ER WEEKLY 10 MCG/HOUR, 15 MCG/HOUR,
- BELBUCA 20 MCG/HOUR, 5 MCG/HOUR, 7.5
- *buprenorphine transdermal patch weekly* MCG/HOUR
- 10 mcg/hour, 15 mcg/hour, 20*
- mcg/hour, 5 mcg/hour*
- BUPRENORPHINE TRANSDERMAL PATCH
- WEEKLY 7.5 MCG/HOUR
- BUTRANS TRANSDERMAL PATCH
- EMBEDA
- HYSINGLA ER
- MORPHABOND ER
- XTAMPZA ER
- ZOHYDRO ER

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 for initial therapy, 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 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 If is there is concern for abuse or dependence with pure opioid agents. For continued use, Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline.</p>

# NP SGLT2

## Products Affected

- FARXIGA
- GLYXAMBI
- INVOKAMET
- INVOKAMET XR
- INVOKANA ORAL TABLET 100 MG, 300 MG
- QTERN
- STEGLATRO
- STEGLUJAN
- XIGDUO XR ORAL TABLET, IR - ER, BIPHASIC 24HR 10-1,000 MG, 10-500 MG, 2.5-1,000 MG, 5-1,000 MG, 5-500 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	Individual has had a trial and inadequate response or intolerance to metformin OR has a contraindication to metformin therapy [such as but not limited to, renal insufficiency (eGFR is less than 45 mL/minute/1.73m <sup>2</sup> )]. AND has had a trial and inadequate response or intolerance to Jardiance (empagliflozin), Synjardy (empagliflozin/metformin), or Synjardy XR (empagliflozin/metformin extended-release).

# NP Statin

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## Products Affected

- ALTOPREV

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

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>

# NP TZD

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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/1.73m <sup>2</sup> )] 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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Using Nplate to normalize platelet counts. Treatment of myelodysplastic syndrome (MDS). Using for low platelet count caused by any condition other than chronic ITP.
<b>Required Medical Information</b>	For initial therapy, individual's degree of thrombocytopenia (platelet count less than 30,000/mm <sup>3</sup> ) 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/mm <sup>3</sup> ) to decrease the risk of bleeding.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 6 months, renewal 1 year.
<b>Other Criteria</b>	



# Nubeqa

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## Products Affected

- NUBEQA

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

# Nucala

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## Products Affected

- NUCALA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For severe eosinophilic asthma: 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.
<b>Age Restrictions</b>	For eosinophilic asthma: 6 years old or older. For eosinophilic granulomatosis with polyangitis (EGPA): 18 years old or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For 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. For individuals with relapsing or refractory eosinophilic granulomatosis with polyangiitis for 6 months or greater and 1) a history or presence of asthma and 2) blood eosinophil level of greater than or equal to 10% of leucocytes or an absolute eosinophil count of greater than 1000 cells per cubic millimeter (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease and known or suspected parasitic infection) and 2) the presence of 2 or more features of eosinophilic granulomatosis with polyangiitis (such as, biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil-rich granulomatosis inflammation, neuropathy, mono or poly(motor deficit or nerve</p>

PA Criteria	Criteria Details
	<p>conduction abnormality), pulmonary infiltrates, non-fixed sino-nasal abnormality, cardiomyopathy, glomerulonephritis, alveolar hemorrhage, palpable purpura or antineutrophil cytoplasmic antibody positive status. For Continuation Therapy after 12 months in individuals with documented relapsing or refractory eosinophilic granulomatosis with polyangiitis when treatment has resulted in clinical improvement as documented by the achievement of remission at some point during tx, defines as the following: Birmingham Vasculitis Activity Score, version 3, of zero on scale from 0 to 63 and receipt of prednisolone or prednisone at dose of 4mg or less per day.</p>

# Nuedexta

## Products Affected

- NUEDEXTA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concomitant use with any of the following: (i.) Agents containing quinidine, quinine, or mefloquine OR (ii.) Agents that both prolong the QT interval and are metabolized by CYP2D6 (for example, thioridazine, pimozide) OR Concomitant monoamine oxidase inhibitor (MAOI) use or use in the preceding 14 days OR Individual has any of the following cardiovascular conditions: (i.) Prolonged QT interval, congenital long QT syndrome, or history suggestive of torsades de pointes OR (ii.) Heart failure OR (iii.) Complete atrioventricular (AV) block without an implanted pacemaker or at high-risk of a complete AV block.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	Individual has a diagnosis of pseudobulbar affect (PBA) AND has a concomitant diagnosis with an unrelated neurologic disease or injury [amyotrophic lateral sclerosis (AAN 2014, Piro et al. 2010), multiple sclerosis (AAN 2016, Piro et al, 2010), stroke (2016 AHA/ASA)].

# Nulojix

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## Products Affected

- NULOJIX

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

# Nuplazid

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial:3 months, Maintenance: 1 Year
<b>Other Criteria</b>	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

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>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.</p>
<b>Age Restrictions</b>	



PA Criteria	Criteria Details
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	<p>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).</p>

# Ocaliva

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## Products Affected

- OCALIVA

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For Initial request, 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). For continuing treatment with Ocaliva (obeticholic acid), individual has previously met the initiation criteria above and: (a) Individual has achieved an adequate response of alkaline phosphatase or total bilirubin AND (b) Documentation has been provided.</p>

# Ocrevus

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## Products Affected

- OCREVUS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Diagnosis of hepatitis B virus infection OR History of life-threatening infusion reaction of ocrelizumab.
<b>Required Medical Information</b>	Being used to treat either primary progressive multiple sclerosis (PPMS) or relapsing multiple sclerosis (RMS) in accordance with the McDonald Criteria.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For treatment of primary progressive multiple sclerosis (PPMS) and able to ambulate more than 5 meters (not considered wheelchair bound). For treatment of relapsing multiple sclerosis (RMS) and able to ambulate without aid or rest for at least 1000 meters.

# Odomzo

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## Products Affected

- ODOMZO

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

# Ofev

## Products Affected

- OFEV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Using in combination with Esbriet (pirfenidone). Individuals with severe hepatic impairment (child pugh class C) or end-stage liver disease.
<b>Required Medical Information</b>	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%.
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Olumiant

## Products Affected

- OLUMIANT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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/mm <sup>3</sup> , lymphocyte count less than 500 cells/mm <sup>3</sup> , 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 m <sup>2</sup> (KDIGO 2012)] or severe [less than 30 mL/min/1.73 m <sup>2</sup> (KDIGO 2012)] renal impairment.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Using in combination with another serine protease inhibitor [such as but not limited to, paritaprevir, or asunaprevir].
<b>Required Medical Information</b>	Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a genotype and a reactive HCV antibody, and a subsequent positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND 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).
<b>Age Restrictions</b>	Individual is 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, 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 OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni (ledipasvir/sofosbuvir) which is not also in Olysio or Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with 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. OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni or Epclusa which is not also in Olysio or Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni or Epclusa.</p>

# Oncaspar

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## Products Affected

- ONCASPAR

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

# Onfi

## Products Affected

- *clobazam oral suspension* MG
- *clobazam oral tablet 10 mg, 20 mg* • SYMPAZAN ORAL FILM 10 MG, 20 MG, 5
- ONFI ORAL SUSPENSION MG
- ONFI ORAL TABLET 10 MG, 20 MG, 5

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Diagnosis (all ages) and if over 65 years of age or older, Prescriber must acknowledge this is a high risk medication (HRM) [as identified by American Geriatric Society] and medication benefits outweigh potential risk for this individual.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Onpattro

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## Products Affected

- ONPATTRO

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

# Onsolis

## Products Affected

- ONSOLIS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Treatment of acute or postoperative pain OR treatment of migraine headache pain OR treatment of non-cancer related breakthrough pain.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- OPDIVO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Current ECOG performance status 0-2. For renal cell carcinoma, histologic confirmation with clear-cell component.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 resected advanced melanoma for up to 12 months when nivolumab is used as a single agent. For malignant pleural mesothelioma, used as subsequent therapy OR individual is ineligible for platinum-based therapy, defined as having one or more of the following risk factors for platinum-based chemotherapy toxicity: ECOG performance status equal to 1, Glomerular filtration rate less than 60ml/min, hearing loss (measured at audiometry) of 25 dB at two contiguous frequencies, or Grade 2 or greater peripheral neuropathy.</p>



# Opsumit

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## Products Affected

- OPSUMIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual is initiating therapy and has a diagnosis of clinically significant/severe anemia or in combination with other endothelin receptor antagonist (ERA) agents, such as but not limited to Letairis (ambrisentan) or Tracleer (bosentan).
<b>Required Medical Information</b>	Individual has catheterization-proven diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) AND Individual has WHO Functional Class II-IV symptoms.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Oralair

## Products Affected

- ORALAIR SUBLINGUAL TABLET 100  
INDX REACTIVITY, 300 INDX  
REACTIVITY

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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 eosinophilic esophagitis.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is between the ages of 10 years and 65 years old.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Treatment is initiated at least 16 weeks before the expected onset of grass pollen season and is continued throughout the season.

# Orencia

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## Products Affected

- ORENCIA (WITH MALTOSE)
- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SYRINGE 125 MG/ML, 50 MG/0.4 ML, 87.5 MG/0.7 ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	For RA, Patient is 18 years of age or older. For JIA, Patient is 2 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 and inadequate response or intolerance to Humira OR Enbrel. For PsA, agent is being used to reduce signs or symptoms or induce or maintain clinical response AND individual has had an inadequate response to ONE conventional therapy including DMARDs AND has had a trial nd inadequate response or intolerance 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 and inadequate response or intolerance 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).</p>

# Orenitram

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## Products Affected

- ORENITRAM

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

# Orfadin

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## Products Affected

- *nitisinone*
- ORFADIN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual's plasma tyrosine level is maintained below 500 micromol/L to reduce risk of ocular symptoms, developmental delay, or hyperkeratotic plaques.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Orilissa

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## Products Affected

- ORILISSA ORAL TABLET 150 MG, 200 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial approval is 6 months, Renewal is 6 months. Requests to continue therapy beyond 24 months (2

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>



# Orkambi

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## Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

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

# Otezla

## Products Affected

- OTEZLA
- OTEZLA STARTER ORAL TABLETS,DOSE PACK 10 MG (4)-20 MG (4)-30 MG (47), 10 MG (4)-20 MG (4)-30 MG(19)

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 Individual is unable to take biologic agent due to product warning or contraindication for any of the following reasons: (a) serious infection or sepsis, or (b) chronic or recurrent infection, or (c) tuberculosis infection, or (d) malignancy.</p>

# Oxandrin

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## Products Affected

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

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

# OxyContin

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 11 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 3 months. Maintenance 6 months. Cancer Pain/Terminal Dx or Palliative Care 1 Year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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). 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 OR (c) already receiving and tolerating a minimum daily opioid dose of at least 20mg oxycodone orally or its equivalent. For continued use, Attestation (verbal or written) that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline.</p>

# Ozurdex Implant

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## Products Affected

- OZURDEX

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

# PAH - B

## Products Affected

- *epoprostenol (glycine)*
- FLOLAN
- VELETRI

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



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>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</p>

# Palynziq

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## Products Affected

- PALYNZIQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has a confirmed prescription for an auto-injectable epinephrine agent.
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 continues to meet the initial request approval criteria and is showing signs of continuing improvement, as evidenced by blood PHE levels.

# Perjeta

## Products Affected

- PERJETA

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 early stage, locally advanced or inflammatory breast cancer and will undergo neoadjuvant therapy (prior to surgery) or adjuvant systemic therapy AND primary tumor is larger than 2cm or individual is lymph node positive (for neoadjuvant therapy: 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 pertuzumab is used for a maximum of 18 cycles (12 month course).</p>

# Piqray

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## Products Affected

- PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X1-50 MG X1), 300 MG/DAY (150 MG X 2)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has confirmed (written or verbal attestation is acceptable) PIK3CA mutation using an FDA-approved test (such as the theascreen PIK3CA RGQ PCR Kit).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Pomalyst

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## Products Affected

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

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

# Praluent

## Products Affected

- PRALUENT PEN
- PRALUENT SYRINGE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent use with Juxtapid or Kynamro.
<b>Required Medical Information</b>	Individual is at High Risk for Acute Coronary Syndrome (ACS) as identified by one of the following: (A) Heterozygous Familial Hypercholesterolemia (HeFH) confirmed by: 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: 1.Acute coronary syndromes 2.Coronary Artery Disease (CAD) 3. 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 (PAD).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 3 month. Continuation 1 yr.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For initial request, individual meets one of the following: (A) Individual is 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 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. 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 there is confirmation of LDL reduction.</p>



# Probuphine Implant

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## Products Affected

- PROBUPHINE

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>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.</p>

# Prolia

## Products Affected

- PROLIA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Osteoporosis is defined as a BMD T-Score of less than or equal to - 2.5 OR a clinical diagnosis based on a history of a low trauma fracture (fragility fracture) at high risk for fracture. 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).
<b>Age Restrictions</b>	For Osteoporosis 18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	For osteoporosis treatment, individual 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 POWDER IN PACKET
- PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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 10 <sup>9</sup> /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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For initial therapy: 1) Diagnosis of chronic immune (idiopathic) thrombocytopenia (ITP) AND individual has platelet count of less than 30 x 10<sup>9</sup>/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 10<sup>9</sup>/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-thymocyte 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 10<sup>9</sup>/L) to decrease the risk of bleeding.</p>

# Protopic

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## Products Affected

- PROTOPIC
- *tacrolimus topical*

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

# Purixan

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## Products Affected

- PURIXAN

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



# quinine

## Products Affected

- QUALAQUIN
- *quinine sulfate*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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 <i>P. falciparum</i> malaria, prevention of malaria, individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency, individuals with myasthenia gravis, or individuals with optic neuritis .
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has been diagnosed with uncomplicated malaria caused by one of the following: <i>Plasmodium falciparum</i> known or suspected to be resistant to chloroquine (CDC 2013) OR chloroquine-resistant <i>Plasmodium vivax</i> (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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is between the ages of 18 years and 65 years old.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Treatment is initiated at least 12 weeks before the expected onset of ragweed pollen season and is continued throughout the season.

# Ravicti

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## Products Affected

- RAVICTI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Using for the management of acute hyperammonemia. Using to treat N-acetylglutamate synthase deficiency (NAGS).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	2 months of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has had a trial and inadequate response or intolerance to sodium phenylbutyrate (Buphenyl) OR Individual has any of the following: (a) Congestive heart failure or (b) Severe renal insufficiency or (c) A clinical state where there is sodium retention with edema.

# Reclast

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## Products Affected

- RECLAST
- *zoledronic acid-mannitol-water intravenous piggyback 5 mg/100 ml*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Bone metastases documented on imaging or bone pain associated with imaging-documented metastases from breast, prostate, lung, kidney, thyroid, or other solid tumors.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 glucocorticoid-induced 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 Hypercalcemia of malignancy, treatment or Multiple myeloma 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 age-specific normal reference range or those who are symptomatic or at risk for complication from their disease. Prevention of osteoporosis during androgen deprivation therapy in prostate cancer.</p>

# Regranex

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## Products Affected

- REGRANEX

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

# RELISTOR

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has a known or suspected mechanical gastrointestinal obstruction.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

## Products Affected

- INFLECTRA
- REMICADE
- RENFLEXIS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	For Crohn's Disease or Ulcerative colitis, 6 yr of age or older. For JIA, 2 yr of age or older. For all other indications 18 yr of age.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year



PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 failed to respond to, is intolerant of, or has a medical</p>

PA Criteria	Criteria Details
	<p>contraindication to phototherapy or ONE other systemic therapy (such as 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]).</p>

# Remodulin

## Products Affected

- REMODULIN
- *treprostinil sodium*

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>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.</p>

# Repatha

## Products Affected

- REPATHA PUSHTRONEX
- REPATHA SURECLICK
- REPATHA SYRINGE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concurrent use with Juxtapid or Kynamro.
<b>Required Medical Information</b>	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 diagnosis confirmed by: 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.Coronary Artery Disease (CAD) 3. 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 (PAD).
<b>Age Restrictions</b>	For Dx HeFH, 18 years of age or older. For Dx HoFH, 13 years of age or older.
<b>Prescriber Restrictions</b>	

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November 2019

PA Criteria	Criteria Details
<b>Coverage Duration</b>	Initial 3 month. Continuation 1 yr.
<b>Other Criteria</b>	<p>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 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 AND Individual is on ezetimibe (applies to individuals on statin therapy only). 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 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. For continuation, criteria outlined for initial Prior Authorization has been satisfied AND There is confirmation of LDL reduction.</p>

# Restasis

## Products Affected

- RESTASIS
- RESTASIS MULTIDOSE

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

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## Products Affected

- RETISERT

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



# Revatio

## Products Affected

- REVATIO ORAL SUSPENSION FOR RECONSTITUTION *suspension for reconstitution*
- REVATIO ORAL TABLET *sildenafil (antihypertensive) oral tablet*
- *sildenafil (antihypertensive) oral*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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, isosorbide 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).
<b>Required Medical Information</b>	Catheterization-proven diagnosis of Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO Group I) and WHO Functional Class II-IV symptoms.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Revatio IV

## Products Affected

- REVATIO INTRAVENOUS
- *sildenafil (antihypertensive) intravenous*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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, isosorbide 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).
<b>Required Medical Information</b>	Catheterization-proven diagnosis of Pulmonary Arterial Hypertension (PAH) World Health Organization (WHO Group I) and WHO Functional Class II-IV symptoms.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	For sildenafil INJ, individual is temporarily unable to take oral dose forms and requires continued therapy. For Individual with a diagnosis of persistent pulmonary hypertension of the newborn (AHA/ATS 2015) AND Individual was started and stabilized on Revatio (sildenafil) in the hospital and requires continued outpatient therapy.

# Revlimid

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## Products Affected

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

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

# Rexulti

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## Products Affected

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

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

# Rozlytrek

## Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	For metastatic non-small cell lung cancer (NSCLC), 18 years of age or older. For a diagnosis of a solid tumor, 12 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	For solid tumors, the individual has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation with confirmed genetic test results.

# Rubraca

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## Products Affected

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

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

# Ruconest

## Products Affected

- RUCONEST

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual is using for prophylaxis or in individuals with laryngeal attacks.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	13 years and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	



# Rydapt

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## Products Affected

- RYDAPT

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

# Sabril

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## Products Affected

- SABRIL
- *vigabatrin*
- VIGADRONE

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

# Samsca

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## Products Affected

- SAMSCA ORAL TABLET 15 MG, 30 MG

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

# SANCUSO

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## Products Affected

- SANCUSO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 due to the following: (A)The presence of head and neck cancer OR (B)Mucositis due to recent radiation to the head and neck area.

# Sandostatin IR

## Products Affected

- *octreotide acetate injection solution*      SOLUTION 500 MCG/ML  
     *1,000 mcg/ml, 100 mcg/ml, 200 mcg/ml,*
- *octreotide acetate injection syringe*
- *50 mcg/ml*      • SANDOSTATIN
- OCTREOTIDE ACETATE INJECTION

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 short-acting octreotide acetate (Sandostatin) is approved for rapid relief of symptoms or for breakthrough symptoms in individuals taking long-acting octreotide acetate.</p>

# Sandostatin LAR

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## Products Affected

- SANDOSTATIN LAR DEPOT

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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).</p>



# Seroquel Line

## Products Affected

- *quetiapine oral tablet extended release 24 hr 150 mg, 200 mg, 300 mg, 400 mg, 50 mg* • 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
- SEROQUEL ORAL TABLET 100 MG, 200

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

# Signifor IR

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## Products Affected

- SIGNIFOR

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

# Signifor LAR

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## Products Affected

- SIGNIFOR LAR

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

# Siklos

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## Products Affected

- SIKLOS

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

# Siliq

## Products Affected

- SILIQ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Use of brodalumab in combination with other immunosuppressive therapy or phototherapy OR Use of brodalumab in combination with other biologic drugs (such as adalimumab, certolizumab pegol, etanercept, infliximab, ixekizumab, secukinumab, or ustekinumab) OR Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections OR Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control and Prevention (CDC)-recommended equivalent test to evaluate for latent tuberculosis prior to initiating brodalumab.
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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. 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 Siliq 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, Siliq may be allowed without trial of preferred TNF agents (Enbrel/Humira).</p>

# SIMPONI

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## Products Affected

- SIMPONI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Using golimumab in combination with other TNF antagonists. Using in combination with tofacitinib citrate. 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). Using golimumab in combination with the following non-TNF-immunomodulator drugs: abatacept or anakinra.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 18 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 of, or has a medical contraindication to ONE nonbiologic DMARD AND individual has had a trial of and inadequate response or intolerance 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 intolerance to BOTH: Humira AND Enbrel. 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 (e.g. NSAIDs or nonbiologic DMARDs) AND individual has had a trial of and an inadequate response or intolerance 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</p>
	<p>or (d) Serious infections or concurrent sepsis. Simponi may be allowed without trial of preferred TNF agents (Enbrel/Humira).</p>



# Simponi ARIA

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## Products Affected

- SIMPONI ARIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Use of golimumab in combination with tofacitinib citrate, use in combination with the following non-TNF immunomodulatory drugs: abatacept 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).
<b>Required Medical Information</b>	For RA and PsA, 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. For Ankylosing Spondylitis, agent is being used to reduce signs or symptoms of the disease.
<b>Age Restrictions</b>	Individual is 18 years or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 intolerance 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, Simponi Aria may be allowed without trial of preferred TNF agents (Enbrel/Humira). For PsA, individual has failed to respond to, is intolerant of or has a medical contraindication to ONE conventional therapy (such as NSAID or nonbiologic DMARDs) AND has had a trial of and an inadequate response or intolerance 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. For Ankylosing Spondylitis, individual has failed to respond to, is intolerant of or has a medical contraindication to conventional therapy (such as NSAIDs or nonbiologic DMARDs) AND individual has had a trial of and an inadequate response or intolerance 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</p>
	(c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis.

# Sirturo

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## Products Affected

- SIRTURO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Latent infection due to Mycobacterium tuberculosis OR Drug-sensitive tuberculosis OR Extra-pulmonary tuberculosis OR Infections caused by non-tuberculosis mycobacteria.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- SIVEXTRO INTRAVENOUS
- SIVEXTRO ORAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Treatment of gram-negative infections.
<b>Required Medical Information</b>	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 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	30 days

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	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).

# Skyrizi

## Products Affected

- SKYRIZI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Use in combination with other biologic drugs or phototherapy OR Tuberculosis, other active serious infections, or a history of recurrent infections OR 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 risankizumab-rzaa.
<b>Required Medical Information</b>	Dx of chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2011): 1. Plaque Ps involving greater than five percent (5%) body surface area (BSA) OR 2. Plaque Ps involving 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).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For dx of chronic moderate to severe plaque Ps, 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 inadequate response or intolerance to Enbrel (etanercept) OR Humira (adalimumab) OR if the agents tried and failed (Humira (adalimumab)/Enbrel (etanercept)) 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 Skyrizi (risankizumab-rzaa) or (b) Individual's age or (c) Pregnant or planning or becoming pregnant or (d) Serious infections or concurrent sepsis OR individual has either concomitant clinical condition: (a) Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction.</p>

# Solaraze

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## Products Affected

- *diclofenac sodium topical gel 3 %*
- SOLARAZE

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



# Soliris

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## Products Affected

- SOLIRIS

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

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For initial tx of Paroxysmal nocturnal hemoglobinuria (PNH) as documented by flow cytometry, including the presence: (1.) Paroxysmal nocturnal hemoglobinuria type III red cells OR (2.) Glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells (PMNs) AND Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Soliris (eculizumab) (unless the clinical record documents that the risks of delaying Soliris (eculizumab) outweigh the risk of meningococcal infection) AND There is NO evidence of an active meningococcal infection AND Either of the following: (1.) The individual has: (a.) Hemoglobin that is less than or equal to 7 g/dl, or the individual has symptoms of anemia and the hemoglobin is less than or equal to 9 g/dl AND (b.) Lactate dehydrogenase is greater than 1.5 times the upper limit of normal. OR (2.) Documented history of a major adverse vascular event from thromboembolism. For the initial tx of atypical hemolytic uremic syndrome (aHUS) when the following criteria are met: (A.) dx of aHUS is supported by the absence of Shiga toxin-producing E. coli infection AND (B.) Thrombotic thrombocytopenic purpura has been ruled out (for example, normal ADAMTS 13 activity and no evidence of an ADAMTS 13 inhibitor), or if thrombotic thrombocytopenic purpura cannot be ruled out by laboratory and clinical evaluation, a trial of plasma exchange did not result in clinical improvement AND (C) Individual has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of Soliris (eculizumab) (unless the clinical record documents that the risks of delaying Soliris (eculizumab) outweigh the risk of meningococcal infection) AND (D.) There is NO evidence of an active meningococcal infection.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	<p>For PNH 1yr. For aHUS Initial 2 mon. For MG Initial 7 mon. Continuation is 1 year for all dx.</p>

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For initial tx of generalized myasthenia gravis (MG) when the following criteria are met: (A.) Individual has Myasthenia Gravis Foundation of America Clinical Classification Class II to IV disease AND (B.) has a documented positive serologic test for binding anti-acetylcholine receptor antibodies (AChR-ab) AND (C.) has had an inadequate response to, is intolerant of, or has a medical contraindication to two or more immunosuppressive drug agents (such as, azathioprine, cyclosporine, or methotrexate) as monotherapy or in combination therapy for greater than or equal to 12 months OR (D.) has had an inadequate response to, is intolerant of, or has a medical contraindication to one or more immunosuppressive drug agents as monotherapy or in combination therapy and requires chronic plasma exchange or plasmapheresis or intravenous immunoglobulin therapy AND (E.)has been immunized with a meningococcal vaccine at least 2 weeks prior to administration of the first dose of eculizumab (unless the clinical record documents that the risk of delaying eculizumab outweigh the risk of meningococcal infection) AND (F.) There is no evidence of an active meningococcal infection. For Continuation of Soliris (eculizumab) for the treatment of an individual with documented paroxysmal nocturnal hemoglobinuria who is currently receiving treatment with Soliris. For Continuation for the treatment of atypical hemolytic uremic syndrome may be approved when there is clinical improvement after the initial trial (for example, increased platelet count or laboratory evidence of reduced hemolysis). For Continuation for the treatment of generalized myasthenia gravis may be approved when there is documentation of clinical response (that is, a reduction in signs or symptoms that impact daily function).</p>

# Somatuline Depot

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## Products Affected

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

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

# Somavert

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## Products Affected

- SOMAVERT

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

# Sovaldi

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## Products Affected

- SOVALDI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and a reactive HCV antibody, and a subsequent positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND 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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, 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 OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni (ledipasvir/sofosbuvir) which is not also in Sovaldi OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with 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 OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni or Epclusa which is not also in Sovaldi OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni or Epclusa.</p>

# Spinraza

## Products Affected

- SPINRAZA (PF)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	<p>For initial requests, Individual has documentation (written or verbal attestation is acceptable) of a confirmatory diagnosis by either: (1) Spinal Muscular Atrophy (SMA) diagnostic test results confirming 0 copies of SMN1 OR (2) Molecular genetic testing of 5q SMA for any of the following: (a) homozygous gene deletion or (b) homozygous conversion mutation or (c) compound heterozygote. AND Individual has documentation (written or verbal attestation is acceptable) of either: (1) Genetic testing confirming no more than 2 copies of SMN2 (Finkel 2017) OR (2) Onset of SMA-associated signs and symptoms before 21 months of age (Mercuri 2018). For individuals using Spinraza following treatment with Zolgensma (onasemnogene abeparvovec-xioi), mbr meets the above criteria AND (1) Individual does not require use of invasive ventilatory support (tracheotomy with positive pressure) or use of non-invasive ventilator support (BiPAP) for more than 16 hours per day as a result of advanced SMA disease AND (2) Individual has not achieved the expected benefit from gene therapy, as shown by the following: (a) within 3 months of gene therapy, individual has not achieved and sustained a CHOP INTEND score of more than 40 points.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	



<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Coverage Duration</b>	6 Months.
<b>Other Criteria</b>	For continuation requests, meets initial criteria AND Individual has documentation (written or verbal) of clinically significant improvement in spinal muscular atrophy-associated signs and symptoms (i.e., progression, stabilization, or decreased decline in motor function) compared to the predicted natural history trajectory of disease.

# Spravato

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## Products Affected

- SPRAVATO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 3 months, continuation 1 year.
<b>Other Criteria</b>	For initial use, individual has been diagnosed with moderate to severe major depressive disorder AND had an inadequate response to the maximum tolerated dose of two antidepressant therapies during the current major depressive episode (MDE) as defined by less than 50% reduction in symptom severity using a standard rating scale that reliably measures depressive symptoms AND will use Spravato in addition to antidepressant therapy. For continuation, individual has had at least a 50% reduction in symptoms of depression compared to baseline using a standard rating scale that reliably measures depressive symptoms AND will use Spravato in addition to antidepressant therapy.

# Spritam

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## Products Affected

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

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

# Sprycel

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## Products Affected

- SPRYCEL

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

# Stelara

## Products Affected

- STELARA INTRAVENOUS
- STELARA SUBCUTANEOUS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Known to have reversible posterior leukoencephalopathy syndrome (RPLS) while on tx with Stelara. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC) and Prevention-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Stelara (ustekinumab). Individual has tuberculosis invasive fungal infection, other active serious infections or a history of recurrent infections. Using ustekinumab in combination with other immunosuppressive therapy or phototherapy for the treatment of plaque psoriasis.
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	Individual is 18 years of age or older. For Plaque Psoriasis, age 12 and older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For 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 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 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: A tumor necrosis factor antagonist drug OR 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 individual has failed to respond to, is intolerant of, or has demonstrated dependence on systemic corticosteroids AND agent is used for any of the following reasons: to reduce signs/symptoms or to induce/maintain clinical response AND 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 individual has either concomitant clinical condition: (a)</p>

<b>PA Criteria</b>	<b>Criteria Details</b>
	Demyelinating disease or (b) Heart failure with documented left ventricular dysfunction, Stelara may be allowed without trial of preferred TNF agents (Enbrel/Humira). For Crohns, if the TNF agent tried and failed are not acceptable due to additional concomitant clinical conditions including: (c) Malignancy [such as but not limited to, solid or hematologic cancers and excluding superficial skin cancers (such as basal and squamous cell)] or (d) Tuberculosis infection.

# Stivarga

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## Products Affected

- STIVARGA

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



# Strattera

## Products Affected

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

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	age 6 and up
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Strensiq

## Products Affected

- STRENSIQ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial 3 mon. Continuation 1 year
<b>Other Criteria</b>	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.

Y0114\_19\_36674\_I\_011

November 2019

# Subsys

## Products Affected

- SUBSYS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Using for the treatment of acute or postoperative pain. Using for treatment of migraine headache pain. Using for non-cancer related breakthrough pain.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- SUPPRELIN LA

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

# Sutent

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## Products Affected

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

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

# Sylatron

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## Products Affected

- SYLATRON
- SYLATRON 4-PACK

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

# Sylvant

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## Products Affected

- SYLVANT

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

# Symdeko

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## Products Affected

- SYMDEKO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	6 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	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

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## Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

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

# Synagis

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## Products Affected

- SYNAGIS

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

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>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/mm<sup>3</sup> OR undergoing cardiac transplantation.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	5 months

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>

# Synarel Nasal Solution

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## Products Affected

- SYNAREL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Precocious puberty, defined as the beginning of secondary sexual maturation characteristics before age 8 in girls and before age 9 in boys.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Endometriosis: 6 months, all other indications: 1 year
<b>Other Criteria</b>	

# Synribo

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## Products Affected

- SYNRIBO

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

# Tafamidis Agents

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## Products Affected

- VYNDAMAX
- VYNDAQEL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has a history of liver or heart transplantation.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	Individual has a diagnosis of wild type or hereditary transthyretin amyloid cardiomyopathy confirmed by biopsy and DNA mutation analysis (Bozkurt, 2016, Maurer, 2018) AND is using for the treatment of New York Heart Association class I, II or III heart failure symptoms (Maurer, 2018).

# Tafinlar

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## Products Affected

- TAFINLAR

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



# Tagrisso

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## Products Affected

- TAGRISSO ORAL TABLET 40 MG, 80 MG

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

# Takhzyro

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## Products Affected

- TAKHZYRO

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

Y0114\_19\_36674\_I\_011

November 2019

# Taltz

## Products Affected

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

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For a dx of active psoriatic arthritis, the individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional drug therapy (such as nonbiologic DMARDS or TNF antagonists) AND agent is used for any of the following reasons: To reduce signs/symptoms or to induce/maintain clinical response AND individual has tried and failed: Humira OR Enbrel. 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 individual has tried and failed: Humira OR Enbrel. For either of the above indications, if the TNF agent (Humira/Enbrel) 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 Taltz (ixekizumab) 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.</p>

# Talzenna

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## Products Affected

- TALZENNA ORAL CAPSULE 0.25 MG, 1 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation provided to confirm deleterious or suspected deleterious germline BRCA-mutation (gBRCAm) and human epidermal growth factor receptor 2-negative (HER2) breast cancer.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Tarceva

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## Products Affected

- *erlotinib oral tablet 100 mg, 150 mg, 25 mg*
- TARCEVA ORAL TABLET 100 MG, 150 MG, 25 MG

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

# Targretin

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## Products Affected

- *bexarotene*
- TARGRETIN ORAL
- TARGRETIN TOPICAL

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

# Tasigna

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## Products Affected

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

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



# Tasmar

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## Products Affected

- TASMAR
- *tolcapone*

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

# Tavalisse

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## Products Affected

- TAVALISSE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has a platelet count of less than 50 X 10 <sup>9</sup> /L
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Tazorac

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## Products Affected

- *tazarotene*
- TAZORAC

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	May not be approved for cosmetic purposes such as, but not limited to the following: Photoaging, Wrinkles, Hyperpigmentation, Sun damage, or Melasma.
<b>Required Medical Information</b>	For psoriasis, individual has up to 20% of body surface area involvement.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- TECENTRIQ INTRAVENOUS SOLUTION  
1,200 MG/20 ML (60 MG/ML), 840  
MG/14 ML (60 MG/ML)

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has received treatment with another PD-1 agent or PD-L1 (for example, nivolumab or pembrolizumab) and Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>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.</p>

# Tecfidera

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## Products Affected

- TECFIDERA

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

# Technivie

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## Products Affected

- TECHNIVIE

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and a reactive HCV antibody, and a subsequent positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND 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).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>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 OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni/Epclusa which is not also in Technivie OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni/Epclusa OR Individual failed to achieve a 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.</p>



# Tegsedi

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## Products Affected

- TEGSEDI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has a history of acute glomerulonephritis caused by Tegsedi (inotersen)
<b>Required Medical Information</b>	Individual has a baseline platelet count greater than or equal to $100 \times 10^9/L$ AND urinary protein to creatinine ratio (UPCR) less than 1000 mg/g AND Individual has a TTR mutation confirmed by genotyping.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has diagnosis of hereditary transthyretin (hATTR) amyloidosis or familial amyloid polyneuropathy (FAP) AND associated mild to moderate polyneuropathy.

# Testosterone Inj

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## Products Affected

- AVEED
- DEPO-TESTOSTERONE
- *testosterone cypionate*
- *testosterone enanthate*
- *testosterone intramuscular*
- *testosterone propionate*
- XYOSTED

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For initial use of replacement therapy, 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. For Continuation of Testosterone Inj agents for replacement therapy, (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. For treatment of delayed puberty when ALL the criteria below are met: Individual is using to stimulate puberty and individual has few to no signs of puberty. For 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. For treatment of HIV-infected male adults with low testosterone and HIV-associated weight loss and wasting. For 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.</p>

# Thalomid

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## Products Affected

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

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

# Thiola

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## Products Affected

- THIOLA
- THIOLA EC

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 9 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has a diagnosis of severe homozygous cystinuria AND Individual is using to prevent the formation of cysteine kidney stones AND Individual has urinary cystine greater than 500 mg/day AND Individual has had a trial and inadequate response or inability to a conservative treatment program including increased fluid intake (Pearle et al., 2014, Qaseem et al., 2014), restriction of sodium and protein intake (Pearle et al., 2014, Qaseem et al., 2014) and urinary alkalinization (Pearle et al., 2014).

# Tibsovo

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## Products Affected

- TIBSOVO

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

# Topamax

## Products Affected

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

# Topical Acne Antibiotic

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## Products Affected

- VELTIN
- ZIANA

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

## Products Affected

- 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 metered-dose 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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older. For transgender use, individual is 16 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- JUBLIA
- KERYDIN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has a confirmed fungal infection (i.e. physical exam).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- ALTRENO
- ATRALIN
- AVITA
- RETIN-A
- RETIN-A MICRO
- RETIN-A MICRO PUMP
- TRETIN-X
- TRETIN-X CREAM KIT
- *tretinoin*
- *tretinoin (emollient)*
- *tretinoin microspheres*

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

# Torisel

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## Products Affected

- *temsirolimus*
- TORISEL

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>

# Tracleer

## Products Affected

- *bosentan*
- TRACLEER ORAL TABLET
- TRACLEER ORAL TABLET FOR SUSPENSION

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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. Or Individual is initiating therapy and has elevated [greater than 3 times the upper limit of normal (ULN)] baseline aminotransferase levels OR In combination with other endothelin receptor antagonist (ERA) agents, such as but not limited to Letairis (ambrisentan) or Opsumit (macitentan).
<b>Required Medical Information</b>	Catheterization-proven diagnosis of Pulmonary Arterial Hypertension (WHO Group I), and WHO Functional Class II-IV symptoms.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Transmucosal Fentanyl Citrate

## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Using for the treatment of acute or postoperative pain. Using for treatment of migraine headache pain Using for non-cancer related breakthrough pain.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Individual is 16 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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 SUSPENSION FOR RECONSTITUTION 11.25 MG, 22.5 MG, 3.75 MG
- TRELSTAR INTRAMUSCULAR SYRINGE 11.25 MG/2 ML, 22.5 MG/2 ML, 3.75 MG/2 ML
- TRELSTAR LA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	For Prostate cancer: Clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, 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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	



# Tremfya

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## Products Affected

- TREMFYA

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

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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).</p>

# Triptodur

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## Products Affected

- TRIPTODUR

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

# Turalio

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## Products Affected

- TURALIO

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

# Tykerb

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## Products Affected

- TYKERB

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

# Tymlos

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## Products Affected

- TYMLOS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual is male OR When abaloparatide (Tymlos) injection has been used for more than a total lifetime duration of 2 years OR If a parathyroid hormone analog (for example, teriparatide [Forteo]) has been used for more than a total lifetime duration of 2 years' time OR If abaloparatide and a parathyroid hormone analog (for example, teriparatide [Forteo]) have been used for a combined total lifetime duration of 2 years or longer. Individual is using Tymlos in combination with any of the following: (1.) Prolia (denosumab) OR (2.) Bisphosphonate OR (3.) Evista (raloxifene) OR (4.) Miacalcin/Fortical (calcitonin nasal spray) OR (5.) Reclast (zoledronic acid) OR (6.) Forteo (teriparatide).

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>Individual is a postmenopausal female with one of the following: (A) dx of osteoporosis (defined as a bone mineral density [BMD] T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population) OR (B) dx of osteoporosis based on history of an osteoporotic low trauma fracture (fragility fracture) and considered at high risk for additional fracture AND Individual has had one of the following: (a) trial of an oral bisphosphonate OR (b) individual is intolerant to or has a contraindication to oral bisphosphonate therapy as defined by one of the following (1 through 5): (1) Hypersensitivity to TWO oral bisphosphonates (one of which must be generic alendronate) OR (2) Inability to stand or sit upright for at least 30 minutes OR (3) A pre-existing gastrointestinal disorder (for example, Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.) OR (4) Uncorrected hypocalcemia OR (5) Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate AND has sustained an osteoporotic low trauma fracture (fragility fracture) while on an oral bisphosphonate or has been refractory to, intolerant of, or has a contraindication to one of the following drugs (1 or 2): (1) Prolia (denosumab) OR (2) Reclast (zoledronic acid) AND individual has been refractory to, or intolerant of, or has a contraindication to Forteo (teriparatide)</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	2 years. Requests to continue therapy beyond 24 months (2 years) should not be approved.
<b>Other Criteria</b>	

# Tysabri

## Products Affected

- TYSABRI

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

## Products Affected

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

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>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.</p>

# Tyzeka

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## Products Affected

- TYZEKA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	Patient is 16 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has had a previous trial and inadequate response or intolerance to or has a contraindication to an alternative antiviral agent with a higher genetic barrier to resistance for Hepatitis B [such as entecavir or tenofovir] (AASLD 2016).

# Uceris

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## Products Affected

- *budesonide oral tablet, delayed and ext.release*
- UCERIS ORAL

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

# Ultomiris

## Products Affected

- ULTOMIRIS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has evidence of active meningococcal infection. Individual has not been immunized with meningococcal vaccine at least 2 weeks prior to administration of the first dose of Ultomiris unless clinical record documents the risks of delaying Ultomiris outweigh the risk of meningococcal infection.
<b>Required Medical Information</b>	Individual has Paroxysmal Nocturnal hemoglobinuria (PNH) as documented by flow cytometry (Written or Verbal attestation is acceptable)in the presence of 1) PNH type III red cell clone or a measurable granulocyte or monocyte clone OR 2) Glycosylphosphatidylinositol-anchored proteins (GPI-AP)-deficient polymorphonuclear cells(PMNs).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual has Lactate dehydrogenase greater than 1.5 times upper limit of normal AND has one or more PNH related symptoms (such as but not limited to anemia or history of major adverse vascular event from thromboembolism)

# Uptravi

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## Products Affected

- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLETS,DOSE PACK

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

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## Products Affected

- VALCHLOR

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

# Vancocin

## Products Affected

- FIRVANQ
- VANCOGIN ORAL CAPSULE 125 MG, 250 MG
- *vancomycin oral capsule 125 mg, 250 mg*
- *mg*
- *vancomycin oral recon soln*

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual is being treated for enterocolitis caused by Staphylococcal aureus including methicillin-resistant strains. Individual is being treated for clostridium difficile.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	14 days
<b>Other Criteria</b>	



# Vectibix

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## Products Affected

- VECTIBIX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has received prior treatment with cetuximab (Erbix) [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.
<b>Required Medical Information</b>	Extended RAS gene mutation testing with an FDA approved test is documented and the tumor is determined to be RAS wild-type.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	6 months
<b>Other Criteria</b>	Used as a single agent or as part of combination therapy for stage IV colon, rectal, colorectal, small bowel or anal adenocarcinoma.

# Velcade

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## Products Affected

- BORTEZOMIB
- VELCADE

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

# Vemlidy

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## Products Affected

- VEMLIDY

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

# Venclexta

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## Products Affected

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

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

# Ventavis

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## Products Affected

- VENTAVIS

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Other Criteria</b>	<p>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.</p>

# Verzenio

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## Products Affected

- VERZENIO

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

# Vfend

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## Products Affected

- VFEND
- *voriconazole oral suspension for reconstitution*
- *voriconazole oral tablet 200 mg*
- VORICONAZOLE ORAL TABLET 50 MG

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



# Vibativ

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## Products Affected

- VIBATIV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	30 day supply/One time only
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 Year
<b>Other Criteria</b>	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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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].
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	Individual is 18 years of age or older

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	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

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## Products Affected

- *azacitidine*
- VIDAZA

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

# Viekira

## Products Affected

- VIEKIRA PAK
- VIEKIRA XR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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 non-nucleoside 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
<b>Required Medical Information</b>	Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes genotype and a reactive HCV antibody, and a subsequent positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND 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).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.
<b>Other Criteria</b>	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 OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni (ledipasvir/sofosbuvir) which is not also in Viekira OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni.

# Vimizim

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## Products Affected

- VIMIZIM

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



# Vimovo

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## Products Affected

- VIMOVO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	Individual has had a trial and inadequate response or intolerance to one (1) oral generic prescription Non-Steroidal Anti-Inflammatory Drugs (NSAID) AND has had a trial and inadequate response or intolerance to one (1) of the following (Lanza 2009): (a) preferred proton pump inhibitor (PPI) OR (b) Generic misoprostol AND Individual has had an adequate response (pain relief and appropriate gastro protection) with a trial of naproxen and a proton pump inhibitor (such as esomeprazole) used at the same time AND Documentation has been provided for why the combination agent is clinically necessary and not for convenience.

# Virazole

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## Products Affected

- *ribavirin inhalation*
- VIRAZOLE

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

# Vittrakvi

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## Products Affected

- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Written or verbal attestation to confirm genetic test results show the tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Vivitrol

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## Products Affected

- VIVITROL

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

PA Criteria	Criteria Details
<b>Required Medical Information</b>	<p>For alcohol dependence, Individual is not actively drinking at the time of initial injectable naltrexone (Vivitrol) administration AND 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.</p>
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Vizimpro

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## Products Affected

- VIZIMPRO ORAL TABLET 15 MG, 30 MG, 45 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	genetic mutations test result is confirmed by written or verbal attestation.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	

# Vosevi

## Products Affected

- VOSEVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has severe renal impairment (eGFR less than 30 mL/min/1.73m <sup>2</sup> ), end stage renal disease, or requires dialysis OR Individual has moderate or severe hepatic impairment (Child-Pugh B or C).
<b>Required Medical Information</b>	Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a genotype and a reactive HCV antibody, and a subsequent positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND 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).
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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. For Genotype 4 Individual has had a trial of and inadequate response to Harvoni or Eplclusa 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 Eplclusa 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.</p>



# VOTRIENT

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## Products Affected

- VOTRIENT

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

# Vraylar

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## Products Affected

- VRAYLAR ORAL CAPSULE
- VRAYLAR ORAL CAPSULE,DOSE PACK

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

# Vytorin

## Products Affected

- *ezetimibe-simvastatin*
- VYTORIN 10-10
- VYTORIN 10-20
- VYTORIN 10-40
- VYTORIN 10-80

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

# Xalkori

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## Products Affected

- XALKORI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation is provided that tumor is anaplastic lymphoma kinase (ALK)-positive or c-ros oncogene 1 (ROS1) positive.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Xeljanz

## Products Affected

- XELJANZ
- XELJANZ XR

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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/mm <sup>3</sup> , lymphocyte count less than 500 cells/mm <sup>3</sup> , 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).
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For RA and PsA, Individual is using to reduce signs/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: Humira OR 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, for RA only, individual 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). For UC, Individual is using to reduce signs/symptoms or induce/maintain clinical remission and mucosal healing AND 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 has demonstrated dependence on corticosteroids AND has had a trial of and an inadequate response or is intolerant to Humira OR Humira is not acceptable due to concomitant clinical conditions, such as but not limited to any of the following listed above (a-d).</p>

# XENAZINE

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## Products Affected

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

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

# Xermelo

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## Products Affected

- XERMELO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial: 3 months. Continuation: 1 year
<b>Other Criteria</b>	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

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## Products Affected

- XGEVA

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Repeat injection of a previously treated cord within one year of a prior course for treating Dupuytren's contracture.
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	

# Xifaxan - HE

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## Products Affected

- XIFAXAN ORAL TABLET 550 MG

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

# Xifaxan 200mg

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## Products Affected

- AEMCOLO
- XIFAXAN ORAL TABLET 200 MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	For travelers diarrhea (TD) caused by noninvasive strains of Escherichia coli AND Individual has already been started on requested agent 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, 2018): (1)Generic Fluoroquinolone OR(2)Azithromycin.

# Xiidra

## Products Affected

- XIIDRA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	17 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	Individual is using to treat moderate to severe dry eye disease (AAO 2013).

# Xolair

## Products Affected

- XOLAIR SUBCUTANEOUS RECON SOLN
- XOLAIR SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.5 ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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 than 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.
<b>Age Restrictions</b>	Patient is 12 years of age or older for urticaria and 6 years of age or older for moderate to severe persistent asthma
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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.</p>

# Xospata

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## Products Affected

- XOSPATA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Individual has confirmed FMS-like tyrosine kinase 3 (FLT3) mutation (written or verbal attestation is acceptable).
<b>Age Restrictions</b>	18 years of age and older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	



# Xpovio

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## Products Affected

- XPOVIO ORAL TABLET 100 MG/WEEK (20 MG X 5), 160 MG/WEEK (20 MG X 8), 60 MG/WEEK (20 MG X 3), 80 MG/WEEK (20 MG X 4)

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

# Xtandi

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## Products Affected

- XTANDI

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

# Xuriden

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## Products Affected

- XURIDEN

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

# Xyrem

## Products Affected

- XYREM

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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).
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Initial Request 3 months, Renewal is 6 months.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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: (A) One of the following wakefulness promoting 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</p>

# Yervoy

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## Products Affected

- YERVOY

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual has autoimmune disease which requires treatment with immunosuppressant drugs.
<b>Required Medical Information</b>	For small cell lung cancer OR unresectable or metastatic melanoma AND individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>For the treatment of unresectable or metastatic melanoma: 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 lymphadenectomy. For the treatment of small cell lung cancer (SCLC): Yervoy is used in combination with nivolumab (Opdivo) as subsequent therapy for one of the following: 1) demonstrated disease relapse within 6 months following complete or partial response or stable disease with initial treatment, OR 2) no response with initial treatment, OR 3) primary progressive disease.</p>

# Yonsa

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## Products Affected

- YONSA

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



# Zaltrap

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## Products Affected

- ZALTRAP

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Diagnosis of metastatic anal adenocarcinoma or metastatic appendice 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
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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 mm <sup>3</sup> or those at risk developing new bone complications) (Weinreb et al. 2005). Individual has severe renal impairment (less than 30 mL/min/1.73 m <sup>2</sup> ). Individual has mild, moderate or severe hepatic impairment or cirrhosis.
<b>Required Medical Information</b>	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 mm <sup>3</sup> .

PA Criteria	Criteria Details
<b>Age Restrictions</b>	Individual is 18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	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

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## Products Affected

- ZEJULA

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

# Zelboraf

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## Products Affected

- ZELBORAF

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

# Zepatier

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## Products Affected

- ZEPATIER

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Documentation is provided for a diagnosis of chronic hepatitis C (CHC) infection, which includes a genotype and a reactive HCV antibody, and a subsequent positive HCV RNA result to confirm diagnosis (AASLD/IDSA 2017, CDC 2013) AND Individual has received baseline evaluation for liver fibrosis to guide appropriate therapy AND 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).
<b>Age Restrictions</b>	18 years of age or older.
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	Criteria will be applied consistent with current AASLD/IDSA guidance.

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>Criteria will be applied consistent with current AASLD/IDSA guidance. For GT 1, 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 OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni (ledipasvir/sofosbuvir) which is not also in Zepatier OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni OR Individual has concomitant severe or end-stage CKD or requires dialysis. For GT 4, individual has had a prior trial and inadequate response to Harvoni or Eplclusa OR individual is currently on and completing a course of therapy with the requested regimen OR Individual has a documented hypersensitivity, as manifested by a severe allergic reaction, to any ingredient in Harvoni or Eplclusa which is not also in Zepatier OR Individual is concurrently using an agent that cannot be substituted with another agent or temporarily discontinued and is contraindicated or not recommended for concomitant use with Harvoni or Eplclusa OR Individual has concomitant severe or end-stage CKD or requires dialysis.</p>

# Zinbryta

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## Products Affected

- ZINBRYTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Individual with primary progressive MS. Individuals with secondary progressive MS. Combination treatment with other disease modifying biologic MS drug therapies (for example, interferons, glatiramer, alemtuzumab, natalizumab and ocrelizumab). Individuals with hepatic disease, hepatic impairment and autoimmune conditions involving the liver.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	



# Zinplava

## Products Affected

- ZINPLAVA

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

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## Products Affected

- ZOLINZA

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

# Zometa

## Products Affected

- ZOLEDRONIC AC-MANNITOL-0.9NACL
- *zoledronic acid*
- *zoledronic acid-mannitol-water intravenous piggyback 4 mg/100 ml*
- ZOMETA

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	Bone metastases documented on imaging or bone pain associated with imaging-documented metastases from breast, prostate, lung, kidney, thyroid, or other solid tumors.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year

PA Criteria	Criteria Details
<b>Other Criteria</b>	<p>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 glucocorticoid-induced 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 Hypercalcemia of malignancy, treatment or Multiple myeloma 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 age-specific normal reference range or those who are symptomatic or at risk for complication from their disease OR Prevention of osteoporosis during androgen deprivation therapy in prostate cancer.</p>

# Zulresso

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## Products Affected

- ZULRESSO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year.
<b>Other Criteria</b>	Individual is 6 months postpartum or less AND has a diagnosis of moderate to severe postpartum depression consistent with qualifying score using a standardized screening tool for depression (such as, but not limited to, Hamilton Rating Scale for Depression [HAM-D], Patient Health Questionnaire [PHQ-9], Beck Depression Inventory [BDI], Montgomery-Asberg Depression Rating Scale [MADRS], Edinburgh Postnatal Depression Scale [EPDS]).

# Zurampic

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## Products Affected

- ZURAMPIC

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	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.
<b>Required Medical Information</b>	
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Individual remains symptomatic (such as, but not limited to joint pain, swelling, limited range of motion, erythema) despite use of xanthine oxidase inhibitor

# Zydelig

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## Products Affected

- ZYDELIG

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

# Zykadia

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## Products Affected

- ZYKADIA

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



# Zytiga

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## Products Affected

- *abiraterone*
- ZYTIGA ORAL TABLET 250 MG, 500 MG

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

# Zyvox

## Products Affected

- *linezolid oral suspension for reconstitution*
- *linezolid oral tablet*
- ZYVOX ORAL SUSPENSION FOR RECONSTITUTION
- ZYVOX ORAL TABLET

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
<b>Required Medical Information</b>	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.
<b>Age Restrictions</b>	
<b>Prescriber Restrictions</b>	
<b>Coverage Duration</b>	30 days
<b>Other Criteria</b>	

## Index

8-MOP.....	283	<i>alose tron</i> .....	260
<i>abiraterone</i> .....	577	ALOXI.....	24
ABRAXANE.....	1	ALTOPREV.....	324
ABSTRAL.....	2	ALTRENO.....	491
ACTEMRA.....	3	ALUNBRIG ORAL TABLET 180 MG, 30	
ACTEMRA ACTPEN.....	3	MG, 90 MG.....	26
ACTHAR.....	184	ALUNBRIG ORAL TABLETS,DOSE PACK.	26
ACTHAR H.P.....	184	ALYQ.....	9
ACTIMMUNE.....	5	<i>amabelz</i> .....	186
ACTIQ.....	6	AMBIEN.....	186
ACTIVELLA.....	186	AMBIEN CR.....	186
ADCETRIS.....	7	<i>ambrisentan</i> .....	251
ADCIRCA.....	9	<i>amifostine crystalline</i> .....	140
ADDERALL ORAL TABLET 10 MG, 12.5		<i>amitriptyline</i> .....	185
MG, 15 MG, 20 MG, 30 MG, 5 MG, 7.5		<i>amitriptyline-chlordiazepoxide</i> .....	185
MG.....	28	<i>amoxapine</i> .....	185
ADDERALL XR.....	28	<i>amphetamine sulfate oral tablet 10</i>	
ADDYI.....	10	<i>mg, 5 mg</i> .....	141
<i>adefovir</i> .....	181	AMPYRA.....	29
ADEMPAS.....	12	AMRIX.....	186
ADHANSIA XR.....	284	AMYTAL.....	186
AEMCOLO.....	548	ANADROL-50.....	30
AFINITOR.....	14	ANAFRANIL.....	185
AFINITOR DISPERZ.....	14	ANDRODERM.....	325
AFREZZA INHALATION CARTRIDGE		ANDROGEL TRANSDERMAL GEL IN	
WITH INHALER 12 UNIT, 4 UNIT, 4		METERED-DOSE PUMP 12.5 MG/ 1.25	
UNIT (30)/ 8 UNIT (60), 4 UNIT (60)/		GRAM (1 % ).....	325
8 UNIT (30), 4 UNIT (90)/ 8 UNIT		ANDROGEL TRANSDERMAL GEL IN	
(90), 4 UNIT/8 UNIT/ 12 UNIT (60), 8		METERED-DOSE PUMP 20.25 MG/1.25	
UNIT, 8 UNIT (60)/ 12 UNIT (30), 8		GRAM (1.62 % ).....	489
UNIT (90)/ 12 UNIT (90).....	15	ANDROGEL TRANSDERMAL GEL IN	
AIMOVIG AUTOINJECTOR (2 PACK).....	16	PACKET 1 % (25 MG/2.5GRAM), 1 %	
AIMOVIG AUTOINJECTOR		(50 MG/5 GRAM).....	325
SUBCUTANEOUS AUTO-INJECTOR 140		ANDROGEL TRANSDERMAL GEL IN	
MG/ML, 70 MG/ML.....	16	PACKET 1.62 % (20.25 MG/1.25	
AJOVY.....	18	GRAM), 1.62 % (40.5 MG/2.5 GRAM).	489
ALAGESIC LQ.....	186	<i>androxy</i> .....	31
ALDURAZYME.....	19	ANGELIQ.....	186
ALECENSA.....	21	ANTIVERT.....	186
ALIMTA.....	22	APOKYN.....	32
ALIQOPA.....	23	APTENSIO XR.....	284
ALLZITAL.....	186	ARALAST.....	25
ALORA.....	186	ARALAST NP.....	25

ARANESP (IN POLYSORBATE).....	33	<i>bexarotene</i> .....	471
<i>arbinoxa</i> .....	186	BIVIGAM.....	315
ARCALYST.....	35	BLINCYTO.....	53
<i>armodafinil oral tablet 150 mg, 200</i>		BONJESTA.....	186
<i>mg, 250 mg, 50 mg</i> .....	336	BORTEZOMIB.....	514
ARMOUR THYROID.....	186	<i>bosentan</i> .....	494
ARYMO ER.....	321	BOSULIF ORAL TABLET 100 MG, 400	
ARZERRA.....	36	MG, 500 MG.....	54
<i>ascomp with codeine</i> .....	186	BOTOX.....	55
<i>atomoxetine oral capsule 10 mg, 100</i>		BRAFTOVI ORAL CAPSULE 50 MG, 75	
<i>mg, 18 mg, 25 mg, 40 mg, 60 mg, 80</i>		MG.....	57
<i>mg</i> .....	449	BRIVIACT INTRAVENOUS.....	58
<i>atovaquone</i> .....	280	BRIVIACT ORAL SOLUTION.....	58
ATRALIN.....	491	BRIVIACT ORAL TABLET 10 MG, 100	
AUBAGIO.....	37	MG, 25 MG, 50 MG, 75 MG.....	58
AURYXIA.....	38	<i>budesonide oral tablet, delayed and</i>	
AUSTEDO.....	39	<i>ext.release</i> .....	508
AVANDAMET ORAL TABLET 2-1,000		BUPAP.....	186
MG, 2-500 MG, 4-1,000 MG, 4-500 MG	327	BUPHENYL.....	59
AVANDARYL ORAL TABLET 4-1 MG, 4-		<i>buprenorphine transdermal patch</i>	
2 MG, 4-4 MG, 8-2 MG, 8-4 MG.....	327	<i>weekly 10 mcg/hour, 15 mcg/hour, 20</i>	
AVANDIA ORAL TABLET 2 MG, 4 MG, 8		<i>mcg/hour, 5 mcg/hour</i> .....	321
MG.....	327	BUPRENORPHINE TRANSDERMAL	
AVASTIN.....	41	PATCH WEEKLY 7.5 MCG/HOUR.....	321
AVEED.....	482	BUTALBITAL COMPOUND.....	186
AVITA.....	491	<i>butalbital compound w/codeine</i> .....	186
AVONEX.....	213	<i>butalbital-acetaminop-caf-cod</i> .....	186
AVONEX (WITH ALBUMIN).....	213	<i>butalbital-acetaminophen</i> .....	186
AXIRON.....	325	<i>butalbital-acetaminophen-caff</i> .....	186
<i>azacitidine</i> .....	525	<i>butalbital-aspirin-caffeine</i> .....	186
BALVERSA ORAL TABLET 3 MG, 4 MG,		BUTISOL ORAL ELIXIR.....	186
5 MG.....	44	BUTISOL ORAL TABLET 30 MG, 50 MG	186
BANZEL ORAL SUSPENSION.....	45	BUTRANS TRANSDERMAL PATCH	
BANZEL ORAL TABLET 200 MG, 400		WEEKLY 10 MCG/HOUR, 15	
MG.....	45	MCG/HOUR, 20 MCG/HOUR, 5	
BARACLUDE.....	46	MCG/HOUR, 7.5 MCG/HOUR.....	321
BAVENCIO.....	47	CABOMETYX.....	60
BELBUCA.....	321	CALQUENCE.....	61
BELEODAQ.....	49	CAPACET.....	186
BENLYSTA.....	50	CAPRELSA ORAL TABLET 100 MG, 300	
BENTYL ORAL.....	186	MG.....	62
<i>benztropine oral</i> .....	186	CARBAGLU.....	63
BERINERT.....	52	<i>carbinoxamine maleate</i> .....	186
BETASERON.....	213	CARIMUNE.....	315

CARIMUNE NF NANOFILTERED.....	315	COMPLETE ALLERGY MEDICINE.....	186
<i>carisoprodol</i> .....	186	CONCERTA ORAL TABLET EXTENDED	
<i>carisoprodol-asa-codeine</i> .....	186	RELEASE 24HR 18 MG, 27 MG, 36 MG,	
<i>carisoprodol-aspirin</i> .....	186	54 MG.....	284
CAYSTON.....	64	CONZIP.....	319
CELEBREX.....	65	COPAXONE SUBCUTANEOUS SYRINGE	
<i>celecoxib</i> .....	65	20 MG/ML, 40 MG/ML.....	80
CENESTIN.....	186	COPAXONE SUBCUTANEOUS SYRINGE	
CEQUA.....	66	KIT.....	80
CERDELGA.....	67	COPIKTRA.....	81
CEREZYME.....	166	CORLANOR ORAL SOLUTION.....	82
CHANTIX.....	69	CORLANOR ORAL TABLET.....	82
CHANTIX CONTINUING MONTH BOX....	69	COSENTYX.....	83
CHANTIX CONTINUING MONTH PAK....	69	COSENTYX (2 SYRINGES).....	83
CHANTIX STARTING MONTH BOX.....	69	COSENTYX PEN.....	83
CHANTIX STARTING MONTH PAK.....	69	COSENTYX PEN (2 PENS).....	83
CHENODAL.....	70	COTELLIC.....	85
<i>chlordiazepoxide-clidinium</i> .....	186	COTEMPLA XR-ODT.....	284
<i>chlorpropamide oral tablet 100 mg,</i>		CRESEMBA.....	86
<i>250 mg</i> .....	186	CRINONE.....	87
<i>chlorzoxazone oral tablet 375 mg, 500</i>		CUTAQUIG.....	315
<i>mg, 750 mg</i> .....	186	CUVITRU.....	315
CHOLBAM.....	71	<i>cyclobenzaprine</i> .....	186
<i>chorionic gonadotropin, human</i> .....	72	<i>cyproheptadine</i> .....	186
CIALIS ORAL TABLET 2.5 MG, 5 MG....	73	CYRAMZA.....	88
CIMZIA.....	74	D.H.E.45.....	89
CIMZIA POWDER FOR RECONST.....	74	DAKLINZA.....	92
CIMZIA STARTER KIT.....	74	<i>dalfampridine</i> .....	29
CINQAIR.....	76	DALIRESP.....	94
CINRYZE.....	78	DARZALEX.....	95
<i>clemastine oral syrup</i> .....	186	DAURISMO ORAL TABLET 100 MG, 25	
<i>clemastine oral tablet 2.68 mg</i> .....	186	MG.....	96
CLIMARA.....	186	<i>deferasirox</i> .....	144
CLIMARA PRO.....	186	DEMEROL (PF).....	186
<i>clobazam oral suspension</i> .....	348	DEMEROL INJECTION.....	186
<i>clobazam oral tablet 10 mg, 20 mg</i> ....	348	DEMEROL ORAL.....	186
<i>clomipramine</i> .....	185	DEPO-TESTOSTERONE.....	482
<i>codeine-butalbital-asa-caff</i> .....	186	<i>desipramine</i> .....	185
COMBIPATCH.....	186	DESOXYN.....	97
COMETRIQ ORAL CAPSULE 100		<i>dexchlorpheniramine maleate</i> .....	186
MG/DAY(80 MG X1-20 MG X1), 140		<i>dextroamphetamine-amphetamine oral</i>	
MG/DAY(80 MG X1-20 MG X3), 60		<i>capsule,extended release 24hr</i> .....	27
MG/DAY (20 MG X 3/DAY).....	79		
COMFORT PAC-CYCLOBENZAPRINE....	186		

<i>dextroamphetamine-amphetamine oral tablet 10 mg, 12.5 mg, 15 mg, 20 mg, 30 mg, 5 mg, 7.5 mg</i> .....	27	ELESTRIN.....	186
DIABETA ORAL TABLET 1.25 MG, 2.5 MG, 5 MG.....	186	ELIDEL.....	115
DICLEGIS.....	186	ELIGARD.....	116
DICLOFENAC EPOLAMINE.....	158	ELIGARD (3 MONTH).....	116
<i>diclofenac sodium topical gel 3 %</i> .....	432	ELIGARD (4 MONTH).....	116
<i>dicyclomine oral</i> .....	186	ELIGARD (6 MONTH).....	116
DIFICID.....	99	ELITEK.....	117
<i>digitek oral tablet 250 mcg (0.25 mg)</i> .....	186	ELZONRIS.....	118
<i>digox oral tablet 250 mcg (0.25 mg)</i> .....	186	EMBEDA.....	321
<i>digoxin injection solution</i> .....	186	EMFLAZA.....	119
<i>digoxin oral tablet 250 mcg (0.25 mg)</i> .....	186	EMGALITY PEN.....	121
<i>dihydroergotamine injection</i> .....	89	EMGALITY SYRINGE SUBCUTANEOUS SYRINGE 120 MG/ML, 300 MG/3 ML (100 MG/ML X 3).....	121
<i>diphenhydramine hcl oral</i> .....	186	EMPLICITI.....	123
<i>diphenoxylate-atropine</i> .....	186	EMSAM.....	124
<i>dipyridamole oral</i> .....	186	ENBREL MINI.....	125
<i>disopyramide phosphate</i> .....	186	ENBREL SUBCUTANEOUS RECON SOLN.....	125
DIVIGEL.....	186	ENBREL SUBCUTANEOUS SYRINGE 25 MG/0.5 ML (0.5), 50 MG/ML (1 ML)....	125
DOLOPHINE.....	319	ENBREL SURECLICK.....	125
DOPTELET.....	100	ENJUVIA.....	186
DOPTELET (10 TAB PACK).....	100	<i>entecavir</i> .....	46
DOPTELET (15 TAB PACK).....	100	ENTRESTO.....	127
DOPTELET (30 TAB PACK).....	100	ENTYVIO.....	128
DOTTI.....	186	EPCLUSA.....	130
<i>doxepin oral</i> .....	185	EPIDIOLEX.....	131
DOXIL.....	101	EPOGEN.....	132
<i>doxorubicin, peg-liposomal</i> .....	101	<i>epoprostenol (glycine)</i> .....	368
<i>doxylamine-pyridoxine (vit b6)</i> .....	186	ERAXIS(WATER DILUENT).....	134
DUAVEE.....	103	ERBITUX.....	135
DUEXIS.....	104	<i>ergoloid</i> .....	186
DUOBRII.....	105	ERIVEDGE.....	136
DUOPA.....	106	ERLEADA.....	137
DUPIXENT SUBCUTANEOUS SYRINGE 200 MG/1.14 ML, 300 MG/2 ML.....	107	<i>erlotinib oral tablet 100 mg, 150 mg, 25 mg</i> .....	470
DURAGESIC.....	109	ERWINAZE.....	138
DUZALLO.....	111	ESBRIET ORAL CAPSULE.....	139
DYSPORT.....	55	ESBRIET ORAL TABLET 267 MG, 801 MG.....	139
DYUSS.....	186	ESGIC.....	186
EDLUAR.....	186	ESTRACE ORAL.....	186
EGRIFTA.....	112	ESTRADERM.....	186
ELAPRASE.....	114		
ELELYSO.....	166		

<i>estradiol oral</i> .....	186	FETZIMA ORAL CAPSULE,EXTENDED	
<i>estradiol transdermal patch</i>		RELEASE 24 HR 120 MG, 20 MG, 40	
<i>semiweekly</i> .....	186	MG, 80 MG.....	154
<i>estradiol transdermal patch weekly</i> ....	186	FEXMID.....	186
<i>estradiol-norethindrone acet</i> .....	186	FIORICET.....	186
ESTRASORB.....	186	FIORICET WITH CODEINE.....	186
ESTROGEL.....	186	FIORINAL.....	186
<i>estropipate</i> .....	186	FIORINAL-CODEINE #3.....	186
<i>eszopiclone</i> .....	186	FIRAZYR.....	155
ETHYOL.....	140	FIRDAPSE.....	156
EVAMIST.....	186	FIRMAGON KIT W DILUENT SYRINGE	
EVEKEO ODT ORAL		SUBCUTANEOUS RECON SOLN 120	
TABLET,DISINTEGRATING 10 MG, 15		MG, 80 MG.....	157
MG, 20 MG, 5 MG.....	141	FIRMAGON SUBCUTANEOUS RECON	
EVEKEO ORAL TABLET 10 MG, 5 MG..	141	SOLN 120 MG, 80 MG.....	157
EVENITY SUBCUTANEOUS SYRINGE		FIRVANQ.....	512
105 MG/1.17 ML, 210MG/2.34ML (		FLEBOGAMMA.....	315
105MG/1.17MLX2).....	142	FLEBOGAMMA DIF.....	315
EXALGO ER.....	319	FLECTOR.....	158
EXJADE.....	144	FLEXERIL.....	186
EXONDYS 51.....	145	FLOLAN.....	368
EXTAVIA.....	314	FORTEO.....	159
EYLEA.....	146	FORTESTA.....	325
<i>ezetimibe-simvastatin</i> .....	539	FULPHILA.....	299
FABRAZYME.....	147	<i>fulvestrant</i> .....	151
FARXIGA.....	323	FURADANTIN.....	186
FARYDAK ORAL CAPSULE 10 MG, 15		FUSILEV.....	161
MG, 20 MG.....	148	<i>fyavolv</i> .....	186
FASENRA PEN.....	149	GAMASTAN.....	162
FASLODEX.....	151	GAMASTAN S/D.....	162
FEMHRT LOW DOSE.....	186	GAMIFANT.....	164
<i>fentanyl</i> .....	109	GAMMAGARD LIQUID.....	315
<i>fentanyl citrate buccal lozenge on a</i>		GAMMAGARD S/D.....	315
<i>handle</i> .....	495	GAMMAGARD S-D (IGA < 1 MCG/ML).	315
FENTANYL CITRATE BUCCAL TABLET,		GAMMAKED.....	315
EFFERVESCENT.....	152	GAMMAPLEX.....	315
FENTORA BUCCAL TABLET,		GAMMAPLEX (WITH SORBITOL).....	315
EFFERVESCENT 100 MCG, 200 MCG,		GAMUNEX.....	217
400 MCG, 600 MCG, 800 MCG.....	152	GAMUNEX-C.....	217
FERRIPROX.....	153	GATTEX 30-VIAL.....	165
FETZIMA ORAL CAPSULE,EXT REL		GATTEX ONE-VIAL.....	165
24HR DOSE PACK.....	154	GAZYVA.....	169
		GENOTROPIN.....	310
		GENOTROPIN MINIQUICK.....	310



GILENYA.....	170	HUMIRA(CF) PEDI CROHNS STARTER	
GILOTRIF .....	172	SUBCUTANEOUS SYRINGE KIT 80	
GLASSIA.....	25	MG/0.8 ML, 80 MG/0.8 ML-40 MG/0.4	
<i>glatiramer subcutaneous syringe 20</i>		ML.....	194
<i>mg/ml, 40 mg/ml.....</i>	80	HUMIRA(CF) PEN.....	194
<i>glatopa subcutaneous syringe 20</i>		HUMIRA(CF) PEN CROHNS-UC-HS.....	194
<i>mg/ml, 40 mg/ml.....</i>	80	HUMIRA(CF) PEN PSOR-UV-ADOL HS.	194
GLEEVEC ORAL TABLET 100 MG, 400		HUMIRA(CF) SUBCUTANEOUS	
MG.....	173	SYRINGE KIT 10 MG/0.1 ML, 20	
GLEOSTINE.....	174	MG/0.2 ML, 40 MG/0.4 ML.....	194
GLUCOVANCE.....	186	HUMULIN R U-500 (CONC) INSULIN...	197
<i>glyburide micronized oral tablet 1.5</i>		HUMULIN R U-500 (CONC) KWIKPEN.	197
<i>mg, 3 mg, 6 mg.....</i>	186	<i>hydromorphone oral tablet extended</i>	
<i>glyburide oral tablet 1.25 mg, 2.5 mg,</i>		<i>release 24 hr.....</i>	319
<i>5 mg.....</i>	186	<i>hydroxyprogest(pf)(preg presv).....</i>	272
<i>glyburide-metformin oral tablet 1.25-</i>		HYDROXYPROGESTERONE	
<i>250 mg, 2.5-500 mg, 5-500 mg.....</i>	186	CAP(PPRES).....	272
GLYNASE ORAL TABLET 1.5 MG, 3 MG,		<i>hydroxyprogesterone caproate.....</i>	272
6 MG.....	186	<i>hydroxyzine hcl.....</i>	186
GLYXAMBI.....	323	<i>hydroxyzine pamoate.....</i>	186
GRANIX.....	175	HYQVIA.....	315
GRASTEK.....	177	HYSINGLA ER.....	321
<i>guanfacine oral tablet.....</i>	186	IBRANCE.....	198
<i>guanfacine oral tablet extended</i>		<i>icatibant.....</i>	155
<i>release 24 hr.....</i>	214	ICLUSIG ORAL TABLET 15 MG, 45 MG	199
HAEGARDA.....	178	IDHIFA ORAL TABLET 100 MG, 50 MG	200
HALAVEN.....	179	ILARIS (PF).....	201
HARVONI.....	180	ILUMYA.....	203
HEPSERA.....	181	<i>imatinib oral tablet 100 mg, 400 mg...</i>	173
HETLIOZ.....	182	IMBRUVICA ORAL CAPSULE 140 MG,	
HIZENTRA.....	315	70 MG.....	205
HORIZANT ORAL TABLET EXTENDED		IMBRUVICA ORAL TABLET 140 MG,	
RELEASE 300 MG, 600 MG.....	183	280 MG, 420 MG, 560 MG.....	205
HUMATROPE.....	310	IMFINZI.....	206
HUMIRA PEDIATRIC CROHNS START		<i>imipramine hcl.....</i>	185
SUBCUTANEOUS SYRINGE KIT 40		<i>imipramine pamoate.....</i>	185
MG/0.8 ML, 40 MG/0.8 ML (6 PACK)...	194	INCIVEK.....	207
HUMIRA PEN.....	194	INCRELEX.....	209
HUMIRA PEN CROHNS-UC-HS START.	194	INDOCIN ORAL.....	186
HUMIRA PEN PSOR-UEVITS-ADOL HS.	194	<i>indomethacin.....</i>	186
HUMIRA SUBCUTANEOUS SYRINGE		<i>indomethacin sodium.....</i>	186
KIT 10 MG/0.2 ML, 20 MG/0.4 ML, 40		INFLECTRA.....	392
MG/0.8 ML.....	194	INGREZZA INITIATION PACK.....	210



INGREZZA ORAL CAPSULE 40 MG, 80 MG.....	210	KHAPZORY.....	161
INLYTA ORAL TABLET 1 MG, 5 MG.....	211	KINERET.....	237
INREBIC.....	212	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.....	239
INTERMEZZO.....	186	KISQALI ORAL TABLET 200 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3).....	239
INTUNIV ER.....	214	KOMBIGLYZE XR ORAL TABLET, ER MULTIPHASE 24 HR 2.5-1,000 MG, 5-1,000 MG, 5-500 MG.....	102
INVOKAMET.....	323	KORLYM.....	240
INVOKAMET XR.....	323	KRYSTEXXA.....	241
INVOKANA ORAL TABLET 100 MG, 300 MG.....	323	KUVAN.....	242
ISTODAX.....	215	KYNAMRO.....	243
<i>itraconazole oral capsule</i> .....	216	KYPROLIS.....	244
IXEMPRA.....	221	LANOXIN INJECTION.....	186
JADENU.....	222	LANOXIN ORAL TABLET 187.5 MCG (0.1875 MG), 250 MCG (0.25 MG).....	186
JADENU SPRINKLE.....	222	LARTRUVO.....	245
JAKAFI ORAL TABLET 10 MG, 15 MG, 20 MG, 25 MG, 5 MG.....	223	LATUDA ORAL TABLET 120 MG, 20 MG, 40 MG, 60 MG, 80 MG.....	247
JETREA (PF).....	224	LAZANDA.....	248
<i>jevantique lo</i> .....	186	<i>ledipasvir-sofosbuvir</i> .....	180
JEVTANA.....	225	LEMTRADA.....	249
<i>jinteli</i> .....	186	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).....	250
JUBLIA.....	490	LETAIRIS.....	251
JUXTAPID.....	226	LEUKINE.....	252
JYNARQUE ORAL TABLET 15 MG, 30 MG.....	227	<i>leuprolide</i> .....	267
JYNARQUE ORAL TABLETS, SEQUENTIAL.....	227	<i>levoleucovorin calcium</i> .....	161
KADCYLA.....	228	LIBRAX (WITH CLIDINIUM).....	186
KADIAN.....	319	LIBTAYO.....	254
KALBITOR.....	229	<i>lidocaine hcl mucous membrane jelly</i> ..	255
KALYDECO ORAL GRANULES IN PACKET 25 MG, 50 MG, 75 MG.....	230	<i>lidocaine hcl mucous membrane solution 2 %, 4 % (40 mg/ml)</i> .....	255
KALYDECO ORAL TABLET.....	230	<i>lidocaine hcl topical</i> .....	255
KANUMA.....	231		
KARBINAL ER.....	186		
KERYDIN.....	490		
<i>ketorolac injection cartridge</i> .....	186		
<i>ketorolac injection solution</i> .....	186		
<i>ketorolac injection syringe 30 mg/ml</i> ..	186		
<i>ketorolac intramuscular</i> .....	186		
<i>ketorolac oral</i> .....	186		
KEVEYIS.....	232		
KEVZARA.....	233		
KEYTRUDA.....	235		

<i>lidocaine topical adhesive</i>		MARGESIC.....	186
<i>patch, medicated</i> .....	256	<i>marten-tab</i> .....	186
<i>lidocaine topical ointment</i> .....	255	MAVENCLAD (10 TABLET PACK).....	273
<i>lidocaine viscous</i> .....	255	MAVENCLAD (4 TABLET PACK).....	273
LIDODERM.....	256	MAVENCLAD (5 TABLET PACK).....	273
<i>linezolid oral suspension for</i>		MAVENCLAD (6 TABLET PACK).....	273
<i>reconstitution</i> .....	578	MAVENCLAD (7 TABLET PACK).....	273
<i>linezolid oral tablet</i> .....	578	MAVENCLAD (8 TABLET PACK).....	273
<i>lipodox</i> .....	101	MAVENCLAD (9 TABLET PACK).....	273
<i>lipodox 50</i> .....	101	MAVYRET.....	274
LIPTRUZET.....	257	MAYZENT ORAL TABLET 0.25 MG, 2	
LOMOTIL.....	186	MG.....	275
LONSURF.....	258	MEGACE.....	276
<i>lopreeza oral tablet 0.5-0.1 mg</i> .....	186	MEGACE ES.....	186
LOPREEZA ORAL TABLET 1-0.5 MG....	186	<i>megestrol oral suspension 400 mg/10</i>	
LORBRENA ORAL TABLET 100 MG, 25		<i>ml (10 ml), 400 mg/10 ml (40 mg/ml),</i>	
MG.....	259	<i>800 mg/20 ml (20 ml)</i> .....	276
LORZONE.....	186	<i>megestrol oral suspension 625 mg/5</i>	
LOTRONEX.....	260	<i>ml</i> .....	186
LUCENTIS.....	261	<i>megestrol oral tablet</i> .....	277
LUMIZYME.....	262	MEKINIST ORAL TABLET 0.5 MG, 2 MG	
LUMOXITI.....	263	.....	278
LUNESTA.....	186	MEKTOVI.....	279
LUPANETA PACK (1 MONTH).....	264	<i>memantine oral capsule, sprinkle, er</i>	
LUPANETA PACK (3 MONTH).....	264	<i>24hr</i> .....	295
LUPRON DEPOT.....	265	<i>memantine oral solution</i> .....	295
LUPRON DEPOT (3 MONTH).....	265	<i>memantine oral tablet 10 mg, 5 mg</i> ....	295
LUPRON DEPOT (4 MONTH).....	265	<i>memantine oral tablets, dose pack</i> .....	295
LUPRON DEPOT (6 MONTH).....	265	MENEST.....	186
LUPRON DEPOT-PED.....	265	MENOSTAR.....	186
LUPRON DEPOT-PED (3 MONTH)		<i>meperidine (pf)</i> .....	186
INTRAMUSCULAR SYRINGE KIT 11.25		<i>meperidine injection</i> .....	186
MG, 30 MG.....	265	<i>meperidine oral solution</i> .....	186
LYNPARZA ORAL CAPSULE.....	268	<i>meperidine oral tablet</i> .....	186
LYNPARZA ORAL TABLET.....	268	<i>meprobamate</i> .....	186
LYRICA CR.....	271	MEPRON.....	280
LYRICA ORAL CAPSULE 100 MG, 150		MEPSEVII.....	281
MG, 200 MG, 225 MG, 25 MG, 300 MG,		<i>mesna</i> .....	282
50 MG, 75 MG.....	269	MESNEX.....	282
LYRICA ORAL SOLUTION.....	269	METADATE CD.....	284
MACROBID.....	186	<i>metadate er</i> .....	284
MACRODANTIN.....	186	METAXALL.....	186
MAKENA.....	272	<i>metaxalone</i> .....	186
MAKENA (PF).....	272	<i>methamphetamine</i> .....	97

<i>methocarbamol</i> .....	186	MYOZYME.....	293
<i>methoxsalen</i> .....	283	NAGLAZYME.....	294
<i>methyldopa</i> .....	186	NAMENDA ORAL SOLUTION.....	295
<i>methyldopa-hydrochlorothiazide</i> .....	186	NAMENDA ORAL TABLET 10 MG, 5 MG	
<i>methyldopate</i> .....	186	.....	295
METHYLIN ER.....	284	NAMENDA TITRATION PAK.....	295
METHYLIN ORAL SOLUTION 10 MG/5		NAMENDA XR ORAL CAP,SPRINKLE,ER	
ML, 5 MG/5 ML.....	284	24HR DOSE PACK.....	295
METHYLIN ORAL TABLET.....	284	NAMENDA XR ORAL	
METHYLIN ORAL TABLET,CHEWABLE.	284	CAPSULE,SPRINKLE,ER 24HR.....	295
<i>methylphenidate hcl oral capsule, er</i>		NAMZARIC.....	296
<i>biphasic 30-70</i> .....	284	NATPARA.....	297
<i>methylphenidate hcl oral capsule,er</i>		NEMBUTAL SODIUM.....	185
<i>biphasic 50-50 10 mg, 20 mg, 30 mg,</i>		NERLYNX.....	298
<i>40 mg, 60 mg</i> .....	284	NEULASTA.....	299
<i>methylphenidate hcl oral solution 10</i>		NEUPOGEN.....	301
<i>mg/5 ml, 5 mg/5 ml</i> .....	284	NEUPRO.....	304
<i>methylphenidate hcl oral tablet</i>		NEXAVAR.....	305
<i>extended release</i> .....	284	<i>nifedipine oral capsule</i> .....	186
<i>methylphenidate hcl oral tablet</i>		NINLARO.....	306
<i>extended release 24hr 18 mg, 27 mg,</i>		<i>nitisinone</i> .....	358
<i>36 mg, 54 mg, 72 mg</i> .....	284	<i>nitrofurantoin</i> .....	186
<i>miglustat</i> .....	562	<i>nitrofurantoin macrocrystal</i> .....	186
MIMVEY.....	186	<i>nitrofurantoin monohyd/m-cryst</i> .....	186
<i>mimvey lo</i> .....	186	NITYR.....	307
MINIVELLE.....	186	NIVESTYM.....	301
MIRCERA.....	285	NORDITROPIN FLEXPRO.....	190
<i>modafinil oral tablet 100 mg, 200 mg.</i>	287	NORDITROPIN NORDIFLEX.....	190
MORPHABOND ER.....	321	<i>norethindrone ac-eth estradiol oral</i>	
<i>morphine oral capsule, er multiphase</i>		<i>tablet 0.5-2.5 mg-mcg, 1-5 mg-mcg...</i>	186
<i>24 hr</i> .....	319	NORGESIC FORTE.....	186
<i>morphine oral capsule,extend.release</i>		NORPACE.....	186
<i>pellets</i> .....	319	NORPACE CR.....	186
MOTOFEN.....	186	NORPRAMIN.....	185
MOZOBIL.....	289	NORTHERA ORAL CAPSULE 100 MG,	
MS CONTIN ORAL TABLET EXTENDED		200 MG, 300 MG.....	308
RELEASE 100 MG, 15 MG, 200 MG, 30		<i>nortriptyline oral capsule</i> .....	185
MG, 60 MG.....	319	NORTRIPTYLINE ORAL SOLUTION.....	185
MULPLETA.....	290	<i>novarel intramuscular recon soln</i>	
MVASI.....	41	<i>10,000 unit</i> .....	72
MYALEPT.....	291	NOVAREL INTRAMUSCULAR RECON	
MYDAYIS.....	28	SOLN 5,000 UNIT.....	72
MYLOTARG.....	292	NOXAFIL ORAL.....	309
MYOBLOC.....	55	<i>np thyroid oral tablet 120 mg, 15 mg.</i>	186

NP THYROID ORAL TABLET 30 MG, 60 MG, 90 MG.....	186	ORALAIR SUBLINGUAL TABLET 100	
NPLATE.....	328	INDX REACTIVITY, 300 INDX	
NUBEQA.....	329	REACTIVITY.....	354
NUCALA.....	330	ORBIVAN.....	186
NUCYNTA ER.....	319	ORBIVAN CF.....	186
NUDEXTA.....	333	ORENCIA (WITH MALTOSE).....	355
NULOJIX.....	334	ORENCIA CLICKJECT.....	355
NUPLAZID ORAL CAPSULE.....	335	ORENCIA SUBCUTANEOUS SYRINGE	
NUPLAZID ORAL TABLET 10 MG, 17		125 MG/ML, 50 MG/0.4 ML, 87.5	
MG.....	335	MG/0.7 ML.....	355
NUTROPIN.....	310	ORENITRAM.....	357
NUTROPIN AQ.....	310	ORFADIN.....	358
NUTROPIN AQ NUSPIN.....	310	ORLISSA ORAL TABLET 150 MG, 200	
NUVIGIL ORAL TABLET 150 MG, 200		MG.....	359
MG, 250 MG, 50 MG.....	336	ORKAMBI ORAL GRANULES IN PACKET	
OALIVA.....	338	.....	361
OCREVUS.....	340	ORKAMBI ORAL TABLET.....	361
OCTAGAM.....	217	<i>orphenadrine citrate</i> .....	186
<i>octreotide acetate injection solution</i>		ORPHENADRINE COMPOUND.....	186
<i>1,000 mcg/ml, 100 mcg/ml, 200</i>		ORPHENADRINE COMPOUND-DS.....	186
<i>mcg/ml, 50 mcg/ml</i> .....	413	<i>orphenadrine-asa-caffeine</i> .....	186
OCTREOTIDE ACETATE INJECTION		ORPHENGESIC FORTE.....	186
SOLUTION 500 MCG/ML.....	413	OTEZLA.....	362
<i>octreotide acetate injection syringe</i> ....	413	OTEZLA STARTER ORAL	
ODOMZO.....	341	TABLETS,DOSE PACK 10 MG (4)-20	
OFEV.....	342	MG (4)-30 MG (47), 10 MG (4)-20 MG	
OGEN 2.5.....	186	(4)-30 MG(19).....	362
OLUMIANT.....	343	OXANDRIN ORAL TABLET 10 MG, 2.5	
OLYSIO.....	345	MG.....	364
OMNITROPE.....	190	<i>oxandrolone oral tablet 10 mg, 2.5 mg</i>	364
ONCASPAR.....	347	OXSORALEN ULTRA.....	283
ONFI ORAL SUSPENSION.....	348	<i>oxycodone oral tablet extended release</i>	
ONFI ORAL TABLET 10 MG, 20 MG, 5		<i>12 hr</i> .....	365
MG.....	348	<i>oxycodone oral tablet,oral</i>	
ONGLYZA ORAL TABLET 2.5 MG, 5 MG		<i>only,ext.rel.12 hr 10 mg, 15 mg, 20</i>	
.....	102	<i>mg, 30 mg, 40 mg, 60 mg</i> .....	365
ONPATTRO.....	349	OXYCODONE ORAL TABLET,ORAL	
ONSOLIS.....	350	ONLY,EXT.REL.12 HR 80 MG.....	365
OPANA ER.....	319	OXYCONTIN.....	365
OPDIVO.....	351	<i>oxymorphone oral tablet extended</i>	
OPSUMIT.....	353	<i>release 12 hr</i> .....	319
		OZURDEX.....	367
		PALGIC.....	186

<i>palonosetron intravenous solution 0.25 mg/2 ml</i> .....	24	PROLASTIN.....	25
<i>palonosetron intravenous syringe</i> .....	24	PROLASTIN-C.....	25
PALYNZIQ.....	370	PROLIA.....	379
PAMELOR.....	185	PROMACTA ORAL POWDER IN PACKET.....	381
PANZYGA.....	315	PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG.....	381
<i>pentazocine-naloxone</i> .....	186	<i>promethazine</i> .....	186
<i>pentobarbital sodium</i> .....	185	<i>promethazine vc</i> .....	186
PERJETA.....	371	<i>promethazine-phenylephrine</i> .....	186
<i>perphenazine-amitriptyline</i> .....	185	<i>promethegan</i> .....	186
PERSANTINE.....	186	<i>propantheline</i> .....	186
<i>phenadoz</i> .....	186	PROTOPIC.....	383
PHENERGAN INJECTION.....	186	<i>protriptyline</i> .....	185
<i>phenergan rectal</i> .....	186	PROVIGIL ORAL TABLET 100 MG, 200 MG.....	287
<i>phenobarbital oral elixir</i> .....	185	PURIXAN.....	384
<i>phenobarbital oral tablet 100 mg, 15 mg, 16.2 mg, 30 mg, 32.4 mg, 60 mg, 64.8 mg, 97.2 mg</i> .....	185	QTERN.....	323
<i>phenobarbital sodium</i> .....	185	QUALAQUIN.....	385
PHRENILIN FORTE(WITH CAFFEINE)..	186	QUDEXY XR ORAL CAPSULE,SPRINKLE,ER 24HR 100 MG, 150 MG, 200 MG, 25 MG, 50 MG.....	487
<i>pimecrolimus</i> .....	115	<i>quetiapine oral tablet extended release 24 hr 150 mg, 200 mg, 300 mg, 400 mg, 50 mg</i> .....	417
PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X1-50 MG X1), 300 MG/DAY (150 MG X 2).....	373	QUILLICHEW ER ORAL TABLET,CHEW,IR-ER.BIPHASIC24HR 20 MG, 30 MG, 40 MG.....	284
PLEGRIDY.....	213	QUILLIVANT XR.....	284
POMALYST ORAL CAPSULE 1 MG, 2 MG, 3 MG, 4 MG.....	374	<i>quinine sulfate</i> .....	385
POSACONAZOLE.....	309	RAGWITEK.....	386
PRALUENT PEN.....	375	RAVICTI.....	387
PRALUENT SYRINGE.....	375	REBIF (WITH ALBUMIN).....	314
PREFEST.....	186	REBIF REBIDOSE.....	314
<i>pregabalin oral capsule 100 mg, 150 mg, 200 mg, 225 mg, 25 mg, 300 mg, 50 mg, 75 mg</i> .....	269	REBIF TITRATION PACK.....	314
<i>pregabalin oral solution</i> .....	269	RECLAST.....	388
<i>pregnyl</i> .....	72	REGRANEX.....	390
PREMARIN ORAL.....	186	RELEXXII.....	284
PREMPHASE.....	186	RELISTOR ORAL.....	391
PREMPRO.....	186	RELISTOR SUBCUTANEOUS KIT.....	391
PRIVIGEN.....	315	RELISTOR SUBCUTANEOUS SOLUTION.....	391
PROBUPHINE.....	377	RELISTOR SUBCUTANEOUS SYRINGE 12 MG/0.6 ML, 8 MG/0.4 ML.....	391
PROCARDIA.....	186		
PROCRIT.....	132		

REMICADE.....	392	SAMSCA ORAL TABLET 15 MG, 30 MG	411
REMODULIN.....	395	SANCUSO.....	412
RENFLEXIS.....	392	SANDOSTATIN.....	413
REPAN.....	186	SANDOSTATIN LAR DEPOT.....	415
REPATHA PUSHTRONEX.....	397	SECONAL SODIUM.....	186
REPATHA SURECLICK.....	397	SEROQUEL ORAL TABLET 100 MG, 200	
REPATHA SYRINGE.....	397	MG, 25 MG, 300 MG, 400 MG, 50 MG..	417
<i>reserpine</i> .....	186	SEROQUEL XR ORAL TABLET	
RESTASIS.....	399	EXTENDED RELEASE 24 HR 150 MG,	
RESTASIS MULTIDOSE.....	399	200 MG, 300 MG, 400 MG, 50 MG.....	417
RETACRIT.....	132	SEROSTIM.....	310
RETIN-A.....	491	SIGNIFOR.....	418
RETIN-A MICRO.....	491	SIGNIFOR LAR.....	419
RETIN-A MICRO PUMP.....	491	SIKLOS.....	420
RETISERT.....	400	<i>sildenafil (antihypertensive)</i>	
REVATIO INTRAVENOUS.....	402	<i>intravenous</i> .....	402
REVATIO ORAL SUSPENSION FOR		<i>sildenafil (antihypertensive) oral</i>	
RECONSTITUTION.....	401	<i>suspension for reconstitution</i> .....	401
REVATIO ORAL TABLET.....	401	<i>sildenafil (antihypertensive) oral tablet</i>	401
REVLIMID ORAL CAPSULE 10 MG, 15		SILENOR.....	186
MG, 2.5 MG, 20 MG, 25 MG, 5 MG.....	404	SILIQ.....	421
REXULTI ORAL TABLET 0.25 MG, 0.5		SIMPONI.....	423
MG, 1 MG, 2 MG, 3 MG, 4 MG.....	405	SIMPONI ARIA.....	425
<i>ribavirin inhalation</i> .....	530	SIRTURO.....	427
RITALIN LA ORAL CAPSULE,ER		SIVEXTRO INTRAVENOUS.....	428
BIPHASIC 50-50 10 MG, 20 MG, 30		SIVEXTRO ORAL.....	428
MG, 40 MG, 60 MG.....	284	SKELAXIN.....	186
RITALIN SR.....	284	SKYRIZI.....	430
ROBAXIN.....	186	<i>sodium phenylbutyrate</i> .....	59
ROBAXIN-750.....	186	<i>sofosbuvir-velpatasvir</i> .....	130
ROMIDEPSIN.....	215	SOLARAZE.....	432
ROZLYTREK ORAL CAPSULE 100 MG,		SOLIRIS.....	433
200 MG.....	406	SOMA.....	186
RUBRACA ORAL TABLET 200 MG, 250		SOMATULINE DEPOT SUBCUTANEOUS	
MG, 300 MG.....	407	SYRINGE 120 MG/0.5 ML, 60 MG/0.2	
RUCONEST.....	408	ML, 90 MG/0.3 ML.....	436
RUZURGI.....	156	SOMAVERT.....	437
RYCLORA.....	186	SONATA ORAL CAPSULE 10 MG, 5 MG	186
RYDAPT.....	409	SOVALDI.....	438
RYVENT.....	186	SPINRAZA (PF).....	440
SABRIL.....	410	SPORANOX ORAL CAPSULE.....	216
SAIZEN.....	310	SPORANOX PULSEPAK.....	216
SAIZEN CLICK.EASY.....	310	SPRAVATO.....	442
SAIZEN SAIZENPREP.....	310		



SPRITAM ORAL TABLET FOR SUSPENSION 1,000 MG, 250 MG, 500 MG, 750 MG.....	443	TARCEVA ORAL TABLET 100 MG, 150 MG, 25 MG.....	470
SPRYCEL.....	444	TARGRETIN ORAL.....	471
STEGLATRO.....	323	TARGRETIN TOPICAL.....	471
STEGLUJAN.....	323	TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG.....	472
STELARA INTRAVENOUS.....	445	TASMAR.....	473
STELARA SUBCUTANEOUS.....	445	TAVALISSE.....	474
STIVARGA.....	448	<i>tazarotene</i> .....	475
STRATTERA ORAL CAPSULE 10 MG, 100 MG, 18 MG, 25 MG, 40 MG, 60 MG, 80 MG.....	449	TAZORAC.....	475
STRENSIQ.....	450	TECENTRIQ INTRAVENOUS SOLUTION 1,200 MG/20 ML (60 MG/ML), 840 MG/14 ML (60 MG/ML).....	476
SUBSYS.....	451	TECFIDERA.....	478
SUPPRELIN LA.....	452	TECHNIVIE.....	479
SURMONTIL.....	185	TEGSEDI.....	481
SUTENT ORAL CAPSULE 12.5 MG, 25 MG, 37.5 MG, 50 MG.....	453	<i>temsirolimus</i> .....	492
SYLATRON.....	454	<i>tencon</i> .....	186
SYLATRON 4-PACK.....	454	TENEX.....	186
SYLVANT.....	455	TESTIM.....	325
SYMDEKO.....	456	<i>testosterone cypionate</i> .....	482
SYMLINPEN 120.....	457	<i>testosterone enanthate</i> .....	482
SYMLINPEN 60.....	457	<i>testosterone intramuscular</i> .....	482
SYMPAZAN ORAL FILM 10 MG, 20 MG, 5 MG.....	348	<i>testosterone propionate</i> .....	482
SYNAGIS.....	458	<i>testosterone transdermal gel</i> .....	325
SYNAREL.....	461	<i>testosterone transdermal gel in metered-dose pump 10 mg/0.5 gram /actuation, 12.5 mg/ 1.25 gram (1 %)</i>	325
SYNRIBO.....	462	<i>testosterone transdermal gel in metered-dose pump 20.25 mg/1.25 gram (1.62 %)</i> .....	489
<i>tacrolimus topical</i> .....	383	<i>testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram)</i> .....	325
<i>tadalafil (antihypertensive)</i> .....	9	<i>testosterone transdermal gel in packet 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)</i> .....	489
TAFINLAR.....	464	<i>testosterone transdermal solution in metered pump w/app</i> .....	325
TAGRISSO ORAL TABLET 40 MG, 80 MG.....	465	<i>tetrabenazine oral tablet 12.5 mg, 25 mg</i> .....	543
TAKHZYRO.....	466	TEV-TROPIN.....	310
TALTZ AUTOINJECTOR.....	467	THALOMID ORAL CAPSULE 100 MG, 150 MG, 200 MG, 50 MG.....	484
TALTZ AUTOINJECTOR (2 PACK).....	467		
TALTZ AUTOINJECTOR (3 PACK).....	467		
TALTZ SYRINGE.....	467		
TALTZ SYRINGE (2 PACK).....	467		
TALTZ SYRINGE (3 PACK).....	467		
TALWIN.....	186		
TALZENNA ORAL CAPSULE 0.25 MG, 1 MG.....	469		

THIOLA.....	485	TRETIN-X.....	491
THIOLA EC.....	485	TRETIN-X CREAM KIT .....	491
<i>thyroid (pork)</i> .....	186	<i>trihexyphenidyl</i> .....	186
TIBSOVO.....	486	<i>trimipramine</i> .....	185
<i>ticlopidine</i> .....	186	TRIPTODUR.....	499
TOFRANIL.....	185	TROKENDI XR.....	487
TOFRANIL-PM.....	185	TURALIO.....	500
<i>tolcapone</i> .....	473	TYKERB.....	501
TOPAMAX ORAL CAPSULE, SPRINKLE.	487	TYMLOS.....	502
TOPAMAX ORAL TABLET 100 MG, 200		TYSABRI.....	504
MG, 25 MG, 50 MG.....	487	TYVASO.....	505
TOPIRAGEN ORAL TABLET 100 MG,		TYVASO INSTITUTIONAL START KIT ..	505
200 MG, 25 MG, 50 MG.....	487	TYVASO REFILL KIT .....	505
<i>topiramate oral capsule, sprinkle</i> .....	487	TYVASO STARTER KIT .....	505
<i>topiramate oral capsule, sprinkle, er</i>		TYZEKA.....	507
<i>24hr 100 mg, 150 mg, 200 mg, 25 mg,</i>		UCERIS ORAL.....	508
<i>50 mg</i> .....	487	UDENYCA.....	299
<i>topiramate oral tablet 100 mg, 200</i>		ULTOMIRIS.....	509
<i>mg, 25 mg, 50 mg</i> .....	487	ULTRAM ER.....	319
TORISEL.....	492	UPTRAVI ORAL TABLET .....	510
TRACLEER ORAL TABLET .....	494	UPTRAVI ORAL TABLETS, DOSE PACK.	510
TRACLEER ORAL TABLET FOR		VALCHLOR.....	511
SUSPENSION.....	494	VANATOL LQ.....	186
<i>tramadol oral capsule, er biphase 24 hr</i>		VANATOL S.....	186
<i>17-83</i> .....	319	VANCOCIN ORAL CAPSULE 125 MG,	
<i>tramadol oral capsule, er biphase 24 hr</i>		250 MG.....	512
<i>25-75</i> .....	319	<i>vancomycin oral capsule 125 mg, 250</i>	
<i>tramadol oral tablet extended release</i>		<i>mg</i> .....	512
<i>24 hr</i> .....	319	<i>vancomycin oral recon soln</i> .....	512
<i>tramadol oral tablet, er multiphase 24</i>		<i>vandetanib oral tablet 100 mg, 300 mg</i>	62
<i>hr 100 mg, 200 mg, 300 mg</i> .....	319	VECTIBIX.....	513
TRELSTAR DEPOT.....	496	VELCADE.....	514
TRELSTAR INTRAMUSCULAR		VELETRI.....	368
SUSPENSION FOR RECONSTITUTION		VELTIN.....	488
11.25 MG, 22.5 MG, 3.75 MG.....	496	VEMLIDY.....	515
TRELSTAR INTRAMUSCULAR SYRINGE		VENCLEXTA ORAL TABLET 10 MG, 100	
11.25 MG/2 ML, 22.5 MG/2 ML, 3.75		MG, 50 MG.....	516
MG/2 ML.....	496	VENCLEXTA STARTING PACK.....	516
TRELSTAR LA.....	496	VENTAVIS.....	517
TREMFYA.....	497	VERZENIO.....	519
<i>treprostinil sodium</i> .....	395	VFEND.....	520
<i>tretinoin</i> .....	491	VIBATIV.....	521
<i>tretinoin (emollient)</i> .....	491	VIBERZI.....	522
<i>tretinoin microspheres</i> .....	491	VICTRELIS.....	523



VIDAZA.....	525	XIGDUO XR ORAL TABLET, IR - ER, BIPHASIC 24HR 10-1,000 MG, 10-500 MG, 2.5-1,000 MG, 5-1,000 MG, 5-500 MG.....	323
VIEKIRA PAK.....	526	XIIDRA.....	549
VIEKIRA XR.....	526	XOLAIR SUBCUTANEOUS RECON SOLN .....	550
<i>vigabatrin</i> .....	410	XOLAIR SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.5 ML.....	550
VIGADRONE.....	410	XOSPATA.....	552
VIMIZIM.....	528	XPOVIO ORAL TABLET 100 MG/WEEK (20 MG X 5), 160 MG/WEEK (20 MG X 8), 60 MG/WEEK (20 MG X 3), 80 MG/WEEK (20 MG X 4).....	553
VIMOVO.....	529	XTAMPZA ER.....	321
VIRAZOLE.....	530	XTANDI.....	554
VISTARIL.....	186	XURIDEN.....	555
VITRAKVI ORAL CAPSULE 100 MG, 25 MG.....	531	XYLOCAINE JELLY.....	255
VITRAKVI ORAL SOLUTION.....	531	XYLOCAINE MUCOUS MEMBRANE.....	255
VIVELLE-DOT.....	186	XYOSTED.....	482
VIVITROL.....	532	XYREM.....	556
VIZIMPRO ORAL TABLET 15 MG, 30 MG, 45 MG.....	534	YERVOY.....	558
VOGELXO.....	325	YONSA.....	560
<i>voriconazole oral suspension for reconstitution</i> .....	520	<i>zaleplon oral capsule 10 mg, 5 mg</i> .....	186
<i>voriconazole oral tablet 200 mg</i> .....	520	ZALTRAP.....	561
VORICONAZOLE ORAL TABLET 50 MG	520	ZARXIO.....	301
VOSEVI.....	535	ZAVESCA.....	562
VOTRIENT.....	537	ZEBUTAL.....	186
VPRIV.....	166	ZEJULA.....	564
VRAYLAR ORAL CAPSULE.....	538	ZELBORAF.....	565
VRAYLAR ORAL CAPSULE,DOSE PACK.	538	ZEMAIRA.....	25
VYNDAMAX.....	463	<i>zenzedi oral tablet 10 mg, 5 mg</i> .....	98
VYNDAQEL.....	463	ZENZEDI ORAL TABLET 15 MG, 2.5 MG, 20 MG, 30 MG, 7.5 MG.....	98
VYTORIN 10-10.....	539	ZEPATIER.....	566
VYTORIN 10-20.....	539	ZIANA.....	488
VYTORIN 10-40.....	539	ZINBRYTA.....	568
VYTORIN 10-80.....	539	ZINPLAVA.....	569
XALKORI.....	540	ZOHYDRO ER.....	321
XELJANZ.....	541	<i>zoledronic acid</i> .....	571
XELJANZ XR.....	541	<i>zoledronic acid-mannitol-water intravenous piggyback 4 mg/100 ml...</i>	571
XEMBIFY.....	315	<i>zoledronic acid-mannitol-water intravenous piggyback 5 mg/100 ml...</i>	388
XENAZINE ORAL TABLET 12.5 MG, 25 MG.....	543		
XEOMIN.....	55		
XERMELO.....	544		
XGEVA.....	545		
XIAFLEX.....	546		
XIFAXAN ORAL TABLET 200 MG.....	548		
XIFAXAN ORAL TABLET 550 MG.....	547		

ZOLEDRONIC AC-MANNITOL-0.9NAACL	571
ZOLINZA.....	570
<i>zolpidem</i> .....	186
ZOLPIMIST.....	186
ZOMACTON.....	310
ZOMETA.....	571
ZORBTIVE.....	310
ZTLIDO.....	256
ZULRESSO.....	573
ZURAMPIC.....	574
ZYDELIG.....	575
ZYKADIA.....	576
ZYTIGA ORAL TABLET 250 MG, 500 MG.....	577
ZYVOX ORAL SUSPENSION FOR RECONSTITUTION.....	578
ZYVOX ORAL TABLET.....	578