#### PRIOR AUTHORIZATION CRITERIA

This list is current as of December 1, 2018 and pertains to the following formularies:

2018 Independent Health's Medicare Advantage Individual Part D Formulary	
2018 Independent Health's Medicare Advantage Employer Group's Part D Formulary	Version 22

Independent Health requires you (or your physician) to get prior authorization for certain drugs. This means that you will need to get approval from us before you fill your prescriptions. If you do not get approval, we may not cover the drug. These drugs are listed with a "PA" in the Requirements/Notes column on the formularies. This document contains the Prior Authorization requirements that are associated with our Medicare Advantage Part D formularies.

If you have any questions, please contact our Medicare Member Services Department at 1-800-665-1502 or, for TTY users 1-800-432-1110, October 1<sup>st</sup> – February 14<sup>th</sup>: Monday through Sunday from 8 a.m. to 8 p.m., February 15<sup>th</sup> – September 30<sup>th</sup>: Monday through Friday from 8 a.m. to 8 p.m.

Independent Health is a Medicare Advantage organization with a Medicare contract offering HMO, HMO-SNP, HMO-POS and PPO plans. Enrollment in Independent Health depends on contract renewal.

The formulary may change at any time. You will receive notice when necessary.

## **Abaloparatide (Tylmos)**

### **Products Affected**

• TYMLOS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Males
Required Medical Information	Diagnosis of covered use. Documentation of the following may be requested: baseline serum calcium has been obtained and will be monitored throughout therapy, postmenopausal status, and documentation that at least one bisphosphonate has failed (or are contraindicated) and has value that assesses fracture risk (i.e. DEXA scan or prior fracture)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Two Years
Other Criteria	Because of the unknown relevance of the rodent osteosarcoma findings to humans, monitored use of abaloparatide for more than 2 years during a patient's lifetime is not recommended.

## **Abilify MyCite (aripiprazole tablets with sensor)**

#### **Products Affected**

• ABILIFY MYCITE ORAL TABLET 10 MG, 15 MG, 2 MG, 20 MG, 30 MG, 5 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Dementia-related psychosis
Required Medical Information	Diagnosis of covered use, documentation of previous aripiprazole use (see Other Criteria).
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only. For approval, the patient must have documentation of at least a one-month trial of generic aripiprazole solution, tablets, or orally-disintegrating tablets.

## **ACTHAR HP**

### **Products Affected**

• HP ACTHAR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Acthar gel requested for IV administration, treatment of patients under 2 years of age in whom congenital infections are suspected, patients diagnosed with scleroderma, osteoporosis, systemic fungalinfections, ocular herpes simplex, patients with a history of recentsurgery, patients with a history of the presence of a peptic ulcer, congestive heart failure (CHF), uncontrolled hypertension, primaryadrenocortical insufficiency, adrenocortical hyperfunction, sensitivity to proteins of porcine origin
Required Medical Information	Diagnosis of covered use, submission of patient height and weightif medication is requested for the treatment of infantile spasms, submission of blood pressure reading and baseline serum sodiumand potassium levels
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	

# Adagen

### **Products Affected**

ADAGEN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Medication is being requested as preparatory or support therapy for bone marrow transplantation, severe thrombocytopenia
Required Medical Information	Diagnosis of covered use, submission of plasma ADA activity and red blood cell dATP level and confirmation these laboratory values are scheduled to be obtained in accordance with the prescribing information, submission of body weight, submission of platelet count
Age Restrictions	Adagen is not approved for the treatment of adult patients
Prescriber Restrictions	
Coverage Duration	Remainder of the contract year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or clinic for administration, if the medication is being self-administered documentation is provided that the enrollee has been fully trained on how to prepare the injection and to administer the medication safely and effectively if applicable. If these conditions are not satisfied this medication may be covered under Part B.PA applies to all.

## **ADCIRCA**

### **Products Affected**

- ADCIRCA
- tadalafil (pah)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	diagnosis of severe (Child Pugh Class C) hepatic impairment
Required Medical Information	Diagnosis of covered use, patient weight and serum creatinine
Age Restrictions	
Prescriber Restrictions	Limited to Pulmonology/ Cardiology
Coverage Duration	One Year
Other Criteria	PA applies to new starts only.

## **ADEMPAS**

### **Products Affected**

ADEMPAS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Pregnancy,concurrent use with nitrates or nitric oxide donors in any form, concurrent use with phosphodiesterase (PDE) inhibitors
Required Medical Information	Diagnosis of covered use, negative pregnancy test result for female patients of childbearing age, submission of documentation that female patient of childbearing age will have monthly pregenancy tests while on therapy and the month following therapy discontinuation, submission of patient weight and serum creatinine (to calculate creatinine clearance)
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to pulmonologists and cardiologists
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **Adrucil (fluorouracil)**

#### **Products Affected**

- ADRUCIL INTRAVENOUS SOLUTION 500 MG/10ML
- fluorouracil intravenous solution 2.5 gm/50ml, 5 gm/100ml

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Patients in a poor nutritional state, those with depressed bone marrow function, and those with potentially serious infections, or known hypersensitivity to fluorouracil
Required Medical Information	Diagnosis of covered medical use and submission of baseline CBC (including WBC with differential), and submission of patient's weight for purposes of dosage verification
Age Restrictions	
Prescriber Restrictions	Limited to Hematology and Oncology
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office for administration, if the medication is being self-administered documentation is provided that the enrollee has been fully trained on how to prepare the injection and to administer the medication safely and effectively if applicable. If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable. PA Applies to New Starts.

## **AFINITOR**

### **Products Affected**

- AFINITOR
- AFINITOR DISPERZ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use and if prescribed for the treatment of renal cell carcinoma, documented prior use of sunitinib or sorafenib, if prescribed for the treatment of postmenopuasal women with advanced hormone receptor positive, human epidermal growth factor receptor 2 (HER-2) negative breast cancer documentation that Afinitor is being used in combination with exemestane after failure with letrozole or anastrozole therapy
Age Restrictions	1 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **AIMOVIG** (erenumab-aooe)

### **Products Affected**

- AIMOVIG
- AIMOVIG 140 DOSE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of migraine days per month from medical chart, documentation patient has tried and failed or has a contraindication to at least two preferred alternatives such as propranolol, timolol, topiramate, and valproic acid.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	Initially 3 months, then 1 year
Other Criteria	PA applies to all. Continuation requires documentation of clinically relevant response to therapy.

## **AKYNZEO**

### **Products Affected**

AKYNZEO ORAL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, confirmation patient will receive concurrent dexamethasone therapy as indicated based on level of chemotherapy regimen emetogenicity
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	If Akynzeo is being administered related to cancer treatment and is a full replacement for intravenous administration of antiemetic therapy within 48 hours of cancer treatment, it is covered as a Part B benefit. Otherise it is covered as a Part D benefit. In order to eligible for Part B coverage, the prescribing physician must indicate on the prescription that Akynzeo is being used as a full therapeutic replacement for an intravenous antiemetic drug as part of a cancer chemotherapeutic regimen. If Akynzeo is dispensed for use after the 48-hour period, or if prescribed for conditions other than treatment of the effects of cancer treatment, it may be covered as a Part D benefit.PA applies to all.

## **ALDARA**

### **Products Affected**

• imiquimod external

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	Physicians who specialize in the treatment of medical conditions most commonly treated with this medication are exempt from prior authorization including dermatologists, OB-GYN, colorectal surgeons and oncologists.
Coverage Duration	Actinic keratosis, Genital and perianal warts- 16 weeks Superficial basal cell carcinoma- 6 weeks
Other Criteria	PA applies to new starts only.

## **ALECENSA**

### **Products Affected**

ALECENSA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of anaplastic lymphoma kinase (ALK) positive, metastatic non-small cell lung cancer (NSCLC), documentation that patient has progressed on or has a documented intolerance to crizotinib, submission of baseline ALT, AST, bilirubin, and CPK levels and confirmation that all will be monitored every 2 weeks during the first 2 months of therapy, then periodically during treatment, confirmation heart rate and blood pressure will be moniotred regularly, Documentation that females of reproductive potential have been advised to use highly effective contraception during treatment and for 1 week following the final dose and that males have been advised to use highly effective contraception during treatment and for 3 months following the final dose
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Oncology and Hematology
Coverage Duration	3 months initially, then annually thereafter
Other Criteria	Submission of liver function tests and CPK and documented response to treatment are required for continuation of approval. PA Applies to New Starts Only.

## **ALGLUCOSIDASE**

### **Products Affected**

• LUMIZYME

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office for administration, if the medication is being self-administered by the enrollee documentation is provided that the member has been fully trained on how to prepare the medication for injection and to administer the medication safely and effectively if applicable.If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable.PA applies to all.

# Aliqopa (copanlisib)

### **Products Affected**

ALIQOPA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Patients on strong CYP3A inducers such as carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, St. John's wort.
Required Medical Information	Diagnosis of covered use AND documentation that baseline CBC tests and blood glucose levels have been obtained and will be monitored per package labeling AND documentation that patient has optimal blood pressure control and that the provider will monitor BP before and after infusions of copanlisib AND patient will be monitored for signs/symptoms of infections/cutaneous reactions while on therapy AND IF female of reproductive potential, a negative pregnancy test will be obtained prior to initiation AND that the patient will be counseled to use effective contraception during treatment with copanlisib and for at least 1 month after the last dose OR IF male, the patient has been counseled to use effective contraception during treatment and for at least one month after the last dose of copanlisib.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology/Oncology
Coverage Duration	One year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: If a physician is administering the medication, he/she agrees to accept brown-bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration, if the medication is being administered in the enrollee's home, there are no associated safety concerns with preparation and/or administration of the medication documented in the prescribing information and if the medication is being administered in the enrollee's home by a route other than orally or subcutaneously, documentation is provided that the member has been fully trained on how to administer the medication safely and effectively if applicable. If these conditions are not satisfied these medications may be covered under Part B in accordance with the corresponding NCD/LCD if applicable.

# **ALUNBRIG** (brigatinib)

### **Products Affected**

• ALUNBRIG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use-anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	

## AMBISOME (AMPHOTERICIN B)

#### **Products Affected**

- ABELCET
- AMBISOME
- amphotericin b injection

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Patients with a known hypersensitivity to amphotericin B or any other constituents of the product
Required Medical Information	Diagnosis of covered medical use, submission of creatinine clearance or current body weight and serum creatinine level for the purposes of calculation of creatinine clearance by the Cockcroft-Gault equation, patient weight, LFTS (including AST, ALT, GGT, bilirubin, and alkaline phosphatase), CBC, and blood chemistry panel. Documentation of repeat values are required for continuation of approval.
Age Restrictions	
Prescriber Restrictions	Limited to Infectious Disease
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office for administration, if the medication is being self-administered documentation is provided that the enrollee has been fully trained on how to prepare the injection and to administer the medication safely and effectively if applicable. If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable. PA Applies to All.

## **AMPYRA**

### **Products Affected**

- AMPYRA
- dalfampridine er

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	History of seizure disorder, moderate or severe renal impairment (CrCl less than or equal to 50ml/min)
Required Medical Information	Diagnosis of Covered Use and Lab values including serum creatinine and patient weight, objective measurement of walking speed
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to neurology
Coverage Duration	Three months, then every year
Other Criteria	Continuation of therapy requests require that the patient has demonstrated an improvement in walking speed from baseline measure (or maintenance of improvement if patient has been on long term therapy) or other objective measure of walking ability since starting Ampyra.PA applies to all.

## **Anadrol-50**

### **Products Affected**

• ANADROL-50

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Carcinoma of the prostate or breast in male patients. Carcinoma of the breast in females with hypercalcemia- androgenic anabolic steroids may stimulate osteolytic resorption of bones. Oxymetholone can cause fetal harm when administered to pregnant women. It is contraindicated in women who are or may become pregnant. If the patient becomes pregnant while taking the drug, she should be apprised of the potential hazard to the fetus. Nephrosis or the nephrotic phase of nephritis. Hypersensitivity to the drug. Severe hepatic dysfunction
Required Medical Information	Diagnosis of covered use and submission of CBC and liver function tests
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	PA applies to new starts only

## **Antifungal**

### **Products Affected**

- itraconazole oral
- SPORANOX ORAL SOLUTION

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use, fungal culture result identifying causative organism or positive KOH result
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	Infectious Disease are exempt from prior authorization.PA applies to all.

## **ARCALYST**

### **Products Affected**

ARCALYST

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use, TB skin test result obtained within the past 12 months
Age Restrictions	12 YO or older
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	PA applies to all

## **Avelumab**

### **Products Affected**

BAVENCIO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation that provider is monitoring patient for immune-modulated pneumonitis, hepatitis, colitis, endocrinopathy, and nephritis as indicated in labeling and will reduce dose and/or discontinue as warranted, AND that the provider will premedicate the patient or alter the infusion rate as clinically indicated to minimize infusion complications.
Age Restrictions	12 YO and older for Merkle Cell Carcinoma, 18 YO and older for other diagnoses
Prescriber Restrictions	Limited to Hematology and Oncology
Coverage Duration	One year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or clinic for administration, if the medication is being self-administered documentation is provided that the enrollee has been fully trained on how to prepare the injection and to administer the medication safely and effectively if applicable. If these conditions are not satisfied this medication may be covered under Part B.

## **BENLYSTA**

### **Products Affected**

• BENLYSTA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of patient current weight, confirmation the patient will be premedicated for prophylaxis against infusion reactions and hypersensitivity reactions if clinically indicated and the medication is being administered by healthcare providers prepared to properly prepare the infusion and manage hypersensitivity reactions, including anaphylaxis.
Age Restrictions	18yo or older
Prescriber Restrictions	
Coverage Duration	One Year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration, if the medication is being administered in the enrollee's home, documentation is provided that the home care services provider has been fully trained on how to prepare the infusion and to administer the medication safely and effectively and is prepared to manage anaphylaxis. If these conditions are not satified this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable or this clinical criteria. The efficacy of BENLYSTA has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. BENLYSTA has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of BENLYSTA is not recommended in these situations and therefore not authorized. PA applies to new starts.

## **BENZNIDAZOLE**

### **Products Affected**

• BENZNIDAZOLE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Chagas disease
Age Restrictions	Pediatrics age 2 to 12yo
Prescriber Restrictions	Infectious Disease
Coverage Duration	60 days
Other Criteria	

## **BERINERT**

### **Products Affected**

• BERINERT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	History of life-threatening immediate hypersensitivity reactions, including anaphylaxis, to C1 esterase inhibitor preparations
Required Medical Information	Diagnosis of covered medical use, submission of documentation that epinephrine will be immediately available in the event of an acute severe hypersensitivity reaction, and submission of patient's current weight for the purposes of dosage verification.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	This medication may be covered as a Part D benefit if the patient is self-administering the medication and documentation is submitted stating that the patient has been provided instruction and training for self-administration outside of a clinic setting by their healthcare provider or if the provider is administering the medication in the office or infusion center and it is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: The physician/health care provider agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration. This medication may be covered under Part B if obtained and administered by a physician incident to a physician service if the clinical criteria is met.

# **Bevyxxa** (betrixaban)

#### **Products Affected**

• BEVYXXA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Up to 42 days
Other Criteria	

## **Bisphosphonate injection**

#### **Products Affected**

- pamidronate disodium intravenous solution
- zoledronic acid intravenous concentrate
- zoledronic acid intravenous solution
- ZOMETA INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	If requested for zoledronic acid 0.05 mg/ml creatinine clearance less than 35ml/min, for all formulations -pregnancy
Required Medical Information	Diagnosis of covered use for all products and for zoledronic acid 0.05 mg/ml - submission of patient weight and serum creatinine level, submission of serum calcium level, submission of serum alkaline phosphatase level for treatment of Paget's disease. For Zometasubmission of serum calcium level, For pamidronate-submission of serum calcium, magnesium, potassium, creatinine, Hgb and HCT levels, submission of serum alkaline phosphatase level for Paget's disease,
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	one year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy or furnished directly to the patient, it may be covered under Part D provided the following conditions are satisfied:A healthcare professional is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office, infusion center or homecare provider for administration. If these conditions are not satisfied this medication may be covered under Part B. Zoledronic acid 5mg/100ml and Recalst 5mg/100ml may be covered under Part B, for women with osteoporosis who meet the criteria for the Medicare home health benefit and have a bone fracture that a doctor certifies was related to post-menopausal osteoporosis. A doctor must certify that the woman is unable to learn how to or unable to give herself the drug by injection.PA applies to all.

# **Boniva injection**

### **Products Affected**

ibandronate sodium intravenous solution 3 mg/3ml

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Patients with severe renal impairment (serum creatinine greater than 2.3mg/dL or creatinine clearance less than 30 mL/min), requests for self-administration of this medication, uncorrected hypocalcemia
Required Medical Information	Medication is being administered for one of the following indications-treatment of osteoporosis in postmenopausal women or bone metastases in patients with prostate cancer, confirmation of osteoporosis diagnosis either through densitometry (T-score less than or equal to -2.5 at the total hip, femoral neck or lumbar spine) or clinically (documented presence of fragility fracture), submission of patient weight and serum creatinine level, submission of serum calcium level, submission of documentation stating why the IV formulation of Boniva is being given as opposed to the oral form of the drug which demonstrates one of the following-patient has a diagnosis of esophageal stricture, achalasia, or other severe esophageal dysmotility disorder or patient has a history of severe malabsorption making the use of oral bisphosphonates ineffective or patient has the inability to stand or sit upright for 60 minutes or patient has documented adverse effects following the initiation of treatment with the oral form of the medication that required the discontinuation of the oral form of the medication
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	one year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy or furnished directly to the patient, it may be covered under Part D provided the following conditions are satisfied:A healthcare professional is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office, infusion center or homecare provider for administration. If these conditions are not satisfied this medication may be covered under Part B. This medication may be covered under Part B. This medication may be covered under Part B, for women with osteoporosis who meet the criteria for the Medicare home health benefit and have a bone fracture that a doctor certifies was related to post-menopausal osteoporosis. A doctor must certify that the woman is unable to learn how to or unable to give herself the drug by injection.PA applies to all.

## **Bosulif**

### **Products Affected**

• BOSULIF

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation of resistance or intolerance to at least one of the following prior therapies: imatinib, dasatinib, or nilotinib
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to oncologist/hematologist
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **Botulinum Toxins**

#### **Products Affected**

- BOTOX
- DYSPORT
- XEOMIN INTRAMUSCULAR SOLUTION RECONSTITUTED 50 UNIT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Cosmetic purposes
Required Medical Information	Diagnosis of covered use which will be proven with patient progress notes, documentation of labs and other diagnostic procedures supporting diagnosis along with documentation of any previously tried and failed therapies.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Requests for non-FDA approved indications will be evaluated according to CMS guidance on off-label requirements.

# **BRAFTOVI/MEKTOVI** (encorafenib/binimetinib)

#### **Products Affected**

- BRAFTOVI
- MEKTOVI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of FDA-approved test confirming presence of BRAF V600E or V600K mutation, serum potassium, and serum magnesium, confirmation that encorafenib and binimetinib will be co-administered.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.

## **Briviact**

### **Products Affected**

• BRIVIACT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Hypersensitivity to brivaracetam or any of the inactive ingredients
Required Medical Information	Diagnosis of covered use, and documentation that patient will be monitored for the emergence of suicial behavior and ideation, neurological adverse reactions including somnolence and fatigue and psychiatric adverse reactions including psychotic symptoms, irritability, depression, aggressive behavior and anxiety
Age Restrictions	16 YO or older
Prescriber Restrictions	Limited to Neurologists
Coverage Duration	One Year
Other Criteria	PA Applies to all

# **Butalbital Containing products**

#### **Products Affected**

- ascomp-codeine
- butalbital-acetaminophen oral tablet 50-325 butalbital-aspirin-caffeine oral capsule
- butalbital-apap-caff-cod
- butalbital-apap-caffeine oral capsule
- butalbital-apap-caffeine oral tablet 50-325-40 mg
- butalbital-asa-caff-codeine
- phrenilin forte oral capsule 50-300-40 mg
- TENCON ORAL TABLET 50-325 MG
- VANATOL LQ
- ZEBUTAL ORAL CAPSULE 50-325-40 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Patient must have current diagnosis of headache or other medically accepted indication, and patient must have tried and failed, or have a contraindication to a preferred alternative, such as ibuprofen or acetaminophen or rizatriptan and documentation is submitted confirming that the provider is aware the medication is considered a high risk medication for elderly patients according to the Centers for Medicare and Medicaid services and documentation is provided which justifies the benefit of the identified drug and how that benefit outweighs the potential risks to the patient.
Age Restrictions	PA required for 65 YO and older. No PA needed for less than age 65.
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to all

## **CABOMETYX**

### **Products Affected**

CABOMETYX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, submission of baseline blood pressure and documentation that blood pressure will be monitored periodically while on therapy, submission of documentation that females of reproductive potential have been advised to use effective contraception during treatment and for four mothhs after the final dose is administered.
Age Restrictions	18 YO or older
Prescriber Restrictions	limited to Hematology or Oncology
Coverage Duration	One Year
Other Criteria	PA Applies to New Starts Only

# **Calquence (acalabrutinib)**

#### **Products Affected**

CALQUENCE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients on proton pump inhibitors
Required Medical Information	Diagnosis of covered use. Documentation that baseline CBC with differential is on file and will be monitored periodically as indicated by package labeling. Also, documentation that screening for second primary malignancies is being done and that the patient has been counseled to use protection from sun exposure.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to hematology/oncology
Coverage Duration	One year
Other Criteria	

## **CARBAGLU**

### **Products Affected**

• CARBAGLU

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use and lab values including plasma ammonia level
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **CERDELGA**

### **Products Affected**

• CERDELGA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Patients who are CYP2D6 extensive metabolizers (EMs) and intermediate metabolizers (IMs) taking a strong CYP2D6 inhibitor with a strong or moderate CYP3A inhibitor, CYP2D6 IMs and PMs (poor metabolizers) taking a strong CYP3A inhibitor
Required Medical Information	Diagnosis of covered use, CYP2D6 metabolizer status as detected by an FDA-cleared test for determining CYP2D6 genotype, submission of patient's current weight and serum creatinine level or eGFR, submission of baseline ECG
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	one year
Other Criteria	PA applies to all

## **CEREZYME**

### **Products Affected**

 CEREZYME INTRAVENOUS SOLUTION RECONSTITUTED 400 UNIT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of patient body weight, documentation that Gaucher disease results in one or more of the following conditions-anemia (HGB less than 10 g/dL for females, Hgb less than 11 g/dL for males-submission of Hgb required), thrombocytopenia (platelet count less than 100,000/uL-submission of platelet count required), bone disease other than Erlenmeyer flask deformity or mild osteopenia or significant hepatomegaly or splenomegaly as evidenced by MRI or CT scan results showing that spleen is 5 times normal size or liver is 1.25 times normal size, documentation that the healthcare setting and providers are prepared to manage hypersensitivity reactions including anaphylaxis
Age Restrictions	2 YO and older
Prescriber Restrictions	
Coverage Duration	One Year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy or furnished directly to the patient, it may be covered under Part D provided the following conditions are satisfied:A a health care provider is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office, infusion center or to the home care provider for administration. If these conditions are not satisfied this medication may be covered under Part B.PA applies to new starts only.

## **CESAMET**

### **Products Affected**

• CESAMET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of documentation that patient has tried and failed to adequately respond to at least one conventional antiemetic therapy.
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	one year
Other Criteria	If Cesamet is being administered related to cancer treatment and is a full replacement for intravenous administration of antiemetic therapy within 48 hours of cancer treatment, it is covered as a Part B benefit. Otherise it is covered as a Part D benefit. In order to eligible for Part B coverage, the prescribing physician must indicate on the prescription that Cesamet is being used as a full therapeutic replacement for an intravenous antiemetic drug as part of a cancer chemotherapeutic regimen. If Cesamet is dispensed for use after the 48-hour period, or if prescribed for conditions other than treatment of the effects of cancer treatment, it may be covered as a Part D benefit

## **CHENODAL**

### **Products Affected**

• CHENODAL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, patient weight, submission of the following laboratory values: AST, ALT, serum cholesterol
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	24 months
Other Criteria	PA applies to all

## **CHOLBAM**

### **Products Affected**

• CHOLBAM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, submission of baseline liver function tests including AST, ALT, GGT, alkaline phosphatase, bilirubin and INR, submission of patient weight for the purpose of dosage verification
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to all

# **Chorionic gonadotropin**

#### **Products Affected**

• chorionic gonadotropin intramuscular

**RECONSTITUTED 5000 UNIT** 

 novarel intramuscular solution reconstituted
 pregnyl 10000 unit

• NOVAREL INTRAMUSCULAR SOLUTION

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only.

# **CINQAIR**

### **Products Affected**

• CINQAIR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	History of hypersensitivity to reslizumab or excipients in the formulation
Required Medical Information	Diagnosis of covered use of treatment of severe asthma in patients with eosinophilic phenotype, submission of pulmonary function test results including FEV1, submission of blood eosinophil count documenting 150 cells/mcL obtainied within 6 weeks prior to therapy initiation or 300 cells/mcL within 12 months of therapy initiation, submission of documentation that patient's symptoms are poorly controlled with inhaled corticosteroids, frequency of inhaled short-acting beta2-agonist therapy, submission of frequency of daily and nighttime symptoms and exacerbations, effect of exacerbations on activity. Confirmation that the patient will receive treatment in the doctor's office or clinic and be observed for an appropriate amount of time after each treatment, documentation that the healthcare setting and providers are prepared to manage life-threatening anaphylaxis.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Allergy and Pulmonology
Coverage Duration	One Year

PA Criteria	Criteria Details
Other Criteria	Continuation of therapy requests require objective documentation from the prescriber that the patient's symptoms have improved. The medication may be covered under Part D provided the following conditions are satisfied: A physician is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or clinic for administration. If these conditions are not satisfied, the medication may be covered under Part B. PA Applies to All.

## **CINRYZE**

### **Products Affected**

CINRYZE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded by Part D
<b>Exclusion Criteria</b>	
Required Medical Information	diagnosis of covered use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: A physician/health care provider is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration. This medication may be covered under Part B if administered by a physician incident to a physician service.PA applies to new starts only.

# Cometriq

#### **Products Affected**

- COMETRIQ (100 MG DAILY DOSE)
- COMETRIQ (140 MG DAILY DOSE)
- COMETRIQ (60 MG DAILY DOSE)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, baseline blood pressure reading, baseline laboratory values including urine protein values, serum bilirubin level, AST, ALT, documentation that patient will be monitored for symptoms of GI perforation and fistulas, documnetation that patient does not have recent history of hemorhage or hemoptysis, baseline oral examination results and confirmation oral exams will be performed periodically during therapy
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to oncology or hematology
Coverage Duration	One Year
Other Criteria	PA applies to new starts only.

## **CORLANOR**

### **Products Affected**

CORLANOR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Acute decompensated heart failure, Blood pressure less than 90/50 mmHg,Sick sinus syndrome, sinoatrial block or 3rd degree AV block-unless a functioning demand pacemaker is present, Resting heart rate less than 60 bpm prior to treatment, Severe hepatic impairment,Pacemaker dependence (heart rate maintained exclusively by the pacemaker)
Required Medical Information	Diagnosis of covered use described as is indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction less than or equal to 35%, who are in sinus rhythm with resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use, submission of current baseline blood pressure reading, confirmation that patient does not have any of the following: Acute decompensated heart failure, Sick sinus syndrome, sinoatrial block or 3rd degree AV block- unless a functioning demand pacemaker is present, Resting heart rate less than 60 bpm prior to treatment, Severe hepatic impairment or Pacemaker dependence (heart rate maintained exclusively by the pacemaker)
Age Restrictions	18yo or older
Prescriber Restrictions	Requested by or under the documented recommendation of a cardiologist
Coverage Duration	One Year
Other Criteria	PA applies to all

## **COTELLIC**

### **Products Affected**

• COTELLIC

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, submission of FDA-approved test confirming presence of BRAF V600E or V600K mutation, confirmation that Cotellic will be adminsitered in combination with vemurafenib, documentation that patient will be monitored for new primary malignancies including cutaneous and non-cutaneous prior to initiation of therapy, and every 2 months while on therapy and for 6 months following the last dose of Cotellic, confirmation that LVEF has been evaluated prior to therapy initiation and that LVEF is scheduled to be reassessed 1 month after therapy initiation and every 3 months thereafter while on therapy, documentation that opthalmological evaluations will be performed at regular intervals during treatment, submission of baseline liver function tests to include AST and ALT, CPK, and creatinine levels, documentation that females of reproductive potential have been advised to use effective contraception during treatment and for 2 weeks following discontinuation
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Oncology or Hematology
Coverage Duration	One Year
Other Criteria	PA Applies to New Starts Only

## crisaborole

### **Products Affected**

• EUCRISA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	2 YO or older
Prescriber Restrictions	Limited to dermatology
Coverage Duration	Initial 30 days, re-authorization one year
Other Criteria	Re-authorization requires a positive response to therapy.

## **CUPRIMINE**

### **Products Affected**

• CUPRIMINE ORAL CAPSULE 250 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Except for the treatment of Wilson's disease or certain patients with cystinuria, use of penicillamine during pregnancy is contraindicated (see WARNINGS). Although breast milk studies have not been reported in animals or humans, mothers on therapy with penicillamine should not nurse their infants. Patients with a history of penicillamine-related aplastic anemia or agranulocytosis should not be restarted on penicillamine. Because of its potential for causing renal damage, penicillamine should not be administered to rheumatoid arthritis patients with a history or other evidence of renal insufficiency
Required Medical Information	Diagnosis of covered use and laboratory analysis applicable to indication for use.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	PA applies to all.

## **CYRAMZA**

### **Products Affected**

• CYRAMZA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered medical use, if used for treatment of advanced gastric or gastro-esophageal junction adenocarcinoma, documentation of disease progression on or after prior fluopyrimidine or platinum containing regimen, if for treatment of metastatic NSCLC with disease progression on or after platinum-based chemotherapy, if for the treatment of metastataic colorectal cancer, documentation of disease progression on or after prior therapy with bevacizumba, oxaliplatin, and a fluoropyrimidine. Submission of documentation that the Patient will be pretreated with an IV H1 antagonist and if appropriate dexamethasone and APAP. Submission of baseline blood pressure, baseline urinary protein level, baseline thyroid function tests including TSH, patient weight and confirmation patient will be monitored while on therapy for the development of hemorrhage, arterial thromboembolic events, hypertension,GI perforations, impaired wound healing, proteinuria and thyroid dysfunction
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology/Oncology Prescribers
Coverage Duration	one year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician or health care provider is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office, infusion center or homecare provider for administration.If these conditions are not satisfied this medication may be covered under Part B in accordance with this criteria and/or an applicable NCD/LCD. PA for new starts only.

## **CYSTARAN**

### **Products Affected**

CYSTARAN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded by Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only.

## Cytovene

### **Products Affected**

• ganciclovir sodium intravenous solution reconstituted

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Patients with documented hypersensitivity to ganciclovir or acyclovir.
Required Medical Information	Diagnosis of covered use, submission of patient weight and serum creatinine level, submission of CBC and platelet count, submission of documentation that the potential benefits outweigh the risks when prescribed for the treatment of patients less than 18 years of age
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Remainder of the contract year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:A a health care provider is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office, infusion center or to the home care provider for administration If these conditions are not satisfied this medication may be covered under Part B.PA applies to all.

## **DARZALEX**

### **Products Affected**

DARZALEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of patient weight for the purposes of dosage calculation, documentation that the healthcare setting and provider are prepared to manage infusion reactions, including lifethreatening anaphylaxis, documentation that women of reproductive potential have been advised to use effective contraception during treatment and for three months after cessation of therapy
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology or Oncology
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: A healthcare professional with immediate access to emergency equipment and appropriate medical support to manage infusion reactions is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion cetner for administration. If these conditions are not satisfied this medication may be covered under Part B. PA Applies to New Starts Only.

# **Deferasirox (Exjade/Jadenu)**

#### **Products Affected**

- EXJADE
- JADENU
- JADENU SPRINKLE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use, Current lab values including ferritin, CBC, LFTs, serum creatinine, urine protein values, documentation that member has had yearly ophthalmic and auditory testing
Age Restrictions	2 YO or older
Prescriber Restrictions	
Coverage Duration	Three months
Other Criteria	For continuation: Documentation of ferritin level within last 3 months and CBC, LFT, Serum Creatinine, Urine Protein Value, ophthalmic and auditory testing have been performed within the last year.

## **Deflazacort**

### **Products Affected**

• EMFLAZA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use and treatment failure (or intolerance) of prednisone.
Age Restrictions	5 YO and older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	

## **Denosumab**

### **Products Affected**

- PROLIA
- XGEVA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Hypocalcemia, pregnancy, documented hypersensitivity to denosumab
Required Medical Information	Prolia is being requested for one of the following indications-treatment of postmenopausal women with confirmed diagnosis of osteoporosis at high risk for fracture, treatment to increase bone mass in men with osteoporosis at high risk for fracture, treatment to increase bone mass in men at high risk for frature receiving androgen deprivation therapy for nonmetastatic prostate cancer, treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer, confirmation of osteoporosis diagnosis either through densitometry (T-score less than or equal to -2.5 at the total hip, femoral neck or lumbar spine) or clinically (documented presence of fragility fracture), high risk for frature is defined as a history of osteoporotic fracture or multiple risk factors for fracture or patients who have failed or are intolerant of other available osteoporosis therapy, submission of serum calcium level.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Remainder of the contract year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy or furnished directly to the patient, it may be covered under Part D provided the following conditions are satisfied: A healthcare professional is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office, infusion center or homecare provider for administration. If these conditions are not satisfied this medication may be covered under Part B.PA applies to all.

## **DIFICID**

### **Products Affected**

• DIFICID

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One course of therapy (10 days)
Other Criteria	PA applies to all

# Digoxin

#### **Products Affected**

- digitek oral tablet 250 mcg
- digox oral tablet 250 mcg
- digoxin injection
- digoxin oral tablet 250 mcg

• LANOXIN ORAL TABLET 187.5 MCG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Patient must have a current diagnosis of atrial fibrillation or congestive heart failure, patient must have tried and failed to respond adequately to 0.125mg of digoxin and submission of patient's current CrCl (ml per min)(or current weight and serum creatinine level is submitted for the purposes of calculating CrCL)and result is greater than or equal to 30ml per min
Age Restrictions	PA applies to all patients 65 YO or older
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Prior authorization is not required for doses less than or equal to 0.125mg per day. PA applies to all patients 65 YO or older.

# **DOPTELET** (avatrombopag)

### **Products Affected**

DOPTELET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to gastroenterology, hematology, and surgery
Coverage Duration	5 days
Other Criteria	PA applies to all.

## **DUOPA**

### **Products Affected**

• DUOPA ENTERAL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	DUOPA is contraindicated in patients taking nonselective monoamine oxidase (MAO) inhibitors
Required Medical Information	Diagnosis of covered use and confirmation patient has a naso-jejunal tube for short-term administration or a PEG-J for long-term administration.
Age Restrictions	18yo or older
Prescriber Restrictions	Limited to Neurology prescribers
Coverage Duration	One year
Other Criteria	PA applies to all.

# **Dupilumab**

#### **Products Affected**

 DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 300 MG/2ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. Documentation of treatment with at least a moderate strength topical corticosteroid for at four weeks or have a contraindication to their use or therapy is not otherwise advisable.
Age Restrictions	18 YO and older
Prescriber Restrictions	Restricted to dermatology
Coverage Duration	16 weeks then up to one year

PA Criteria	Criteria Details
Other Criteria	For continuation, a positive clinical response must be documented. Upon starting this medication, the continuation period will be granted for only 36 additional weeks if no response was seen at 16 weeks OR if a positive clinical response is seen at 16 weeks approval will be granted for one year. A non-positive clinical response at 52 weeks from the initiation of therapy will be deemed a treatment failure. If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office for administration, if the medication is being self-administered documentation is provided that the enrollee has been fully trained on how to prepare the injection and to administer the medication safely and effectively if applicable. If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable.

# **Durvalumab (Imflinzi)**

### **Products Affected**

• IMFINZI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use. Documentation of that the following baseline laboratory measurements are available and will be monitored throughout use: liver function tests, TSH, HbA1C, platelet count, serum creatinine/eGFR. If a female of reproductive potential, documentation that patient has been counseled to use effective contraception during treatment and for at least 3 months after the last dose of medication.
Age Restrictions	
Prescriber Restrictions	Limited to Hematology/Oncology
Coverage Duration	One year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or clinic for administration, if the medication is being self-administered documentation is provided that the enrollee has been fully trained on how to prepare the injection and to administer the medication safely and effectively if applicable. If these conditions are not satisfied this medication may be covered under Part B.

## **EGRIFTA**

### **Products Affected**

• EGRIFTA SUBCUTANEOUS SOLUTION RECONSTITUTED 1 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Pregnancy
Required Medical Information	Diagnosis of covered use, patient weight, patient waist circumference
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	one year
Other Criteria	Continuation of therapy requests require confirmation that the patient has demonstrated a clinical improvement (or maintenance of improvement once achieved) from baseline. PA applies to all.

## **Elderly High Risk**

#### **Products Affected**

- benztropine mesylate oral
- dipyridamole oral
- disopyramide phosphate oral
- guanfacine hcl er
- guanfacine hcl oral
- INDOCIN ORAL
- indomethacin er
- indomethacin oral
- ketorolac tromethamine oral
- meprobamate
- methyldopa oral

- methyldopa-hydrochlorothiazide
- nifedipine oral
- NORPACE CR
- phenobarbital oral elixir
- phenobarbital oral tablet
- SECONAL
- SPRIX
- TALWIN
- thioridazine hcl oral
- trihexyphenidyl hcl

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	All three of the following criteria are met: 1) Diagnosis of covered use, 2) documentation that provider is aware medication is considered a high risk medication for elderly patients according to the Centers for Medicare and Medicaid services, and 3) documentation that the benefits of the identified drug outweigh the potential risks to the patient.
Age Restrictions	PA applies to patients 65 YO and older
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	

## **EMPLICITI**

### **Products Affected**

• EMPLICITI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, confirmation Empliciti will be used in combination with lenalidomide and dexamethasone and that patient has received one to three prior multiple myeloma therapies, submission of patient weight for the purposes of dose verification, confirmation that the patient will be premiedicated for prophylaxis against infusion reactions and hypersensitivity reactions, and the medication is being administered by healthcare providers prepared to properly prepare the infusion and manage hypersensitivity reactions, including anaphylaxis, submission of baseline liver function tests (AST, ALT, total bilirubin and alkaline phosphatase)and confirmation that liver enzymes will be monitored periodically while on therapy
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology or Oncology
Coverage Duration	One Year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy or furnished directly to the patient, it may be covered under Part D provided the following conditions are satisfied: A healthcare professional is administering the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office, infusion center or homecare provider for administration. If these conditions are not satisfied this medication may be covered under Part B. PA Applies to New Starts Only.

## **EMSAM**

### **Products Affected**

• EMSAM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **Enasidenib (Idhifa)**

#### **Products Affected**

• IDHIFA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use. Documentation of testing for isocitrate dehydrogenase-2 mutation, prior therapies tried and failed, baseline laboratory tests are available such as of CBC, LFTs, serum creatinine, calcium, potassium and phosphorus levels and confirmation these labs will be monitored periodically throughout therapy as indicated per package labeling. Also, documentation that the patient has been counseled about the risks and signs of differentiation syndrome and that therapy will be stopped if signs or symptoms of this occur and that the benefits of treatment outweigh any potential risks.
Age Restrictions	18 YO or older
Prescriber Restrictions	Restricted to Hematology or Oncology
Coverage Duration	One year
Other Criteria	Females of reproductive potential and males with partners of reproductive potential must be counseled that effective contraception should be used throughout therapy and for one month after the last dose of enasidenib.

# **EPCLUSA** (sofosbuvir/velpatasvir)

#### **Products Affected**

• EPCLUSA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	EPCLUSA and ribavirin combination regimen is contraindicated in patients for whom ribavirin is contraindicated
Required Medical Information	Diagnosis of covered use and laboratory confirmation of hepatitis C virus (HCV) genotype 1a, 1b, 2, 3, 4, 5, or 6 infection, submission of baseline HCV RNA level, documentation of whether cirrhosis is present or not and whether or not it is compensated (Child-Pugh A) or decompensated (Child-Pugh B and C), submission of eGFR as the safety and efficacy of Epclusa has not been established in patients with eGFR less than 30ml/min/1.73 m2), confirmation that patients with decompensated cirrhosis will receive concomitant ribavirin therapy unless ribavirin therapy is otherwise clinically not indicated, submission of patient current weight for patients with decompensated cirrhosis for the purposes of verifying ribavirin dosage (recommended dose is 1000mg per day for patients less than 75kg and 1200mg for those weighing at least 75 kg)
Age Restrictions	18 YO and older
Prescriber Restrictions	
Coverage Duration	12 weeks
Other Criteria	PA applies to all.

# **EPIDIOLEX (cannabidiol)**

### **Products Affected**

• EPIDIOLEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	2 years of age or older
Prescriber Restrictions	Restricted to neurology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.

## **ERIVEDGE**

### **Products Affected**

• ERIVEDGE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, pregnancy status for female patients
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to oncology or dermatology
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **ERLEADA** (apalutamide)

### **Products Affected**

• ERLEADA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology.
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.

## **ERWINAZE**

### **Products Affected**

• ERWINAZE INJECTION

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Erwinaze is contraindicated if patients have a history of serious hypersensitivity reactions including anaphylaxis to Erwinaze, and/or a history of serious pancreatitis, serious thrombosis, or serious hemorrhagic events with prior L-asparaginase therapy
Required Medical Information	Diagnosis of covered use including confirmation that patient has developed hypersensitivity to E. coli-derived asparaginase, submission of patient height and current weight, submission of baseline blood glucose level and confirmation blood glucose levels will be moniotred periodically during treatment, confirmation that this medication is being administered in a setting with the proper resuscitation equipment and other agents necessary (epinephrine, oxygen, intravenous steroids, antihistamines etc) to treat anaphylaxis available
Age Restrictions	
Prescriber Restrictions	Limited to oncology and hematology
Coverage Duration	one year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a participating pharmacy, it may be covered under Part D provided the following conditions are satisfied: The physician agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration. If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable.PA applies to new starts only.

## **Erythropoietins**

#### **Products Affected**

- ARANESP (ALBUMIN FREE) INJECTION SOLUTION 100 MCG/ML, 200 MCG/ML, 25 MCG/ML, 300 MCG/ML, 40 MCG/ML, 60 MCG/ML
- ARANESP (ALBUMIN FREE) INJECTION SOLUTION PREFILLED SYRINGE
- EPOGEN INJECTION SOLUTION 10000 UNIT/ML, 2000 UNIT/ML, 20000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML
- PROCRIT
- RETACRIT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use. Lab values from bloodwork indicating hemoglobin or hematocrit AND serum iron AND total iron-binding capacity (TIBC) AND transferrin tests. All lab values must be within 30 days of request date. Documentation that the patient does not have uncontrolled hypertension.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	For non-ESRD related conditions: 90 days, For ESRD related conditions: 1 year
Other Criteria	

# **ESBRIET/OFEV**

### **Products Affected**

- ESBRIET
- OFEV

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline AST, ALT, and bilirubin, confirmation liver function tests will be monitored monthly for the first 3 months after therapy initiation with Ofev and then at least every 3 months thereafter while on therapy, confirmation that liver function tests will be monitored monthly for the the first 6 months after therapy initiation with Esbriet and every 3 months therafter while on therapy,
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	one year
Other Criteria	For Ofev-prescriber documents that the benefits outweigh the potential risks for patients with known bleeding or gastronitestinal perforation risk. For Esbriet-submission of patient's current weight and serum creatinine level for the purposes of calculating creatinine clearance and if the patient is receiving dialysis treatments. PA applies to all.

### **Estrogens**

#### **Products Affected**

- amabelz
- ANGELIQ
- CLIMARA PRO
- COMBIPATCH
- DEPO-ESTRADIOL
- DIVIGEL TRANSDERMAL GEL 0.5 MG/0.5GM,
   MENOSTAR 1 MG/GM
- DUAVEE
- ELESTRIN
- estradiol oral
- estradiol transdermal
- estradiol-norethindrone acet
- estropipate oral
- EVAMIST

- fyavolv
- JINTELI
- lopreeza
- MENEST ORAL TABLET 0.3 MG, 0.625 MG, 1.25 MG
- mimvey
- mimvey lo
- norethindrone-eth estradiol
- PREFEST
- PREMARIN ORAL
- PREMPHASE
- PREMPRO

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

PA Criteria	Criteria Details
Required Medical Information	Submission of documentation that the drug requested is being prescribed for an FDA approved indication for that specific drug and documentation that the provider is aware of the associated risks of systemic estrogen products in elderly women including an increased risk of breast and endometrial cancer with prolonged use and an increased risk of clot formation without cardioprotective effect, confirmation that the prescriber is aware the medication is considered high risk for elderly patients by the Centers for Medicare and Medicaid services and submission of justification by the prescriber which explains the benefits of the requested drug and how that benefit outweighs the potential risks for the specific patient, confirmation that a taper and therapy discontinuation has been attempted after every two years of therapy and documentation of a trial and failure or contraindication to two preferred alternatives for each established indication. With the exception of the treatment of the vasomotor symptoms of menopause for which there are no preferred alternatives but still requires all other criteria listed above, the preferred alternatives include: Vulvar or vaginal atrophy: Estrace cream, Premarin cream, Osteoporosis: alendronate, ibandronate, raloxifene.
Age Restrictions	PA require for 65 YO and older. No PA needed for less than age 65.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	PA applies to all

# **Fabrazyme**

### **Products Affected**

FABRAZYME

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Fabrazyme requested for self-adminsitration in the home setting
Required Medical Information	Diagnosis of covered use, submission of patient weight, documentation that provider and healthcare setting is prepraed to manage life-threatening infusion reactions, documentation that patients with compromised cardiac function will be closely monitored during drug administration
Age Restrictions	8 YO and older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: A physician is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office for administration. If these conditions are not satisfied this medication may be covered under Part B. PA applies to new starts

## **FARYDAK**

### **Products Affected**

• FARYDAK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of covered medical use, documentation that the patient has received at least 2 prior regimens (including bortezomib and an immunomodulatory agent), submission of baseline CBC documenting platelet count is at least 100 x10 9/L and absolute neutrophil count is at least 1.5 x 10 9/L and confirmation CBC will be monitored at least weekly during treatment, submission of baseline ECG documenting QTcF is less than 450 msec prior to initiation of Farydak therapy, submission of baseline serum electrolytes (including potassium and magnesium), submission of baseline liver function tests (including AST, ALT, and total bilirubin)
Age Restrictions	18 YO or older
Prescriber Restrictions	Restricted to Hematology/Oncology
Coverage Duration	8 cycles initially, an additional 8 cycles if clinical benefit seen
Other Criteria	Farydak therapy is not authorized for patients with a history of recent myocardial infarction, unstable angina or patients with active infectionsFor patients with mild hepatic impairment the maximum starting dose authorized is 15mg. For patients with moderate hepatic impairment or those patients receiving concurrent strong CYP3A inhibitor therapy, the maximum starting dose authorized is 10mg.

# Fasenra (benralizumab)

#### **Products Affected**

FASENRA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use of treatment of severe asthma in patients with eosinophilic phenotype, submission of pulmonary function test results including FEV1, submission of laboratory confirmation of eosinophilic asthma diagnosis (serum eosinophil count, sputum eosinophil count or lung biopsy), submission of documentation that patient's symptoms are poorly controlled with inhaled corticosteroids, frequency of inhaled short-acting beta2-agonist therapy, submission of frequency of daily and nighttime symptoms and exacerbations, effect of exacerbations on activity. Confirmation that the patient will receive treatment in the doctor's office or clinic and be observed for an appropriate amount of time after each treatment, documentation that the healthcare setting and providers are prepared to manage life-threatening anaphylaxis.
Age Restrictions	12 YO or older
Prescriber Restrictions	Limited to Allergy, Pulmonology, or Immunology
Coverage Duration	One year

PA Criteria	Criteria Details
Other Criteria	Continuation of therapy requests requires objective documentation from the prescriber that the patient's symptoms have improved. The medication may be covered under Part D provided the following conditions are satisfied: A physician is administering the medication and he/she agrees to accept brown-bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or clinic for administration. If these conditions are not satisfied, the medication may be covered under Part B. PA Applies to All.

# **Fentanyl transmucosal**

#### **Products Affected**

- ABSTRAL
- fentanyl citrate buccal
- FENTORA BUCCAL TABLET 100 MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG
- LAZANDA
- SUBSYS SUBLINGUAL LIQUID 100 MCG, 1200 (600 X 2) MCG, 1600 (800 X 2) MCG, 200 MCG, 400 MCG, 600 MCG, 800 MCG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Treatment of opioid non-tolerant patients, treatment of acute or postoperative pain including headache, migraines or dental pain
Required Medical Information	Diagnosis of covered use, submission of documentation that patient who is already receiving and is tolerant to opioid therapy requires fentanyl transmucosal for the management of their underlying, persistent cancer pain
Age Restrictions	18 years or older (buccal film, buccal tablet, sublingual tablet, sublingual spray, intranasal spray) or 16 years or older (lozenge, lollipop)
Prescriber Restrictions	Oncology prescribers are exempt for prior authorization
Coverage Duration	One Year
Other Criteria	PA applies to all except when prescribed by oncology.

## **FERRIPROX**

### **Products Affected**

FERRIPROX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, lab values including serum ferritin levels, CBC, ANC, platelet count, serum ALT, plasma zinc level
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **FIRAZYR**

### **Products Affected**

• FIRAZYR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **FLECTOR**

### **Products Affected**

• FLECTOR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Flector Patch is contraindicated in patients with a known hypersensitivity to diclofenac. Flector Patch is contraindicated in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Flector Patch is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery. Flector Patch is contraindicated for use on non-intact or damaged skin resulting from anyetiology, including exudative dermatitis, eczema, infection lesions, burns or wounds
Required Medical Information	Diagnosis of covered use which includes the topical treatment of acute pain due to minor strains, sprains, and contusions.
Age Restrictions	18 YO or Older
Prescriber Restrictions	
Coverage Duration	Three months
Other Criteria	Approval is only provided for three months of therapy as Flector is only indicated for the treatment of acute pain due to minor strains, sprains and contusions. Acute pain is defined as short-term pain not lasting longer than a three month period.PA applies to all.

## **FORTEO**

### **Products Affected**

• FORTEO SUBCUTANEOUS SOLUTION 600 MCG/2.4ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of Covered Use, postmenopausal, Lab values (serum calcium level), documentation that other treatment options have failed (or are contraindicated) and has value that asseses fracture risk.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	2 Years
Other Criteria	This medication may be covered under Part B, for women with osteoporosis who meet the criteria for the Medicare home health benefit and have a bone fracture that a doctor certifies was related to postmenopausal osteoporosis. A doctor must certify that the woman is unable to learn how to or unable to give herself the drug by injection. PA applies to all.

# **GALAFOLD** (migalastat)

### **Products Affected**

• GALAFOLD

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Severe renal impairment (eGFR less than 30 mL/min/1.73 m2) or end stage renal disease requiring dialysis
Required Medical Information	Diagnosis of covered use. Documentation that the patient has an amenable galactosidase alpha gene variant (see section 12.1, table 2 of package insert for full list) based on in vitro assay data as interpreted by a clinical genetics professional.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.

## **GATTEX**

### **Products Affected**

• GATTEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of documentation that a colonoscopy (or alternate imaging) of the entire colon with polyp removal was performed within 6 months prior to starting treatment and is scheduled to be performed at the end of year 1 of Gattex therapy, submission of baseline laboratory values including bilirubin, alkaline phosphatase, lipase and amylase obtained within 6 months prior to starting Gattex therapy and confirmation these laboratory assessments are scheduled to be performed every 6 months while on therapy, submission of serum creatinine and patient weight for the purposes of creatinine clearance calculation and dose verification
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **GILOTRIF**

### **Products Affected**

• GILOTRIF

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use. Documentation that females of reproductive potential have been advised to use highly effective contraception during Gilotrif therapy and for at least two weeks after therapy discontinuation, documentation that patient will have periodic liver function monitoring while on therapy
Age Restrictions	18 YO or older
Prescriber Restrictions	limited to oncology or hematology
Coverage Duration	one year
Other Criteria	PA applies to new starts only

## **GLEEVEC**

### **Products Affected**

• imatinib mesylate

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	Limited to Oncologists or Hematologists
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **GnRH Antagonists**

#### **Products Affected**

- ELIGARD
- FIRMAGON
- LUPRON DEPOT (1-MONTH)
- LUPRON DEPOT (3-MONTH)
- LUPRON DEPOT (4-MONTH)

- LUPRON DEPOT (6-MONTH)
- LUPRON DEPOT-PED (1-MONTH)
  INTRAMUSCULAR KIT 11.25 MG, 15 MG
- LUPRON DEPOT-PED (3-MONTH) INTRAMUSCULAR KIT 30 MG (PED)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, documentation of baseline prostate- specific antigen (PSA) and serum testosterone level, documentation of baseline ECG and serum electrolyte levels (degarelix only)
Age Restrictions	
Prescriber Restrictions	Limited to Hematology/Oncology, Endocrinologist, Gynecologist and Urology Prescribers
Coverage Duration	One year
Other Criteria	

# **Gocovri (amantidine ER)**

#### **Products Affected**

- GOCOVRI
- OSMOLEX ER ORAL TABLET EXTENDED RELEASE 24 HOUR 129 MG, 193 MG, 258 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients with end stage renal disease
Required Medical Information	Diagnosis of covered use
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to neurology
Coverage Duration	One year
Other Criteria	

## Grastek

### **Products Affected**

GRASTEK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Severe, unstable or uncontrolled asthma, history of any severe systemic allergic reaction, history of any severe local reaction to sublingual allergen immunotherapy, history of eosinophilic esophagitis, hypersensitivity to gelatin, mannitol and sodium hydroxide
Required Medical Information	Grastek is being requested for the treatment of grass pollen induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens, therapy is being initiated at least 12 weeks before the expected onset of each grass pollen season, confirmation that the first dose of medication will be administered in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases and that the patient will be observed for at least 30 minutes after administration of the first dose to monitor for signs and symptoms of a severe systemic or severe local allergic reaction.
Age Restrictions	Patients 5 through 65 years of age
Prescriber Restrictions	Limited to Allergy or Immunology Prescribers
Coverage Duration	one year
Other Criteria	Confirmation auto-injectable epinephrine therapy has been prescribed and patient has been instructed on the proper use of emergency self-injection epinephrine.PA applies to all.

## **Growth Hormone**

#### **Products Affected**

- GENOTROPIN
- GENOTROPIN MINIQUICK
- HUMATROPE
- NORDITROPIN FLEXPRO
- NUTROPIN AQ NUSPIN 10
- NUTROPIN AQ NUSPIN 20

- NUTROPIN AQ NUSPIN 5
- OMNITROPE
- SAIZEN
- SAIZEN CLICK.EASY
- SAIZENPREP
- ZOMACTON

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use, growth failure documentation, IGF 1 levels, bone age if applicable based on patient age and diagnosis, height, weight, creatinine clearance, fasting glucose, lipid profile, DEXA scan
Age Restrictions	
Prescriber Restrictions	Limited to Endocrinologist and Nephrologist.
Coverage Duration	one year
Other Criteria	Requests for continuation of therapy require annual submission of updated IGF 1 levels, bone age if applicable based on patient age and diagnosis, height, weight, creatinine clerance and at least one of the following for the treatment of adult patients: fasting glucose, lipid profile or DEXA scan. PA applies to all.

# Haegarda (C1 esterase inhibitor)

### **Products Affected**

• HAEGARDA

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

## **HARVONI**

### **Products Affected**

HARVONI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use and laboratory confirmation of hepatitis C virus (HCV) genotype 1a, 1b, 4, 5, and 6 infection, submission of baseline HCV RNA level, documentation of patient's CHC treatment status as either treatment-naive or treatment-experienced and whether cirrhosis is present or not, submission of eGFR
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 or 24 weeks of therapy depending on treatment status and presence of cirrhosis
Other Criteria	For treatment-naive patients with cirrhosis or treatment-naive or treatment-experienced without cirrhosis approval is for 12 weeks of therapy. For treatment-naive patients without cirrhosis who have pretreatment HCV RNA less than 6 million IU/mL, 8 weeks of therapy may be considered by the provider. For treatment-experienced patients with cirrhosis approval is for 24 weeks of therapy. PA applies to all.

# Hemangeol

### **Products Affected**

HEMANGEOL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	asthma or history of bronchospasm, premature infant with corrected age less than 5 weeks, infants weighing less than 2 kg, bradycardia (less than 80 beats per minute), greater than first degree heart block, decompensated heart failure, blood pressure less than 50/30mmHg, pheochromocytoma, known hypersensitivity to propranolol
Required Medical Information	Diagnosis of covered use, Infant is at least 5 weeks corrected age or older, submission of current weight (must be at least 2 kg), treatment is being initiated at ages 5 weeks to 5 months
Age Restrictions	Minimum patient age of 5 weeks up to 1 year of age
Prescriber Restrictions	limited to pediatric otolarangologist or ENT specialist or pediatric ophthalmologist
Coverage Duration	6 months
Other Criteria	PA applies to all

## **HETLIOZ**

### **Products Affected**

HETLIOZ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	None
Required Medical Information	Diagnosis of covered use
Age Restrictions	18 YO or older
Prescriber Restrictions	limited to sleep specialists and neurologists
Coverage Duration	One Year
Other Criteria	PA applies to all

### **HYDROXYZINE**

#### **Products Affected**

- hydroxyzine hcl oral tablet
- hydroxyzine pamoate oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	hypersensitivity to cetirizine or levocetirizine
Required Medical Information	1. Patient must have a diagnosis of: Anxiety or Pruritus AND 2. For treatment of pruritus patient must have tried and had an inadequate response to a second generation antihistamine such as levocetirizine or desloratadine. AND 3. For treatment of anxiety, patient must have tried and failed or had an inadequate response to at least 2 other FDA-approved products for the management of anxiety. OR 4. for the treatment of sedation when used as premedication and following general anesthesia 5. Documentation is submitted confirming that the provider is aware the medication is considered a high risk medication for elderly patients according to the Centers for Medicare and Medicaid services AND 6. Justification is submitted which explains the benefits of the identified drug and how that benefit outweighs the potential risks to the patient.
Age Restrictions	Applies to 65 years of age and older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	

### **IBRANCE**

#### **Products Affected**

• IBRANCE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, submission confirming HER2-negative status, confirmation that the treatment regimen will include concomitant use of an aromatase inhibitor or fulvestrant, submission of baseline CBC.
Age Restrictions	
Prescriber Restrictions	Limited to Hematology/Oncology
Coverage Duration	One year
Other Criteria	PA applies to new starts only.

### **ILARIS**

#### **Products Affected**

- ILARIS (150MG DELIVERED)
- ILARIS SUBCUTANEOUS SOLUTION

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use. TB skin test result obtained within past 12 months, submission of pediatric patient weight, submission of documentation that patient has received all recommended vaccinations as appropriate including pneumococcal vaccine and inactivated influenza vaccine prior to initiation of therapy. When requested for the treatment of CAPS-confirmed diagnosis of CAPS including genetic testing for variant FCAS or MWS, documentation patient is not receiving concomitant TNF inhibitor therapy. When requested for the treatment of SJIA-patient with confirmed diagnosis of active SJIA defined by the prominence of systemic and inflammatory features including spiking fevers, rash, swelling and inflammation of lymph nodes, liver and spleen, and high white blood cell and platelet counts, submission of CBC including platelet count.
Age Restrictions	2 YO and older
Prescriber Restrictions	when requetsed for SJIA limited to rheumatology
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: A physician/health care provider is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration. This medication may be covered under Part B if administered by a physician incident to a physician service. Continuation of therapy requires submission of objective documentation of positive patient response or maintenance of response, Submission of updated TB skin test result obtained within the past 12 months.PA applies to all.

### **IMBRUVICA**

#### **Products Affected**

• IMBRUVICA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of baseline CBC and confirmation that patient will have CBC checked monthly, submission of baseline serum creatinine level and confirmation that patient's serum creatinine levels will be monitored periodically while on therapy
Age Restrictions	18 YO or older
Prescriber Restrictions	limited to oncology and hematology
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

### **Immune Globulin**

#### **Products Affected**

- BIVIGAM
- CARIMUNE NF INTRAVENOUS SOLUTION RECONSTITUTED 12 GM, 6 GM
- CUVITRU
- FLEBOGAMMA DIF
- GAMASTAN S/D
- GAMMAGARD
- GAMMAGARD S/D LESS IGA

- GAMMAKED
- GAMMAPLEX INTRAVENOUS SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 20 GM/400ML, 5 GM/100ML, 5 GM/50ML
- GAMUNEX-C
- OCTAGAM
- PRIVIGEN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use. Documentation of baseline laboratory analysis/diagnostic procedures to indicate the need for Immune Globulin therapy at initiation. Baseline labs must be within the last 30 days.
Age Restrictions	For HIV diagnosis ONLY: 13 YO or younger
Prescriber Restrictions	
Coverage Duration	Acute conditions/New starts: 3 months Renewal of Chronic Condition: 1 year
Other Criteria	Immune Globulin therapy is covered as a part B benefit if administered in the home for the treatment of primary immune deficiency. It is covered as a Part D benefit for all other indications when administered in the home. For all indications, if administered in the physician office or infusion center it is covered as a Part B benefit. For continuation of all diagnosis documentation of the clinical response to therapy must be submitted.

## **INCRELEX/IPLEX**

#### **Products Affected**

INCRELEX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use, documentation of primary IGFD or growth hormone gene deletion in patients who have developed neutralizing antibodies to growth hormone, IGF-1 level, growth hormone level
Age Restrictions	
Prescriber Restrictions	Limited to Endocrinologist.
Coverage Duration	6 Months
Other Criteria	PA applies to all

# Ingrezza (valbenazine)

#### **Products Affected**

INGREZZA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. For the treatment of adults with tardive dyskinesia (TD)
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	

### **Injectable Oncology Drugs**

#### **Products Affected**

- ABRAXANE
- ALIMTA
- ARRANON
- ARZERRA INTRAVENOUS CONCENTRATE 100 MG/5ML
- AVASTIN
- azacitidine
- BELEODAQ
- BICNU
- bleomycin sulfate injection solution reconstituted 30 unit
- bortezomib
- busulfan
- cisplatin intravenous solution 100 mg/100ml, 50 mg/50ml
- clofarabine
- COSMEGEN
- cytarabine (pf) injection solution 100 mg/ml
- · cytarabine injection solution
- dacarbazine intravenous solution reconstituted 200 mg
- dactinomycin
- daunorubicin hcl intravenous injectable
- daunorubicin hcl intravenous solution
- decitabine
- dexrazoxane intravenous solution reconstituted 250 mg
- docetaxel intravenous concentrate 80 mg/4ml
- docetaxel intravenous solution 160 mg/16ml, 20 mg/2ml, 80 mg/8ml
- doxorubicin hcl intravenous solution
- doxorubicin hcl liposomal
- ELITEK
- epirubicin hcl intravenous solution 200 mg/100ml, 50 mg/25ml
- ERBITUX INTRAVENOUS SOLUTION 100 MG/50ML

- FASLODEX INTRAMUSCULAR SOLUTION 250 MG/5ML
- fludarabine phosphate intravenous solution reconstituted
- FOLOTYN INTRAVENOUS SOLUTION 40 MG/2ML
- gemcitabine hcl intravenous solution reconstituted 1 gm
- HALAVEN
- HERCEPTIN
- idarubicin hcl intravenous solution 10 mg/10ml
- ifosfamide intravenous solution reconstituted 1 gm
- irinotecan hcl intravenous solution 100 mg/5ml
- ISTODAX (OVERFILL)
- IXEMPRA KIT INTRAVENOUS SOLUTION RECONSTITUTED 45 MG
- JEVTANA
- KADCYLA
- melphalan hcl
- mesna
- mitoxantrone hcl intravenous concentrate 25 mg/12.5ml
- MUSTARGEN
- NIPENT
- oxaliplatin intravenous solution 100 mg/20ml
- oxaliplatin intravenous solution reconstituted
- paclitaxel intravenous concentrate 100 mg/16.7ml, 300 mg/50ml
- PROLEUKIN
- SYNRIBO
- TREANDA INTRAVENOUS SOLUTION RECONSTITUTED
- TRELSTAR MIXJECT

- TRISENOX
- VECTIBIX INTRAVENOUS SOLUTION 100 MG/5ML
- VELCADE INJECTION
- vinblastine sulfate intravenous solution
- vincasar pfs
- vincristine sulfate intravenous
- vinorelbine tartrate intravenous solution 50 mg/5ml
- VYXEOS
- YERVOY INTRAVENOUS SOLUTION 50 MG/10ML
- ZANOSAR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded by Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered FDA-labeled indication, submission of CBC including platelet count
Age Restrictions	
Prescriber Restrictions	limited to hematology, oncology, or HIV specialist
Coverage Duration	One Year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration, if the medication is being administered in the enrollee?s home, there are no associated safety concerns with preparation and/or administration of the medication documented in the prescribing information and if the medication is being administered in the enrollee?s home by a route other than orally or subcutaneously, documentation is provided that the member has been fully trained on how to administer the medication safely and effectively if applicable. If these conditions are not satisfied these medications may be covered under Part B in accordance with the corresponding NCD/LCD if applicable.PA applies to all.

## **Injectable Testosterone**

#### **Products Affected**

- testosterone cypionate intramuscular solution 100 mg/ml, 200 mg/ml
- testosterone enanthate intramuscular solution

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use, serum testosterone level, documentation that patient has been evaluated for the presence of prostate cancer prior to initiation of therapy
Age Restrictions	
Prescriber Restrictions	Urology and Endocrinology prescribers are exempt.
Coverage Duration	One Year
Other Criteria	PA applies to all except when written by Urology and Endocrinology prescribers.

### **INLYTA**

#### **Products Affected**

• INLYTA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, documentation of one prior systemic therapy failure, submission of laboratory values including baseline ALT, AST, bilirubin, TSH, urine protein values, pregnancy status for female patients, submission of baseline blood pressure reading
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

### **INTRON-A**

#### **Products Affected**

• INTRON A

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	autoimmune hepatitis, decompensated liver disease
Required Medical Information	Diagnosis of covered use, for all approved indications for use-submission of triglyceride levels, hemoglobin, complete and differential white blood cell counts, platelet count, serum electrolytes, ALT, serum bilirubin level, serum albumin level, TSH, for the treatment of malignant melanomasubmission of the date of surgical treatment, for the treatment of AIDS-Related Kaposi's Sarcoma-submission of total CD4 count, for the treatment of chronic hepatitis C-submission of the following laboratory values HCV RNA, prothrombin time, baseline serum creatinine level, laboratory confirmation of hepatitis C virus, documentation of previous response to therapy if applicable, for chronic Hepatitis B infection-documentation patient has been serum HBsAG positive for at least 6 months with evidence of HBV replication, submission of the following laboratory values Prothrombin time.
Age Restrictions	18 YO ot older for the treatment of Hairy Cell Leukemia, malignant melanoma, follicular lymphoma, Condylomata Acuminata, AIDS-Related Kaposi's Sarcoma 3 YO or older for the treatment of Chronic Hepatitis C 1 YO or older for the treatment of Chronic Hepatitis B
Prescriber Restrictions	
Coverage Duration	One Year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration, if the medication is being administered in the enrollee?s home, documentation is provided that the member has been fully trained on how to prepare the injection and to administer the medication safely and effectively. If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable.PA applies to new starts only.

### **INVEGA TRINZA**

#### **Products Affected**

• INVEGA TRINZA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Known hypersensitivity to paliperidone, risperidone, or to any excipients in the formulation
Required Medical Information	Diagnosis of covered medical use, documentation that the patient has been adequately treated with the 1-month palipderidone palmitate extended-release injectable suspension for at least four (4) months.
Age Restrictions	18 YO and older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: A physician/health care provider is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration If these conditions are not satisfied this medication may be covered under Part B.

### **IRESSA**

#### **Products Affected**

• IRESSA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, confirmation of EGFR exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test, submission of baseline liver function tests (AST, ALT, bilirubin)and confirmation periodic liver function testing will be performed while on therapy, documentation that females of reproductive potential have been advised to use highly effective contraception during therapy and for at least two weeks following completion of therapy
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology or Oncology
Coverage Duration	One Year
Other Criteria	PA Applies to New Starts Only

### **IVIG**

#### **Products Affected**

• GAMASTAN S/D

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	IgA deficient patients with antibodies against IgA and a history of hypersensitivity, patients with a history of severe systemic reactions to human immunoglobulin

PA Criteria	Criteria Details
Required Medical Information	IVIG is requested for one of the following conditions-Primary Immunodeficiency, Immune-mediated Thrombocytopenia (ITP), Kawasaki disease, Human Immunodeficiency Virus (HIV) (for pediatric use only), Bone marrow transplantation, Chronic B-cell lymphocytic leukemia (CLL) and for the following biopsy-proven conditions-Pemphigus vulgaris, Bullous pemphigoid, Mucous membrane pemphigoid, benign mucous membrane pemphigoid, with or without mention of ocular movement, Epidermolysis bullosa acquisita in patients who demonstrate rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. Primary humoral immunodeficiency is defined as severe impairment of antibody capacity with 1 of the following conditions: Congenital agammaglobulinemia, Common variable immunodeficiency, Wiskott-Aldrich syndrome, X-linked immunodeficiency with hyper-IgM, Severe combined immunodeficiencies, Deficient qualitative or quantitative antibody production, patients with at least 1 bacterial infection directly attributable to this deficiency. For ITP submission of platelet count, for CLL-IgG level of less than 600 mg/dl and Recent history of serious bacterial infection requiring either oral or IV antibiotic therapy, for HIV-Age younger than 14 years old and Evidence of qualitative or quantitative humoral immunologic defects and Current bacterial infections, despite appropriate antimicrobial prophylaxis, for CIDP-unequivocal CIDP diagnosis and patient has proved refractory to or intolerant of prednisone or azathioprine given in therapeutic doses over at least 3 months and patient has a Rankin Scale neurologic function assessment score of at least 3 at the time of initial therapy, for Dermatomyositis, Polymyositis-patient with severe active illness.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	remainder of the contract year

PA Criteria	Criteria Details
Other Criteria	IVIG is covered as a part B benefit if administered in the home for the treatment of primary immune deficiency. It is covered as a Part D benefit for all other indications when administered in the home. For all indications if administered in the physician office or infusion center it is covered as a Part B benefit.PA applies to all.

### Jakafi

#### **Products Affected**

JAKAFI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use and lab values including CBC, platelet count. Patient's creatinine clearance is required.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to oncology or hematology
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## Jublia/Kerydin

#### **Products Affected**

- JUBLIA
- KERYDIN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of culture proven Trichophyton rubrum or Trichophyton mentagrophytes infection, patient has tried and failed to respond to or tolerate oral terbinafine therapy or a documented contraindication to its use exists
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	48 weeks
Other Criteria	PA applies to all

### **JUXTAPID**

#### **Products Affected**

JUXTAPID

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Pregnancy or moderate or severe hepatic impairment (Child-Pugh Class B or C) or active liver disease.
Required Medical Information	Diagnosis of covered use and lab values including baseline transaminase levels including: ALT, AST,alkaline phosphatase, total bilirubin, baseline LDL-C, total cholesterol (TC), apoB, non-HDL-C, documentation of negative pregnancy test result in females of reproductive potential, confirmed diagnosis of HoFH and renal indices, documentation of treatment failure with Repatha or contraindication to use.
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# JYNARQUE (tolvaptan)

#### **Products Affected**

• JYNARQUE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	History of signs or symptoms of significant liver impairment or injury (not including uncomplicated polycystic liver disease), uncorrected abnormal blood sodium concentrations, inability to sense or respond to thirst, hypovolemia, uncorrect urinary outflow obstruction, anuria
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to nephrology
Coverage Duration	1 year
Other Criteria	PA applies to all.

### **KALYDECO**

#### **Products Affected**

KALYDECO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, cystic fibrosis mutation test result, baseline ALT and AST laboratory values
Age Restrictions	2 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

### Kanuma

#### **Products Affected**

KANUMA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of patient's current weight for the purposes of dosage calculation, documentation that the healthcare setting and providers are prepared to manage infusion reactions including anaphylaxis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may becovered under Part D provided the following conditions are satisfied: A a physician/health care provider is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration. If these conditions are not satisfied this medication may be covered under Part B. PA applies to all.

### **KETOCONAZOLE**

#### **Products Affected**

ketoconazole oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Patients with acute or chronic liver diease, treatment of fungal meningitis or fungal infections of the skin or nails, patients receiving concomitant therapy with aplrazolam, midazolam, triazolam, cisapride, dofetilide, HMG-CoA reductase inhibitors, nisoldipine, pimozide, eplerenone, ergot alkaloids or quinidine
Required Medical Information	Ketoconazole is being requested for the treatment of one of the following culture proven, systemic fungal infections in patients who have failed or who are intolerant to other therapies: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis or paracoccidioidomycosis, submission of baseline ALT, AST, total bilirubin, alkaline phosphatase, prothrombin time and INR, confirmation patient's ALT will be moniotred weekly for the duration of treatment, confirmation from the prescriber that the potential benefits of therapy outweigh the risks
Age Restrictions	2 YO or older
Prescriber Restrictions	
Coverage Duration	Six months
Other Criteria	PA applies to all

### **KEVEYIS**

#### **Products Affected**

KEVEYIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Concomitant use of high dose aspirin, hypersensitivity to dichlorphenamide or other sulfonamides, severe pulmonary disease limiting compensation to metabolic acidosis, hepatic insufficiency
Required Medical Information	Diagnosis of primary hyperkalemic periodic paralysis, primary hypokalemic period paralysis, or related variants, submission of baseline serum potassium and baseline serum bicarbonate and confirmation these lab values will be measured periodically while on therapy
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	Initially 2 months, then annually thereafter
Other Criteria	Documentation of patient's response to Keveyis at 2 months is required for continuation of approval. PA Applies to All.

### **KEYTRUDA**

#### **Products Affected**

• KEYTRUDA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, submission of baseline AST and ALT, baseline serum creatinine, baseline thyroid function tests, documentation that appropriate dose adjustments will be made as needed and/or corticosteroid administration, in the event of immunemediated adverse reactions, submission of patient's current weight.
Age Restrictions	
Prescriber Restrictions	Limited to Hematology and Oncology Prescribers
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: The provider administering the medication agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration. If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable or this clinical criteria. PA applies to new starts only.

## **KISQALI** (ribociclib)

#### **Products Affected**

- KISQALI 200 DOSE
- KISQALI 400 DOSE
- KISQALI 600 DOSE
- KISQALI FEMARA 200 DOSE

- KISQALI FEMARA 400 DOSE
- KISQALI FEMARA 600 DOSE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients on rifampin, phenytoin, and carbamazepine
Required Medical Information	Diagnosis of covered use and genetic tumor testing showing that the primary tumor type is HR Positive, HER-2 negative and attestation that patient has advanced or metastatic disease and will be taking concurrently with an aromatase inhibitor. The provider must also attest that baseline ECG, LFT's, CDC have been obtained and will be monitored per prescribing guidelines.
Age Restrictions	
Prescriber Restrictions	Limited to oncology or hematology
Coverage Duration	One year
Other Criteria	

### **KORLYM**

#### **Products Affected**

KORLYM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	pregnancy, patients on concurrent long-term, life-saving corticosteroid therapy, patients on concurrent simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges, such as cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, and tacrolimus, female patient with a histoy of unexplained vaginal bleeding, female patient with endometrial hyperplasia with atypia or endometrial carcinoma
Required Medical Information	Diagnosis of covered use, submission of baseline serum potassium level, submission of negative pregnancy test result in female patients of reproductive potential, submission of serum creatinine level and patient's weight (for creatinie clearance calculation and dose verification), submission of baseline AST, ALT and alkaline phosphatase
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

### **KUVAN**

#### **Products Affected**

• KUVAN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, phenylalanine level, patient weight
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	PA applies to all

### **KYNAMRO**

#### **Products Affected**

 KYNAMRO SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Patients with moderate or severe hepatic impairment, or active liver disease, including unexplained persistent elevations of serum transamniases
Required Medical Information	Diagnosis of covered use, submission of the following baseline lab values ALT, AST, alkaline phosphatase, total bilirubin, LDL-C, apo B, TC, non-HDL-C, documentation patient is using Kynamro as an adjunct to lipid-lowering medications
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	six months
Other Criteria	PA applies to all

# **Kyprolis (Carfilzomib)**

#### **Products Affected**

KYPROLIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use including documentation of prior therapies consistent with NCCN guidelines and/or FDA approved indications, documentation that the following values will be monitored to ensure safe dosing of carfilzomib: Left Ventricular Ejection Fraction (LVEF), serum creatinine, serum uric acid level, blood pressure, platelet counts, liver enzymes (including AST, ALT, and Bilirubin), documentation that if any of the preceding values are elevated or uncontrolled that consideration to stopping therapy and/or dose reduction will be given. Documentation that thromboprophylaxis has been considered for patients at high risk of thrombosis while on carfilzomib. Documentation that provider is aware that inadequate hydration while using carfilzomib will increase the risk of tumor lysis syndrome/renal toxicity.
Age Restrictions	18 YO and older
Prescriber Restrictions	Limited to hematology and oncology providers
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office for administration. If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable. PA for New Starts Only.

# **LARTRUVO** (olaratumab)

#### **Products Affected**

• LARTRUVO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. LARTRUVO™ is a platelet-derived growth factor receptor alpha (PDGFR-a) blocking antibody indicated, in combination with doxorubicin, for the treatment of adult patients with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, confirmation patient will receive concurrent doxorubicin therapy and patient is not a candidate for curative treatment with radiotherapy or surgery, submission of patient weight for purposes of dose verification, confirmation patient will be premedicated with diphenhydramine and dexamethasone and that Lartruvo will be administered by IV infusion only, confirmation female patients of reproductive potential have been advised of thepotential risk to the fetus and to use effective contraception duringtreatment with Lartruvo and for 3 months after the last dose
Age Restrictions	18yo or older
Prescriber Restrictions	
Coverage Duration	One year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: The provider administering the medication agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration. If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable or this clinical criteria. PA applies to new starts only.

### **LENVIMA**

#### **Products Affected**

- LENVIMA 10 MG DAILY DOSE
- LENVIMA 12 MG DAILY DOSE
- LENVIMA 14 MG DAILY DOSE
- LENVIMA 18 MG DAILY DOSE

- LENVIMA 20 MG DAILY DOSE
- LENVIMA 24 MG DAILY DOSE
- LENVIMA 4 MG DAILY DOSE
- LENVIMA 8 MG DAILY DOSE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, submission of creatinine clearance or current body weight and serum creatinine level for the purposes of calculation of creatinine clearance by the Cockcroft-Gault equation, submission of baseline blood pressure showing blood pressure is controlled, confirmation patient will be monitored for clinical symptoms or signs of cardiac decompensation, submission of baseline ALT and AST, submission of baseline protinuria evaluation via dipstick (at least less than 2 grams), submission of baseline serum calcium and TSH level, Documentation that blood pressure will be monitored after 1 week, then every 2 weeks for the first 2 months, and then at least monthly thereafter, documentation that liver function will be evaluated before initiation, then every 2 weeks for the first 2 months, and a least monthly thereafter, documentation that serum calcium will be monitored at least monthly, documentation that TSH will be monitored monthly
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology/Oncology
Coverage Duration	one year
Other Criteria	

## Letairis

### **Products Affected**

• LETAIRIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Pregnancy, idiopathic pulmonary fibrosis
Required Medical Information	Diagnosis of covered use, negative pregnancy test result for female patients of childbearing age, submission of baseline AST, ALT and bilirubin levels, submission of basline HGB level and confirmation HGB will be measured after 1 month of therapy and periodically thereafter
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Pulmonologists and Cardiologists
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## Leukine

### **Products Affected**

• LEUKINE INTRAVENOUS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, WBC count, ANC
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 Months
Other Criteria	PA applies to all

## **LIDODERM**

### **Products Affected**

• lidocaine external patch 5 %

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	lidocaine transdermal is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.
Required Medical Information	Diagnosis of covered use
Age Restrictions	18YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to all

## **Long Acting Somatostatin Analogs**

#### **Products Affected**

- SANDOSTATIN LAR DEPOT
- SIGNIFOR LAR INTRAMUSCULAR SUSPENSION RECONSTITUTED ER
- SOMATULINE DEPOT SUBCUTANEOUS

SOLUTION 120 MG/0.5ML, 60 MG/0.2ML, 90 MG/0.3ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, documentation of baseline serum GH and IGF-1 levels and degree of control of clinical acromegaly symptoms patient has (for acromegaly requests only), documentation of TSH and blood glucose levels
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to endocrinologist or oncology
Coverage Duration	Three months initially then up to one year
Other Criteria	Continuation of therapy requires a positive clinical response.

## **LONSURF**

### **Products Affected**

• LONSURF

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use: metastatic colorectal cancer for patients who have been previously treated with fluoropyrimidine, oxaliplatin, and ironotecan based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy, submission of patient's height and current weight to calculate BSA to confirm dosage, submission of CBC prior to initiation of therapy and confirmation that it will be monitored on Day 15 of each cycle, documentation that women of reproductive potential have been advised to use effective contraception during treatment, documenation of of patient's KRAS status
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology and Oncology
Coverage Duration	One Year
Other Criteria	PA Applies to New Starts Only

# **LUCEMYRA** (lofexidine)

### **Products Affected**

• LUCEMYRA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Congenital long QT syndrome, severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	14 days
Other Criteria	PA applies to all.

## **LYNPARZA**

### **Products Affected**

• LYNPARZA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, BRCA mutation status, documentation that the patient has been treated with three or more prior lines of chemotherapy, submission of baseline CBC and confirmation that CBC will be monitored monthly thereafter.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to hematology and oncology prescribers
Coverage Duration	one year
Other Criteria	PA applies to new starts only

## **MARINOL (DRONABINOL)**

### **Products Affected**

dronabinol

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients with a known hypersensitivity to dronabinol, cannabinoid, and/or sesame oil
Required Medical Information	Diagnosis of covered medical use, if authorization is requested for treatment of nausea and vomiting associated with cancer therapy, documentation is required of previous conventional antiemetic therapies utilized
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	If the medication is being requested for the use of nausea and vomiting associated with cancer chemotherapy, approval may be covered under Part B. If the medication is being requested for the use of anorexia associated with weight loss in patients with AIDs, approval may be covered under Part D. PA Applies to All.

# Mavyret (glecaprevir/pibrentasvir)

#### **Products Affected**

MAVYRET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Patients with severe hepatic impairment (Child-Pugh class C or worse) and patients on rifampin or atazanavir
Required Medical Information	Diagnosis of covered use and laboratory confirmation of hepatitis C virus (HCV) as indicated consistent with current AASLD-IDSA guidance
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	12 weeks
Other Criteria	

## **MEGESTEROL**

#### **Products Affected**

- megestrol acetate oral suspension 40 mg/ml, 625 mg/5ml
- megestrol acetate oral tablet

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Submission of documentation that the drug requested is being prescribed for an FDA approved indication for that specific drug and documentation that the provider is aware of the associated risks of megesterol including an increased risk of thrombotic events and death (with minimal effect on weight gain), confirmation that the prescriber is aware the medication is considered high risk for elderly patients by the Centers for Medicare and Medicaid services and submission of justification by the prescriber which explains the benefits of the requested drug and how that benefit outweighs the potential risks for the specific patient, and the physician has provided clinical rationale as to why a safer formulary alternative is not appropriate for the patient or documentation of a trial and failure or contraindication to two preferred alternatives including dronabinol or mirtazapine.
Age Restrictions	PA applies to patients 65 YO or older
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	

## **MEKINIST**

### **Products Affected**

MEKINIST

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of FDA- approved test confirming presence of BRAF V600E or V600K mutation, submission of baseline LVEF and confirmation that LVEF is scheduled to re-assessed after one month of treatment and then every 2 to 3 months thereafte, submission of blood pressure reading
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to oncology or hematology
Coverage Duration	One Year
Other Criteria	Mekinist is not indicated for the treatment of patients who have received prior-BRAF-inhibitor therapy. PA applies to new starts only.

# Methamphetamine

### **Products Affected**

• methamphetamine hcl

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Exogenous Obesity- if this drug is being used for this indication, the drug is not covered as it is part of the excluded categories described in Chapter 6 Medicare Prescription Drug Manual Rev. 1-15-16.  Methamphetamine hydrochloride tablets are contraindicated during or within 14 days following the administration of monoamine oxidase inhibitors,in patients with glaucoma, advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism or known hypersensitivity or idiosyncrasy to sympathomimetic amines. Methamphetamine should not be given to patients who are in an agitated state or who have a history of drug abuse.
Required Medical Information	Diagnosis of covered use, submission of baseline blood pressure
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	For patients 65 years of age and older- submission of documentation that provider is aware medication is considered a high risk medication for elderly patients according to the Centers for Medicare and Medicaid services and that the benefits of methamphetamine therapy outweighs the potential risks to the patient.

## **Methotrexate Oral Solution (Xatmep)**

#### **Products Affected**

• XATMEP

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Pregnancy (if female)
Required Medical Information	Diagnosis of covered use. For pJIA patients confirmation that member is are intolerant of or had an inadequate response to first-line therapy. For ALL confirmation that medication is being used as a component of a combination chemotherapy maintenance regimen. Documentation that the patient/caregiver has been counseled on proper dosing technique and frequency of the medication, baseline CBS with platelets, LFT, and Serum Creatinine/eGFR have been obtained and will be monitored throughout therapy.
Age Restrictions	2 YO to 18 YO
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	

## **Methyl Testosterone Products**

#### **Products Affected**

- METHITEST
- methyltestosterone oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Male patients with carcinomas of the breast or prostate, female patients who are or may become pregnant
Required Medical Information	Diagnosis of Covered Use, for male patients- documentation that patient has been evaluated for the presence of prostate cancer prior to initiation of therapy, for female patients diagnosed with disseminated breast carcinoma who are 1 to 5 years postmenopausa- submission of baseline urine and serum calcium levels and confirmation calcium levels will be monitored during the course of androgen therapy, submission of baseline X-ray bone age examination result of the hand or wrist in prepubertal male patients and confirmation re-examinations will be performed every 6 months, for all patients-submission of baseline HGB, HCT, ALT, AST and total bilirubin levels and confirmation liver function tests will continue to be monitored periodically while on therapy, submission of baseline GFR
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	one year
Other Criteria	For patients 65 years of age and older- submission of documentation that provider is aware medication is considered a high risk medication for elderly patients according to the Centers for Medicare and Medicaid services and that the benefits of methyltestosterone therapy outweighs the potential risks to the patient. PA applies to all.

## **METOCLOPRAMIDE**

### **Products Affected**

• metoclopramide hcl injection

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Metoclopramide carries risk of Tardive dyskinesia, a serious movement disorder which is often irreversible. The risk is greater in elderly patients, therefore the American Geriatric Society (through the Beers Criteria) recommends metoclopramide not be used. For all diagnoses of covered use justification must be submitted which explains the benefits of the drug and how that benefit outweighs the potential risks to the patient. In addition, the following diagnosis specific criteria are required for coverage. For diagnosis of chemotherapy induced nausea and vomiting, coverage will be provided for patients who have tried and failed or had an inadequate response to ondansetron or granisetron. For diagnosis of GERD coverage will be provided for patients who have tried and failed or had an inadequate response to maximally tolerated doses of at least one (1) formulary PPI and one (1) H2 blocker. For diagnosis of diabetic gastroparesis and for post lung transplant metoclopramide is the preferred first line agent and use generally outweighs risks.
Age Restrictions	PA applies to patients 65 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	

# **Midostaurin (Rydapt)**

### **Products Affected**

RYDAPT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Patients on strong CYP3A4 inducers (i.e. Carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, St. John's wort)
Required Medical Information	Diagnosis of covered use. Documentation of that the following baseline laboratory measurements are available and will be monitored throughout use: liver function tests, CBC with platelets, serum sodium and calcium levels. Documentation that the patient has been counseled to report any signs of pulmonary toxicity while on medication immediately and that consideration will be given to stopping medication is they are felt to be due to therapy with Midostaurin. If a male or female of reproductive potential, documentation that patient has been counseled to use effective contraception during treatment and for at least 4 months after the last dose of medication.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology/Oncology
Coverage Duration	One year
Other Criteria	

## **MOZOBIL**

### **Products Affected**

MOZOBIL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline CBC and platelet counts, confirmation medication is being used in combination with granulocyte-colony stimulating factor, submission of patient's current weight, submission of baseline serum creatinine level.
Age Restrictions	18 YO or older
Prescriber Restrictions	limited to oncology and hematology
Coverage Duration	one treatment course (4 days of therapy)
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: A physician/health care provider is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration. This medication may be covered under Part B if administered by a physician incident to a physician service. PA applies to all

# **MULPLETA** (lusutrombopag)

### **Products Affected**

• MULPLETA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology, gastroenterology, and surgery
Coverage Duration	7 days
Other Criteria	PA applies to all. This medication should not be administered to patients with chronic liver disease in an attempt to normalize platelet counts and will not be approved for this indication.

## **MYALEPT**

### **Products Affected**

MYALEPT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	patients with general obesity not associated with congenital leptin deficiency
Required Medical Information	diagnosis of covered use, submission of patient weight, submission of leptin level laboratory test result confirming leptin deficiency, submission of baseline HbA1c, fasting glucose and fasting triglyceride levels
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	one year
Other Criteria	Continuation of approval requires submission of patient weight, updated HbA1c, fasting glucose and fasting triglyceride levels.PA applies to all.

## **Mylotarg**

### **Products Affected**

 MYLOTARG INTRAVENOUS SOLUTION RECONSTITUTED 4.5 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use demonstrating that patient has CD33-positive disease. Patients with a history of or predisposition for QTc prolongation have a baseline electrocardiogram (ECG) AND patients with hyperleukocytosis (leukocyte count greater than or equal 30 x 10^9/L) have had cytoreduction AND patient has not previously received gemtuzumab ozogamicin AND for patients with Acute Myeloid Leukemia (AML): Patient has newly-diagnosed disease AND Used in combination with daunorubicin and cytarabine AND Patient has de novo disease AND Patient does not have adverse-risk cytogenetics OR cytogenetic results are not yet known OR Used as a single agent OR patient has relapsed or refractory disease AND Must be used as a single agent. Confirmation that females of reproductive potential have been counseled to use effective contraception during treatment with gemtuzumab and for at least 6 months after the last dose. Males with female partners of reproductive potential have been counseled to use effective contraception during treatment with gemtuzumab and for at least 3 months after the last dose. Documentation of baseline laboratory analysis of the following which will be needed to determine if any potential medication-related adverse reactions are occurring: ALT, AST, total bilirubin, and alkaline phosphatase, and platelet counts. Also, confirmation that these labs will be drawn and monitored as required by package labeling. Confirmation that the patient will be premedicated to prevent infusion reactions as directed in package labeling. Additionally, confirmation must be given that the provider will appropriately monitor patients during infusions and for at least one (1) hour after each infusion in a setting that will allow for prompt treatment of any infusion-related reactions, should they occur.
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	requested by an oncologist or hematologist (or under the documented recommendation of an oncologist or hematologist)
Coverage Duration	One year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: If a physician is administering the medication, he/she agrees to accept brown-bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration, if the medication is being administered in the enrollee's home, there are no associated safety concerns with preparation and/or administration of the medication documented in the prescribing information and if the medication is being administered in the enrollee's home by a route other than orally or subcutaneously, documentation is provided that the member has been fully trained on how to administer the medication safely and effectively if applicable. If these conditions are not satisfied these medications may be covered under Part B in accordance with the corresponding NCD/LCD if applicable.

# **MYTESI** (crofelemer)

### **Products Affected**

MYTESI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. Previously Fulyzaq
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	18YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts

# Naglazyme

### **Products Affected**

NAGLAZYME

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of patient weight, documentation that the healthcare setting and provider are prepared to manageinfusion reactions including life-threatening anaphylaxis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:A a physician is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration If these conditions are not satisfied this medication may be covered under Part B. PA applies to new starts only.

## **NAMZARIC**

### **Products Affected**

NAMZARIC

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, submission of documentation that the patient has been stablizied on memantine hydrochloride (5mg twice daily, 10mg twice daily, 14mg extended-release daily, or 28mg extended-release daily) and donepezil hydrochloride 10mg daily, submission of patient current weight and serum creatinine level for the purposes of calculating creatinine clearance
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	one year
Other Criteria	

## **NATPARA**

### **Products Affected**

NATPARA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, prior to initiation of therapy documentation that serum calcium (albumin-corrected) is greater than 7.5 mg/dL and confirmation that 25-hydroxyvitamin D stores are sufficient, confirmation that serum calcium concentration will be measured every 3 to 7 days after starting or adjusting Natpara dose
Age Restrictions	18 YO or older
Prescriber Restrictions	Natpara REMS program certified healthcare providers
Coverage Duration	one year
Other Criteria	Patients and caregivers who will administer Natpara will receive appropriate training and instruction by a trained healthcare professional prior to the first use of Natpara

# **NERLYNX** (neratinib)

#### **Products Affected**

NERLYNX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients on Strong or Moderate CYP3A4 Inhibitors OR Inducers
Required Medical Information	Diagnosis of covered use and genetic tumor testing showing that the primary tumor type is HR Positive, HER2-Positive and that the member has completed adjuvant trastuzumab-based therapy. Additionally, the provider must attest that medication will be initiated along with loperamide as per package labeling guidelines and that the medication will be permanently stopped if grade 4 diarrhea should occur or Grade 2 or greater diarrhea that occurs after maximal dose reduction.  Documentation of baseline laboratory values of liver function tests, CBC, serum creatinine must have been drawn and provider attests that LFT's will be drawn monthly for the first three months of treatment and then every three months thereafter. Also if a female of reproductive potential, the provider must attest counseling patient to use effective contraception during treatment and for at least 1 month after the last dose.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology/Oncology
Coverage Duration	One year
Other Criteria	

## **NEULASTA**

### **Products Affected**

- NEULASTA ONPRO
- NEULASTA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	PBPC Mobilization
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 Months
Other Criteria	PA applies to all

## **NEXAVAR**

### **Products Affected**

NEXAVAR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new strats only

## **NINLARO**

### **Products Affected**

NINLARO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, and documentation that medication will be administered concomitantly with lenalidomide and dexamethasone, documentation of prior therapy regimen for multiple myeloma, submission of baseline platelet count and absolute neutrophil count, submission of creatinine clearance or current body weight and serum creatinine level for the purposes of creatinine clearance calculation using the Cockcroft-Gault equation, submission of baseline LFTs and bilirubin
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology and Oncology
Coverage Duration	3 months initially, then annually thereafter
Other Criteria	Documentation of platelet count greater than 30,000mm3, ANC greater than 500/mm3, and Grade 1 or lower non-hematological toxicities (including rash, peripheral neuropathies) required for continuation of approval. Submission of documentation of patient's hepatic (serum bilirubin and LFTs)and renal function (creatinine clearnace) is required annually. PA Applies to New Starts Only.

## **NORTHERA**

### **Products Affected**

NORTHERA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	18 years of age
Prescriber Restrictions	
Coverage Duration	2 weeks initially, then 1 year
Other Criteria	PA applies to all

## **NUCALA**

### **Products Affected**

NUCALA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	History of hypersensitivity to mepolizumab or excipients in the formulation
Required Medical Information	Diagnosis of covered use of treatment of severe asthma in patients with eosinophilic phenotype, submission of pulmonary function test results including FEV1, submission of blood eosinophil count documenting 150 cells/mcL obtainied within 6 weeks prior to therapy initiation or 300 cells/mcL within 12 months of therapy initiation, submission of documentation that patient's symptoms are poorly controlled with inhaled corticosteroids, frequency of inhaled short-acting beta2-agonist therapy, submission of frequency of daily and nighttime symptoms and exacerbations, effect of exacerbations on activity. Confirmation that the patient will receive treatment in the doctor's office or clinic and be observed for an appropriate amount of time after each treatment, documentation that the healthcare setting and providers are prepared to manage life-threatening anaphylaxis.
Age Restrictions	12 YO or older
Prescriber Restrictions	Limited to Allergy, Pulmonology, or Immunology
Coverage Duration	One Year

PA Criteria	Criteria Details
Other Criteria	Continuation of therapy requests require objective documentation from the prescriber that the patient's symptoms have improved. The medication may be covered under Part D provided the following conditions are satisfied: A physician is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or clinic for administration. If these conditions are not satisfied, the medication may be covered under Part B. PA Applies to All.

# **NULOJIX (belatacept)**

#### **Products Affected**

NULOJIX

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Kidney transplant: The medication is being used for prevention of kidney transplant organ rejectionAND The patient is immune to the Epstein-Barr virus (i.e. EBV seropositive) AND The patient isprescribed concurrent therapy with mycophenolate and corticosteroids
Age Restrictions	18 YO or older
Prescriber Restrictions	Prescriber is experienced in immunosuppressive therapy and management oftransplant patients
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: If a physician is administering the medication, he/she agrees to accept brown-bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office for administration, if the medication is being self-administered documentation is provided that the enrollee has been fully trained on how to prepare the injection and to administer the medication safely and effectively if applicable. If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable. Additionally provider must attest that medication will be given under conditions where they may be monitored for hypersensitivity reactions.

## **NUPLAZID**

#### **Products Affected**

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

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, confirmation patient does not have severe renal impairment or hepatic impairment
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	Continuation of approval requires documentation of a patient's positive response to therapy including a decrease in the frequency and/or severity of hallucinations and delusions or a maintenance of the initial response to therapy  PA applies to ALL

# **NYMALIZE**

#### **Products Affected**

NYMALIZE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. Attestation by the provider of the following: medication is being started within 96 hours of the subarachnoid hemorrhage and will be continued for 21 consecutive days, blood pressures will be frequently monitored throughout therapy. If the patient is also on a strong CYP3A4 inhibitor or inducer, the provider must provide a clinical rationale for how they are mitigating the risks of either increased clearance of nimodipine or increased levels of nimodipine. If the member is known or suspected to have cirrhosis, a clinical rationale must be provided for how the provider is mitigating the risks of adverse events to the patient.
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	21 Days
Other Criteria	

# **OCALIVA**

#### **Products Affected**

OCALIVA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients with complete biliary obstruction
Required Medical Information	Diagnosis of covered medical use, documentation that Ocaliva will be used in combination with ursodeoxycholic acid (UDCA) in adult patients who have failed to achieve an adequate response to at least one year of UDCA monotherapy or if Ocaliva is being prescribed as monotherapy, documentation patient is unable to tolerate UDCA, submission of baseline LFTs including ALP and total bilirubin, submission of baseline lipid levels including HDL-C and confirmation patient will be monitored for changes in serum lipid levels while on therapy
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	Submission of ALP, total bilirubin and HDL-C obtained withing the previous 3 months is required for continuation of therapy. PA Applies to All.

# **ODOMZO**

#### **Products Affected**

• ODOMZO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of baseline serum creatinine kinase (CK) and creatinine levels and confirmation that these levels will be monitored periodically during treatment, documentation that female patient of reproductive potential is not pregnant prior to therapy initiation and confirmation that females of reproductive potential have been advised to use highly effective contraception during treatment and for at least 20 months after the last dose, confirmation that male patients with female partners have been advised to use condoms, even after a vasectomy, during treatment and for at least 8 months after the last dose
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology or Oncology
Coverage Duration	One Year
Other Criteria	PA Applies to New Starts

# **ONCASPAR**

#### **Products Affected**

• ONCASPAR INJECTION

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Oncaspar is contraindicated if patients have a history of serious allergic reactions to Oncaspar, and/or a history of pancreatitis, serious thrombosis, or serious hemorrhagic events with prior L-asparaginase therapy
Required Medical Information	Diagnosis of covered use, submission of patient height and current weight, submission of baseline blood glucose level and confirmation blood glucose levels will be moniotred periodically during treatment, confirmation that this medication is being administered in a setting with the proper resuscitation equipment and other agents necessary (epinephrine, oxygen, intravenous steroids, antihistamines etc) to treat anaphylaxis available and that patients will be observed for one hour after Oncaspar administration
Age Restrictions	
Prescriber Restrictions	limited to oncology and hematology
Coverage Duration	one year
Other Criteria	PA applies to all

# **OPDIVO**

#### **Products Affected**

• OPDIVO INTRAVENOUS SOLUTION 100 MG/10ML, 40 MG/4ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, submission of baseline LFTs (including AST, ALT, and total bilirubin), baseline serum creatinine, baseline thyroid function tests, submission of patient current weight, documentation patient with unresctable or metastatic melanoma has experienced disease progression following ipilimumab and if BRAF V600 mutation positive, a BRAF inhibitor, documenation patient with metastatic squamous non-small cell lung cancer has experienced disease progression on or after platinum-based chemotherapy
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology/Oncology prescribers
Coverage Duration	one year
Other Criteria	PA applies to new starts only

# **OPSUMIT**

#### **Products Affected**

OPSUMIT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Pregnancy
Required Medical Information	Diagnosis of covered use, negative pregnancy test result for female patients of childbearing age and confirmation pregnancy will be excluded monthly during treatment and for 1 month after stopping treatment, submission of baseline AST, ALT and bilirubin levels, and submission of baseline HGB level and confirmation that these lab values will be monitored during treatment as clinically indicated
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to pulmonologists and cardiologists
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **ORALAIR**

#### **Products Affected**

ORALAIR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Severe, unstable or uncontrolled asthma, history of any severe systemic allergic reaction, history of any severe local reaction to sublingual allergen immunotherapy, hypersensitivity to mannitol, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate or lactose monohydrate
Required Medical Information	Oralair is being requested for the treatment of grass pollen induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for any of the following grass sepcies:Sweet Vernal, Orchard, Perennial Rye, Timothy and Kentucky Blue Grass, therapy is being initiated 4 months before the expected onset of each grass pollen season, confirmation that the first dose of medication will be administered in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of severe allergic reactions and that the patient will be observed for at least 30 minutes after administration of the first dose to monitor for signs and symptoms of a severe systemic or severe local allergic reaction.
Age Restrictions	Patients 10 through 65 years of age
Prescriber Restrictions	Limited to allergy and immunology
Coverage Duration	one year
Other Criteria	Confirmation auto-injectable epinephrine therapy has been prescribed and patient has been instructed on the proper use of emergency self-injection epinephrine. PA applies to all.

# **ORBACTIV**

#### **Products Affected**

ORBACTIV

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	patients with known medical need for intravenous unfractionated heparin sodium within 120 hours (5 days) of Orbactiv administration
Required Medical Information	Diagnosis of covered use, submission of culture proven infection caused by susceptible isolates of one of the following Gram-positive micoorganisms: Staphyloccocus aureus (including methiciliin-resistant MRSA) and methicillin-susceptible (MSSA) isolates, Stretococcus pyogenes, Streptococcus agalactiae, streptococcus dysgalactiae, Streptococcus anginosus Group(including Streptococcus anginosus, intermedius and constellatus), and Enterococcus faecalis (vancomycinsusceptible isolates only), confirmation Orbactiv will be administered by IV infusion over at least 3 hours
Age Restrictions	18 years of age or older
Prescriber Restrictions	Limited to infectious disease specialists
Coverage Duration	one dose
Other Criteria	If this medication is being administered in the enrollee's home via an infusion pump it is covered as a Part B benefit. If it being administered in the enrollee's home via IV drip it is covered as a Part D benefit. Serious hypersensitivity reactions and infusion related reactions have been reported. Healthcare professional and place of administration must be properly trained on how to prepare and administer the medication and be equipped to treat hypersensitivity and infusion related reactions. PA Applies to All.

# **ORENITRAM**

#### **Products Affected**

ORENITRAM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	idiopathic pulmonary fibrosis, including idiopathic pulmonary fibrosis patients with pulmonary hypertension or WHO group 3.
Required Medical Information	Diagnosis of covered use, submission of baseline AST, ALT and bilirubin levels, submission of basline HGB level and confirmation HGB will be measured after 1 month of therapy and periodically thereafter
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Pulmonologists and Cardiologists
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **ORFADIN**

#### **Products Affected**

- NITYR
- ORFADIN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, urine succinylacetone levels, liver function tests, alpha-fetoprotein level, serum tyrosine level, serum phenylalanine level, patient weight
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	PA applies to all

# ORILISSA (elagolix)

#### **Products Affected**

• ORILISSA ORAL TABLET 150 MG, 200 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy, severe (Child-Pugh class C) hepatic impairment, known osteoporosis
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to endocrinology and gynecology
Coverage Duration	Up to 24 months based on liver function and coexisting dyspareunia. See "Other Criteria" section.
Other Criteria	PA applies to all. For endometriosis with dyspareunia or in women with moderate hepatic impairment, up to 6 months. For endometriosis without dyspareunia, 150 mg daily up to 24 months.

# **ORKAMBI**

#### **Products Affected**

• ORKAMBI ORAL TABLET

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, documentation that the patient is homozygous for the F508del mutation in the CFTR gene provided from an FDA-cleared CF mutation test, submission of baseline AST/ALT, bilirubin, and documentation of the patients ppFEV1, submission of documentation that baseline and follow-up ophthalmologic exams will be performed in pediatric patients starting on therapy.
Age Restrictions	12 years of age and older
Prescriber Restrictions	Limited to Pulmonology
Coverage Duration	One Year
Other Criteria	Submission of documentation the liver function tests will be assessed every 3 months during the first year of treatment, and annually thereafter. Additional monitoring may be required for patients with ppFEV1 less than 40 percent.

### **OTREXUP**

#### **Products Affected**

 OTREXUP SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.4ML, 12.5 MG/0.4ML, 15 MG/0.4ML, 17.5 MG/0.4ML, 20 MG/0.4ML, 22.5 MG/0.4ML, 25 MG/0.4ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Pregnancy, treatment of nursing mother, patient with alcoholism or liver disease, patient with immunodeficiency syndromes or preexisitng blood dyscrasias
Required Medical Information	Diagnosis of covered use, documentation of other therapies tried and patient response, submission of negative pregnancy test result for women of reproductive potential, submission of baseline complete blood counts, renal function tests, liver functions tests and confirmation that complete blood counts, renal function tests and liver function tests are scheduled to be monitored periodically while on therapy, submission of pediatric patient weight
Age Restrictions	
Prescriber Restrictions	Limited to rheumatologists or dermatologists
Coverage Duration	one year
Other Criteria	PA applies to all

# **OXERVATE** (cenegermin-bkbj)

#### **Products Affected**

OXERVATE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	
Prescriber Restrictions	Restricted to optometry and ophthalmology
Coverage Duration	8 weeks
Other Criteria	PA applies to all.

# PALYNZIQ (pegvaliase-pqpz)

#### **Products Affected**

PALYNZIQ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of blood phenylalanine concentration.
Age Restrictions	18 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to all. Continuation of therapy after 1 year requires documentation of blood phenylalanine concentration below 600 micromol/L or at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline.

# **PCSK-9 Inhibitor**

#### **Products Affected**

- PRALUENT SUBCUTANEOUS SOLUTION PEN REPATHA SURECLICK INJECTOR
- REPATHA
- REPATHA PUSHTRONEX SYSTEM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use as medically indicated for the treatment of heterozygous familial hypercholesterolemia (HeFH) or ASCVD. If medication is required for the treatment of HeFH, documentation of genetic test result documenting HeFH or diagnosis by clinical criteria using Simon Broom or WHO/Dutch Lipid Network criteria, and submission of documentation that medication is being used with maximally tolerated statin therapy, or documentation of inability to tolerate statin therapy (with at least one hydrophilic statin having been tried and failed). If requested for treatment of ASCVD, patient has history of one of the following: MI, ACS, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, PAD or ASCVD risk score is equal to or greater than 7.5% and documentation that medication is being used as an adjunct to maximally tolerated statin therapy, or documentation of inability to tolerate statin therapy (with at least one hydrophilic statin having been tried and failed). Submission of LDL level obtained within the previous 6 months and providers stated LDL-C goal.
Age Restrictions	13 YO or older
Prescriber Restrictions	The authorization must be submitted by or under the documented recommendation of a cardiologist, lipidologist, or endocrinologist with experience and focus on lipid management
Coverage Duration	Six months initially, then one year thereafter

PA Criteria	Criteria Details
Other Criteria	Submission of LDL level documenting clinically significant response to therapy will be required for reauthorization.

# **PEGYLATED INTERFERONS/RIBAVIRIN**

#### **Products Affected**

- MODERIBA 1200 DOSE PACK
- MODERIBA 800 DOSE PACK
- MODERIBA ORAL TABLET 200 MG
- PEGASYS PROCLICK
- PEGASYS SUBCUTANEOUS SOLUTION
- PEGINTRON
- REBETOL ORAL SOLUTION

- RIBASPHERE
- RIBASPHERE RIBAPAK ORAL TABLET 400 MG, 600 MG
- RIBASPHERE RIBAPAK ORAL TABLET THERAPY PACK
- ribavirin oral capsule
- ribavirin oral tablet 200 mg

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	For pegylated interferon therapy-automimmune hepatitis, hepatic decompensation (Child-Pugh score greater than 6 [class B and C]) in cirrhotic CHC patients before or during treatment, for ribavirin therapywomen who are or may become pregnant or men whose female partners are pregnant, patients diagnosed with hemoglobinopathies (thalassemia majore, sickel-cell anemia), creatinine clearance less than 50ml/min
Required Medical Information	Diagnosis of Covered Use and submission of Lab values (HCV RNA level, ALT, AST, genotype), patient weight, for patients receiving combination therapy with ribavirin- submission of neagtive preganancy test result prior to therapy, documentation that at least two forms of contraception will be used during treatment and that patient will undergo monthly pregnancy tests, submission of current (obtained within the previous three months) serum creatinine level to calculate creatinine clearance
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	48 weeks
Other Criteria	Coverage duration may vary based on indication. PA applies to all.

# **POMALYST**

#### **Products Affected**

POMALYST

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Pregnancy
Required Medical Information	Diagnosis of covered use, submission of baseline laboratory values including serum creatinine, serum bilirubin, AST and ALT, CBC including ANC and platelet count
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to oncology or hematology
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **POTELIGEO** (mogamulizumab-kpkc)

#### **Products Affected**

POTELIGEO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Pregnancy
Required Medical Information	Diagnosis of covered use, confirmation of use of one prior systemic therapy for the covered use.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.

# **Prevymis (letermovir)**

#### **Products Affected**

• PREVYMIS ORAL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients on pimozide, ergot alkaloids, or those who will be taking a combination of letermovir, cyclosporine, AND simvastatin OR pitavastatin
Required Medical Information	Diagnosis of covered use.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to hematology/oncology/infectious disease
Coverage Duration	Up to 100 days per HSCT
Other Criteria	The provider must attest to what day post HSCT patient is and if the patient has received any previous doses of letermovir to allow for an appropriate duration of therapy.

# **Prior Auth to Override Specialty Restrictions**

#### **Products Affected**

- ACITRETIN
- ACTIMMUNE
- APOKYN SUBCUTANEOUS SOLUTION CARTRIDGE
- cladribine intravenous solution 10 mg/10ml
- CRINONE
- FABIOR
- ICLUSIG
- mitomycin intravenous

- NUEDEXTA
- SYLATRON SUBCUTANEOUS KIT 200 MCG, 300 MCG, 600 MCG
- tazarotene external
- TAZORAC
- VABOMERE
- VALCHLOR
- XYREM

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	Physicians who specialize in the treatment of medical conditions most commonly treated with this medication are exempt from prior authorization.PA applies to new starts only.

# **PROCYSBI**

#### **Products Affected**

PROCYSBI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Hypersensitivity to cysteamine, penicillamine, or any component of the formulation
Required Medical Information	Diagnosis of covered use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	one year
Other Criteria	PA applies to new starts only

# **Promacta**

#### **Products Affected**

• PROMACTA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, previous therapies tried (corticosteroids, immunoglobulins), lab values (including ALT, AST, bilirubin, CBC with differentials and platelet count)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	six months
Other Criteria	PA applies to all

# **PROMETHAZINE**

#### **Products Affected**

- phenadoz rectal suppository 12.5 mg
- PHENERGAN RECTAL
- promethazine hcl injection
- promethazine hcl oral syrup

- promethazine hcl oral tablet
- promethazine hcl rectal
- promethegan rectal suppository 25 mg, 50 mg

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Promethazine is a potent anticholinergic considered high risk in the elderly due to risks of confusion, dry mouth, constipation, and decreased clearance with advanced age. For all diagnoses of covered use justification must be submitted which explains the benefits of the drug and how that benefit outweighs the potential risks to the patient. In addition, the following diagnosis specific criteria are required for coverage. For diagnosis of allergic condition coverage will be provided for patients who have tried and failed or had an inadequate response to a second generation antihistamine such as cetirizine or loratadine. For diagnosis of nausea and vomiting, coverage will be provided for patients who have tried and failed or had an inadequate response to ondansetron or granisetron.
Age Restrictions	Applies to 65yo and older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	

# PROVIGIL/NUVIGIL

#### **Products Affected**

- armodafinil
- modafinil

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use and sleep latency test results may be required
Age Restrictions	17 YO or older
Prescriber Restrictions	
Coverage Duration	one year
Other Criteria	PA applies to all

# **Purified Proteinase Inhibitor**

#### **Products Affected**

- ARALAST NP INTRAVENOUS SOLUTION RECONSTITUTED 1000 MG, 500 MG
- GLASSIA
- PROLASTIN-C INTRAVENOUS SOLUTION

RECONSTITUTED 1000 MG

ZEMAIRA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Individuals with immunoglobulin A (IgA) deficiency who have known antibodies against IgA, patients who have previously demonstrated hypersensitivity, anaphylaxis or severe systemic response to alpha1-proteinase inhibitor products
Required Medical Information	Diagnosis of covered use, submission of patient body weight, confirmation that patient has clinically evident emphysema secondary to congenital alpha-PI deficiency by submission of pulmonary function testing (e.g. spirometry or body plethysmography), X-ray radiography or Diffusing capacity of the lung for carbon monoxide (DLCO).
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to pulmonology
Coverage Duration	One Year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician or health care provider is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office, infusion centeror homecare provider for administration, if the medication is being self-administered documentation is provided that the enrollee has been fully trained on how to prepare the injection and to administer the medication safely and effectively if applicable. If these conditions are not satisfied this medication may be covered under Part B.PA applies to new starts only.

# **RADICAVA** (edaravone)

#### **Products Affected**

• RADICAVA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Neurology
Coverage Duration	One year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: If a physician is administering the medication, he/she agrees to accept brown-bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office for administration, if the medication is being self-administered documentation is provided that the enrollee has been fully trained on how to prepare the injection and to administer the medication safely and effectively if applicable. If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable. Additionally, provider must attest that medication will be given under conditions where they may be monitored for hypersensitivity reactions.

# **RAGWITEK**

#### **Products Affected**

• RAGWITEK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Severe, unstable or uncontrolled asthma, history of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy, history of eosinophilic esophagitis, hypersensitivity to gelatin, mannitol, or sodium hydroxide
Required Medical Information	Ragwitek is being requested for the treatment of grass pollen induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen, therapy is being initiated at least 12 weeks before the expected onset of ragweed pollen season, confirmation that the first dose of medication will be administered in a healthcare setting under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases and that the patient will be observed for at least 30 minutes after administration of the first dose to monitor for signs and symptoms of a severe systemic or severe local allergic reaction.
Age Restrictions	Patients 18 through 65 years of age
Prescriber Restrictions	Limited to allergy and immunology
Coverage Duration	one year
Other Criteria	Confirmation auto-injectable epinephrine therapy has been prescribed and patient has been instructed on the proper use of emergency self-injection epinephrine. PA applies to all.

### **RASUVO**

#### **Products Affected**

 RASUVO SUBCUTANEOUS SOLUTION AUTO-INJECTOR 10 MG/0.2ML, 12.5 MG/0.25ML, 15 MG/0.3ML, 17.5 MG/0.35ML, 20 MG/0.4ML, 22.5 MG/0.45ML, 25 MG/0.5ML, 30 MG/0.6ML, 7.5 MG/0.15ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Contraindicated in pregnancy, nursing mothers, alcoholism or liver disease, immunodeficiency syndromes, preexisting blood dyscrasias, hypersensitivity to methotrexate, treatment of neoplastic conditions
Required Medical Information	Diagnosis of covered use, documentation of intolerance or inadequate response to first-line therapy, submission of complete blood count (CBC)with differential and platelet count, submission of baseline hepatic enzymes, renal function tests and a chest X-ray, submission of current height and weight for pediatric patients for the purposes of dosage verification
Age Restrictions	
Prescriber Restrictions	limited to rheumatology or dermatology
Coverage Duration	One Year
Other Criteria	PA applies to all

# **RAVICTI**

#### **Products Affected**

• RAVICTI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	patients with a known hypersensitivity to phenylbutyrate
Required Medical Information	Diagnosis of covered use, submission of patient's height and current weight for dose verification purposes, submission of baseline fasting plasma ammonia level
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	remainder of the contract year
Other Criteria	PA applies to all

# Remodulin

#### **Products Affected**

• REMODULIN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of patient weight
Age Restrictions	
Prescriber Restrictions	Limited to pulmonology or cardiology
Coverage Duration	One Year
Other Criteria	

# **REVATIO**

#### **Products Affected**

- REVATIO ORAL SUSPENSION RECONSTITUTED
- sildenafil citrate intravenous
- sildenafil citrate oral tablet 20 mg

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	Limited to Pulmonologists/Cardiologists
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **REVLIMID**

#### **Products Affected**

• REVLIMID

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use, pregnancy negative, Lab values (CBC)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **RITUXAN**

#### **Products Affected**

• RITUXAN INTRAVENOUS SOLUTION

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically-accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, confirmation that patient does not have a severe, active infection and for the treatment of rheumatoid arthritisthe patient is diagnosed with moderately-to severely active RA, the number of swollen and tender joints is submitted, the patient has tried and failed to achieve an adequate response to at least one prior TNF antagonist therapy, submission of confirmation that patient will receive concurrent methotrexate therapy and submission of one of the following: CRP, sed rate or rheumatoid factor, for the treatment of Wegener's Granulomatosis (GPA)- medication is requested to be used in combination with glucocorticoid therapy, for the treatment of GPA, NHL and CLL submission of patient's height and current weight, for the treatment of NHL and CLL- baseline CBC including platelet count is submitted, for the treatment of CLL medication is requested to be used in combination with fludarabine and cyclophosphamide (FC)
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	For RA-6 months all other diagnoses-1 year

PA Criteria	Criteria Details
Other Criteria	Approval for the treatment of RA will be two 1000mg IV infusions separated by 2 weeks (days 1 and 15), incombination with methotrexate.Retreatment for RA may be considered after 16 weeks provided patient has demonstrated a positive clinical response based on the required baseline objective clinical measures. If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration, if the medication is being administered in the enrollee's home, there are no associated safety concerns with preparation and/or administration of the medication documented in the prescribing information and documentation is provided that the member has been fully trained on how to administer the medication safely and effectively if applicable. If these conditions are not satisfied the medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable. PA applies to new starts only.

# Rituximab-hyaluronidase (RITUXAN Hycela)

### **Products Affected**

• RITUXAN HYCELA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients unable to tolerate intravenous rituxamab products
Required Medical Information	Diagnosis of covered use, documentation that patient has received one full dose of rituximab, baseline HBsAg and anti-HBc and documentation that patient will be monitored for signs of Hepatitis B infection if clinically warranted. Documentation that the patient will be monitored for signs of neurological changes, indicative of PML, AND severe mucocutaneous reactions with consideration of stopping therapy if these complications arise.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology or Oncology
Coverage Duration	Six months
Other Criteria	Rituxan Hycela is not approved for the treatment of non-malignant conditions, such as rheumatoid arthritis and the severe forms of vasculitis (e.g. Wegener's Granulomatosis and Microscopic Polyangiitis).

# **RUBRACA** (rucaparib)

### **Products Affected**

RUBRACA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, documentation of deleterious BRCA mutation as detected by FDA approved companion diagnostic test, documentation that the patient has been treated with two or more chemotherapies, confirmation that female patients of reproductive potential have been advised to use effective contraception during treatment and for 6 months after the last dose of Rubraca, confirmation patients will be monitored for hematologic toxicity at baseline and monthly thereafter while on therapy
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA Applies to New Starts Only

## **RUCONEST**

### **Products Affected**

RUCONEST

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Known or suspected allergy to rabbits and rabbit-derived products, history of immediate hypersensitivity to C1 esterase inhibitors
Required Medical Information	Diagnosis of covered use, submission of patient's current weight, confirmation treatment will be initiated under the supervision of a qualified healthcare professional experienced in the treatment of hereditary angioedema
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Plan Year
Other Criteria	Member has been instructed on proper administration technique if self-administering. PA applies to new starts only.

# Safinamide (Xadago)

### **Products Affected**

XADAGO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Patients on other MAOI's or linezolid, opioid drugs (e.g., tramadol, meperidine, and related derivatives), selective norepinephrine reuptake inhibitors, tri-or tetra-cyclic or triazolopyridine antidepressants, cyclobenzaprine, methylphenidate, amphetamine, and their derivatives, St. John's wort and patients with severe hepatic impairment (Child-Pugh Score C or higher)
Required Medical Information	Diagnosis of covered use. Prescription history positive for or documentation that medication will be given concurrently with levodopa/carbidopa. Documentation of following baseline clinical data and that these will continue to be monitored throughout therapy: blood pressure, history of dyskinesia, and liver function tests
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	For continuation of therapy, a positive clinical response (or maintenance) to therapy must be demonstrated along with no clinically significant documented changes in the baseline measures.

## **SAMSCA**

### **Products Affected**

• SAMSCA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use and Lab Values (Serum sodium)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	30 days
Other Criteria	PA applies to all

## **Sedating antihistamines**

#### **Products Affected**

- carbinoxamine maleate oral solution
- carbinoxamine maleate oral tablet 4 mg
- clemastine fumarate oral tablet 2.68 mg
- cyproheptadine hcl oral

• diphenhydramine hcl oral elixir

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	1)Must have a current diagnosis requiring the use of a sedating antihistamine such as allergic conjunctivitis, rhinitis, puritis, rhinorrhea, angioedema, urticaria, or a severe allergic reaction AND2)Patient must have tried and failed or had an inadequate response to a second generation antihistamine such as cetirizine or loratadine and 3)Documentation is submitted confirming that the provider is aware the medication is considered a high risk medication for elderly patients according to the Centers for Medicare and Medicaid services and5)justification is submitted which explains the benefits of the identified drug and how that benefit outweighs the potential risks to the patient.
Age Restrictions	PA applies to patients 65 YO or older. PA does not apply to patients 64 YO or younger
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to all

# **Self Injectable Drug Policy**

#### **Products Affected**

• leuprolide acetate injection

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **SEROSTIM**

### **Products Affected**

• SEROSTIM SUBCUTANEOUS SOLUTION RECONSTITUTED 4 MG, 5 MG, 6 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of Covered Use, patient height and weight
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **SIGNIFOR**

### **Products Affected**

• SIGNIFOR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of the following lab values- fasting plasma glucose, hemoglobin A1c, ALT, aspartate aminotransferase, alkaline phosphatase, total bilirubin, TSH, free T4, GH/IGF-1, 24-hour urinary free cortisol, submission of ECG results, submission of gallbladder ultrasound results
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	one year
Other Criteria	PA applies to all

## SIMVASTATIN HIGH DOSE

#### **Products Affected**

- ezetimibe-simvastatin oral tablet 10-80 mg
- simvastatin oral tablet 80 mg

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Any new start to therapy: not recommended as initial therapy nor for patients already taking lower doses of simvastatin whose response is not adequate, coadministration with strong cytochrome P450 (CYP-450) 3A4 inhibitors (eg, itraconazole, ketoconazole, posaconazole, voriconazole, HIV protease inhibitors, boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin, nefazodone, cobicistat-containing products), gemfibrozil, cyclosporine, or danazol, patients with active liver disease, nursing mothers, women who are pregnant or may become pregnant
Required Medical Information	Diagnosis of covered use, submission of documentation that patient has been taking simvastatin for 12 months or longer without ill effect, submssion of current (obtained within the previous 12 months) lipid panel including HDL, LDL and triglyceride levels, submission of current (obtained within the previous 12 months) liver function tests including ALT, AST and total bilirubin, submission of current (obtained within the previous three months) serum creatinine level and patient weight, for women of childbearing age submission of negative pregnancy test result and documenation that patient has been counseled about the potential hazards of therapy if pregnancy occurs,
Age Restrictions	10 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **SIRTURO**

### **Products Affected**

• SIRTURO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded by Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, confirmation that patient will receive at least 3 other drugs in combination with Sirturo to which the patient's infection has been shown to be susceptible, submission of baseline ECG and confirmation that ECG will be obtained at 2, 12 and 24 weeks after starting therapy, submission of baseline serum potassium, calcium and magnesium levels, submission of baseline ALT, AST, alkaline phosphatase and bilirubin and confirmation these lab values will be obtained monthly while on treatment
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to infectious disease specialist
Coverage Duration	24 weeks
Other Criteria	PA applies to all

## **SIVEXTRO**

### **Products Affected**

SIVEXTRO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of culture proven infection caused by susceptible isolates of one of the following Gram-positive micoorganisms: Staphyloccocus aureus (including methiciliin-resistant MRSA) and methicillin-susceptible (MSSA) isolates, Stretococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus Group(including Streptococcus anginosus, intermedius and constellatus), and Enterococcus faecalis, submission of baseline neutrophil count documenting at least 1000 cells/mm3.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to infectious disease specialist
Coverage Duration	6 days of therapy
Other Criteria	If this medication is being administered in the enrollee's home via an infusion pump it is covered as a Part B benefit. If it being administered in the enrollee's home via IV drip it is covered as a Part D benefit. PA applies to all

## **Skeletal Muscle Relaxants**

#### **Products Affected**

- carisoprodol oral
- chlorzoxazone oral tablet 500 mg
- cyclobenzaprine hcl oral
- metaxall

- metaxalone
- methocarbamol oral
- orphenadrine citrate er

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	For diagnosis of fibromyalgia, coverage will be provided for cyclobenzaprine for patients who have tried and failed to tolerate or had an inadequate response to at least two of the following: gabapentin, fluoxetine, pregabalin, or milnacipran. For treatment of acute, painful musculoskeletal conditions, coverage will be provided when the prescriber attests to understanding the risks of skeletal muscle relaxants in the elderly, which include increased risk of fall and fracture due to sedation and anticholinergic effects. Additionally, the prescriber must attest to how the benefits outweigh the risks for the specific patient.
Age Restrictions	PA applies to patients 65 YO or older. PA does not apply to patients 64 YO or younger
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to all.

# **SOLARAZE** diclofenac gel

#### **Products Affected**

• diclofenac sodium transdermal gel

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use which includes the topical treatment of actinic keratoses (AK), confirmation that patient has been instructed to avoid sun exposure during treatment.
Age Restrictions	18yo or older
Prescriber Restrictions	limited to dermatology
Coverage Duration	90 Days
Other Criteria	PA applies to all

## **SOMAVERT**

### **Products Affected**

SOMAVERT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use, submission of the following baseline laboratory values: IGF-1, ALT, AST, ALP and serum total bilirubin
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Endocrinologist
Coverage Duration	one year
Other Criteria	Contuinuation of therapy requests require submission of updated IGF-1, ALT, AST, ALP and serum total bilirubin levels.PA applies to all.

## **SOVALDI**

### **Products Affected**

SOVALDI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use and laboratory confirmation of hepatitis C virus (HCV) as indicated consistent with current AASLD-IDSA guidance
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	24 weeks based on genotype or 48 weeks for hepatocellular carcinoma pts awaiting transplant
Other Criteria	PA applies to all

## **SPRYCEL**

### **Products Affected**

SPRYCEL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of Covered Use, documentation of prior therapy (except for the treatment of adults with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase) for Philadelphia chromosome-positive acute lymphoblastic leukemia and chronic, accelerated, or myeloid or lymphoid blast phase Philadelphia chromosome-positive chronic myeloid leukemia, CBC including platelet count and ANC.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Oncologists/Hematologists.
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **STIVARGA**

### **Products Affected**

• STIVARGA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of the following laboratory tests: ALT, AST, serum bilirubin, submission of baseline blood pressure reading
Age Restrictions	18 YO or older
Prescriber Restrictions	limited to oncologists/hematologists
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **STRENSIQ**

### **Products Affected**

STRENSIQ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of perinatal, infantile, or juvenile onset hypophosphatasia (HPP), submission of body weight for the purposes of dosage calculation, documentation that patient has been trained on proper injection technique, submission of baseline opthalmology examination and renal ultrasound and confirmation these will be moniotred periodically during treatment.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA Applies to All

## **SUCRAID**

### **Products Affected**

• SUCRAID

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## Sutent

### **Products Affected**

• SUTENT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **SYMDEKO** (tezacaftor/ivacaftor)

### **Products Affected**

• SYMDEKO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use. Documentation that the patient is homozygous for the F508del mutation or has at least one mutation in the CTFR gene responsive to the drug (see section 12.1, table 4 of package insert for full list) provided from an FDA-cleared CF mutation test. Submission of baseline AST, ALT, and bilirubin. Submission of documentation that baseline and follow-up ophthalmologic exams will be performed in pediatric patients starting on therapy.
Age Restrictions	12 years of age or older
Prescriber Restrictions	Restricted to pulmonology
Coverage Duration	1 year
Other Criteria	PA applies to all.

### **SYMLIN**

#### **Products Affected**

- SYMLINPEN 120 SUBCUTANEOUS SOLUTION PEN-INJECTOR
- SYMLINPEN 60 SUBCUTANEOUS SOLUTION PEN-INJECTOR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use, HbA1C, previous or current use of an insulin
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	Endocrinologists are exempt from PA. PA applies to all except when prescribed by endocrinology.

# Symproic (naldemedine)

### **Products Affected**

• SYMPROIC

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Known or suspected gastrointestinal obstruction or increase risk of obstruction
Required Medical Information	Diagnosis of Covered use and confirmation that patient has been on at least 30mg Morphine daily dose (or equivalent) for at least four weeks prior to initiation and the provider must attest that if the opioid medication is stopped for any reason they will discontinue the naldemedine.
Age Restrictions	18 yo or older
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	

## **SYNAGIS**

### **Products Affected**

• SYNAGIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of patient's current weight. For the treatment of BPD- patient is 24 months of age or less at the start of Synagis season, patient required ventilatory support or supplemental oxygen beyond 36 weeks gestational age, within the six months preceding Synagis administration infant had one or more of the following clinical needs-Daily use of inhaled or oral bronchodilators, Recent use of oral or inhaled corticosteroid therapy or Regular or intermittent use of diuretics to treat pulmonary disease. For the treatment of CHD-patient is 24 months of age or less at the start of Synagis season, patient is receiving medication to control congestive heart failure or patient has moderate to severe pulmonary hypertension or patient has cyanotic heart disease. For patients with a history of premature birth-submission of patient's gestational age at birth. For patients 28 weeks gestational age at birth or less patient is 12 months of chronological age or less at the start of Synagis season, for patients 29 ? 32 weeks gestation age at birth patient is less than 6 months of chronological age at the start of Synagis season, for patients 32 weeks, 0 days through 34 weeks, 6 days gestation age at birth, patient was born less than three months prior to the start of Synagis season or is born during the RSV season and one of the following two risk factors is present: Currently attends day care or has a sibling younger than 5 years of age.
Age Restrictions	patients up to 24 months of age
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	One complete season (as defined by respective community)
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: A physician/health care provider is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration. This medication may be covered under Part B if administered by a physician incident to a physician service. Synagis may be authorized for a maxiumum of five doses (one complete season) from November 1st-March 31st depending on patient diagnosis, history of prematurity and when during the RSV season treatment is begun.PA applies to all.

## **SYNAREL**

### **Products Affected**

• SYNAREL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **SYPRINE**

### **Products Affected**

trientine hcl

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use and intolerant to penicillamine
Age Restrictions	6 YO and older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to all

## **TAFINLAR**

### **Products Affected**

• TAFINLAR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, submission of FDA- approved test confirming presence of BRAF V600E or V600K mutation, documentation is submitted stating female patient of reproductive potential has been advised to use a highly effective non-hormonal method of contraception during treatment and for 2 weeks following discontinuation of treatment with dabrafenib or for 4 months following combination treatment with dabrafenib and trametinib.
Age Restrictions	18 YO or older
Prescriber Restrictions	limited to oncology and hematology
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **TAGRISSO**

### **Products Affected**

• TAGRISSO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, confirmation of the presence of T790M mutation postive non-small cell lung cancer (NSCLC), documentation that the patient has progressed on or after EGFR TKI therapy, LVEF assessment by echocardiogram or MUGA scan before the inititation of therapy and confirmation this will be assessed at 3 month intervals while on treatment, confirmation that patients who have a history of or predisposition for QTc prolongation or those taking medications known to prolong the QTc interval will have periodic electrocardiogram and serum electrolyte monitoring, documentation that patients of reproductive potential have been advised to use highly effective contraception during Tagrisso therapy and for 6 weeks after the final dose for females, or for 4 months after the final dose for males
Age Restrictions	18 years of age or older
Prescriber Restrictions	Limited to Hematology and Oncology
Coverage Duration	3 months initially, then annually thereafter
Other Criteria	Continuation of approval requires submission of clinical benefit and absence of unacceptable toxicities and confirmation that required laboratory monitoring and cardiac imaging studies will be performed as clinically indicated. PA Applies to New Starts Only.

# **TAKHZYRO** (lanadelumab-flyo)

#### **Products Affected**

TAKHZYRO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use.
Age Restrictions	12 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.

# **TAVALISSE** (fostamatinib)

### **Products Affected**

TAVALISSE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of platelet count, documentation patient had an insufficient response to prior treatment (including at least one of the following: corticosteroids, immunoglobulins, splenectomy, and/or a thrombopoietin receptor agonist).
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology
Coverage Duration	Initially 12 weeks, then 1 year
Other Criteria	PA applies to all. Continuation of therapy requires submission of documentation of platelet count.

## **TECENTRIQ**

### **Products Affected**

TECENTRIQ

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered medical use, submission of baseline LFTs (including AST, ALT, and total bilirubin)and submission of baseline thyroid function tests and confirmation these lab values will be monitored periodically while on therapy, confirmation patient will be monitored for signs and symptoms of pneumonitis, hepatitis, diarrhea or colitis, endocrinopathies, hypophysitis ,meningitis or encephalitis, motor and sensory neuropathy, acute pancreatitis and infection, documentation that patient has had disease progression during or following platinum-containing chemotherapy, or has had disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing therapy
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology/Oncology Prescribers
Coverage Duration	One Year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: The provider administering the medication agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration. If these conditions are not satisfied this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable or this clinical criteria. PA applies to new starts only.

# **Telavancin (Vibativ)**

#### **Products Affected**

• VIBATIV INTRAVENOUS SOLUTION RECONSTITUTED 750 MG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients on Unfractionated Heparin Sodium
Required Medical Information	Diagnosis of use. Documentation of a culture and sensitivity showing that the suspected causative agent is susceptible to this agent.  Documentation of Creatinine Clearance must be obtained (or patient weight and serum creatinine level) and IF less than 50 ml/min the provider must attest that he is aware of the risks of use of this medication and that they feel that the anticipated benefit to the patient outweighs the potential risk.
Age Restrictions	18 YO or older
Prescriber Restrictions	Restricted to infection disease specialists
Coverage Duration	Up to 21 days depending on infection
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or clinic for administration, if the medication is being self-administered documentation is provided that the enrollee has been fully trained on how to prepare the injection and to administer the medication safely and effectively if applicable. If these conditions are not satisfied this medication may be covered under Part B.

## **Testosterone Replacement**

#### **Products Affected**

- ANDRODERM TRANSDERMAL PATCH 24 HOUR
- ANDROGEL PUMP TRANSDERMAL GEL 20.25 MG/ACT (1.62%)
- ANDROGEL TRANSDERMAL GEL 20.25 MG/1.25GM (1.62%), 40.5 MG/2.5GM (1.62%)
- FORTESTA
- NATESTO
- STRIANT

- TESTIM
- TESTOSTERONE TRANSDERMAL GEL 10 MG/ACT (2%)
- testosterone transdermal gel 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)
- testosterone transdermal solution
- VOGELXO TRANSDERMAL GEL 50 MG/5GM (1%)

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use, serum testosterone level, documentation that patient has been evaluated for the presence of prostate cancer prior to initiation of therapy
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to all

# **TIBSOVO (ivosidenib)**

### **Products Affected**

• TIBSOVO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of FDA-approved test confirming presence of IDH1 mutation.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Restricted to hematology and oncology
Coverage Duration	1 year
Other Criteria	PA applies to new starts only.

# TIGAN/ trimethobenzamide

### **Products Affected**

• trimethobenzamide hcl oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	1)Patient has a current diagnosis of nausea and vomiting and 2)Patient must have tried and failed, or had an inadequate response to at least one other antiemetic medication such as Zofran or 3)Patient must have documentation of risk factors precluding them from therapy with alternative antiemetic therapy and 4)Documentation is available recording the provider is aware medication is considered a high risk medication for elderly patients according to the Centers for Medicare and Medicaid services and 5)Documentation is available explaining the benefits of the identified drug and how that benefit outweighs the potential risks to the patient.
Age Restrictions	PA applies to age 65yo and older. PA is not required for under age 65yo.
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	PA applies to all

## **TOBI PODHALER**

### **Products Affected**

TOBI PODHALER

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	28 days
Other Criteria	PA applies to new starts only

## **TRACLEER**

### **Products Affected**

• TRACLEER

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Pregnancy
Required Medical Information	Diagnosis of Covered Use and Liver function tests
Age Restrictions	
Prescriber Restrictions	Limited to Pulmonologists or Cardiologists
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **Tricyclic Antidepressants**

#### **Products Affected**

- amitriptyline hcl oral
- chlordiazepoxide-amitriptyline
- clomipramine hcl oral
- doxepin hcl oral

- imipramine hcl oral
- IMIPRAMINE PAMOATE
- perphenazine-amitriptyline
- trimipramine maleate oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	The requested drug must be used to treat a medically accepted disease or condition including depression, headache treatment and prophylaxis ,neurpathic pain or other compendial use not otherwise excluded from Part D and patient must have tried and failed to tolerate or had an inadequate response to two preferred alternative therapies for labeled or off labeled indications including- For depression (applies to amitriptyline, imipramine, doxepin, and trimipramine): paroxetine, sertraline, venlafaxine, duloxetine, citalopram, escitalopram, fluoxetine, and trazodone, for headache treatment and prophylaxis (applies to amitriptyline): propranolol, timolol, topiramate, valproic acid and divalproex, for anxiety (applies to doxepin): paroxetine, venlafaxine, duloxetine, and buspirone, for postherpetic neuralgia (applies to amitriptyline) or other neuropathic pain: gabapentin and pregabalin, for obsessive-compulsive disorder (applies to clomipramine): paroxetine, sertraline, fluoxetine, and fluvoxamine, for Irritable bowel syndrome (applies to amitriptyline, trimipramine and doxepin): laxatives or loperamide and Documentation is submitted confirming that the prescriber is aware the medication is considered a high risk medication for elderly patients according to the Centers for Medicare and Medicaid services and justification is submitted by the prescriber which explains what the benefit is and how the benefit outweighs the potential risks for the specific patient.
Age Restrictions	PA applies to patients 65 YO or older
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	One Year
Other Criteria	PA applies to new starts only.

## **TYKERB**

### **Products Affected**

TYKERB

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Documentation that Tykerb is being requested for the treatment of human epidermal growth factor receptor type 2 (HER2) overexpressing advanced or metastatic breast cancer in combination with capecitabine in patients who have received prior therapy including an anthracycline, a taxane, and trastuzumab or for the treatment of HER2 overexpressing hormone receptor?positive metastatic breast cancer in combination with letrozole in postmenopausal women where hormone therapy is indicted, submission of baseline ECG and LVEF and confirmation that evaluations of LVEF will continue during treatment, submission of baseline ALT ,AST and total bilirubin and confirmation liver functions tests will be monitored as clinically indicated during treatment, submission of baseline serum potassium and magnesium levels
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Oncologists/Hematologists
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## Tysabri

### **Products Affected**

TYSABRI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	Patients who have or have had PML, patients who have had a hypersensitivity reaction to Tysabri, requests for doses greater than 300mg every four weeks
Required Medical Information	Diagnosis of covered use, documentation of previous therapies tried for MS or Crohn's diease and patient's response to these therapies, documentation that the patient is not receiving concurrent antineoplastic, immunosuppressant, or immunomodulating agents, for the treatment of Crohn's disease- submission of CDAI score, confirmation that the medication is being prescribed, dispensed and administered in accordance with the TOUCH prescribing program to patients enrolled in and who meet all the requirements of the TOUCH precribing program, documentation that the healthcare setting and providers are prepared to manage infusion related reactions including life-threatening anaphylaxis
Age Restrictions	18YO or older
Prescriber Restrictions	Limited to neurology or gastroenterology
Coverage Duration	For MS-One Year, for CD 12 weeks initially then if positive patient response-One Year

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:A a physician is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or infusion center for administration If these conditions are not satisfied this medication may be covered under Part B.PA applies to all.

## **Uptravi**

### **Products Affected**

UPTRAVI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use (pulmonary arterial hypertension (PAH, WHO Group I)
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Pulmonologists and Cardiologists
Coverage Duration	One Year
Other Criteria	PA Applies to All.

## **VANDETANIB**

### **Products Affected**

CAPRELSA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Patients with congenital long QT syndrome
Required Medical Information	Diagnosis of covered use and lab values including: serum potassium, calcium, magnesium, bilirubin, and TSH, creatinine clearance, baseline ECG
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **VECAMYL**

### **Products Affected**

VECAMYL

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	patients with mild, moderate, labile hypertension, patients with coronary insufficiency or history of recent myocardial infarction (MI), patients diagnsoed with uremia, glaucoma or organic pyloric stenosis, patients receiving antibiotic and sulfonamide therapy
Required Medical Information	Diagnosis of covered use, submission of patient weight, submission of serum creatinine and BUN values, submission of documentation confirming patient does not have any of the following- coronary insufficiency, history of recent MI, uremia, glaucoma, organic pyloric stenoisis
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	PA applies to all

## **VEMLIDY (TENOFOVIR ALAFENAMIDE)**

#### **Products Affected**

VEMLIDY

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, confirmation patients will be tested for HIV infection prior to initiation of Vemlidy and that therapy will not be used in patients with HIV infection, confirmation baseline serum creatinine, serum phosphorous, estimated creatinine clearance, urine glucose, and urine protein will be assessed before initiation of therapy and during therapy as clinically appropriate
Age Restrictions	18 YO or older
Prescriber Restrictions	Prior Authorization is not required for Gastroenterology or Infectious Disease Specialists
Coverage Duration	One Year
Other Criteria	PA Applies to All.Vemlidy is not recommended in patients with estimated creatinine clearance below 15 mL per minute. Vemlidy is not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment

## **Venclexta**

### **Products Affected**

- VENCLEXTA
- VENCLEXTA STARTING PACK

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Concomitant use with strong CYP3A inhibitors during initiation and rampup period
Required Medical Information	Diagnosis of covered medical use, documentation of 17p deletion, as detected by an FDA approved test who have received one prior therapy, documentation that tumor burden assessments will be performed prior to initiation and if necessary TLS prophylaxis may be administered based on results, submission of baseline CBC
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to Hematology and Oncology
Coverage Duration	One Year
Other Criteria	

## **Ventavis**

### **Products Affected**

VENTAVIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of baseline blood pressure reading, documentation that Ventavis will be inhaled using either the Ineb AAD system or the Prodose AAD system
Age Restrictions	18 YO or older
Prescriber Restrictions	limited to cardiology or pulmonology
Coverage Duration	One Year
Other Criteria	This medication is covered as a Part B benefit except for enrollees residing in a long-term care facility. PA applies to new starts only when covered as a Part D benefit.

# Verzenio (abemaciclib)

#### **Products Affected**

VERZENIO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use. Documentation that baseline WBC and LFT has been obtained and will be monitored routinely throughout therapy. Additionally, if being given to a female of reproductive potential, documentation of a negative pregnancy prior to initiation and that the patient has been counseled to use effective contraception during treatment and for at least three weeks after the last dose.
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to hematology/oncology
Coverage Duration	One year
Other Criteria	

## **VFEND**

### **Products Affected**

- voriconazole intravenous
- voriconazole oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use, patient weight
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 Months
Other Criteria	Infectious Disease Specialists are exempt from prior authorization. For intravenous preparation a B vs D determination must be made based on whether it is being administered via an infusion pump (B benefit) or not (part D benefit). PA applies to all.

## **VIBERZI**

### **Products Affected**

VIBERZI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction, alcoholism, alcohol abuse, alcohol addiction, or patients who drink more than 3 alcoholic beverages/day, history of pancreatitits, structural diseases of pancrease, including known or suspected pancreated duct obstruction, severe hepatic impairment (Child-Pugh Class C), severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction
Required Medical Information	Diagnosis of covered use, documentation of hsitory of cholecystectomy for the purposes of dose verification
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA Applies to All

## **VOLTAREN GEL**

### **Products Affected**

• diclofenac sodium transdermal gel

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Known hypersensitivity to diclofenac, aspirin, or other NSAIDs. History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery.
Required Medical Information	Diagnosis of covered use which includes the relief of pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands.
Age Restrictions	18yo and older
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	Voltaren® Gel was not evaluated for use on joints of the spine, hip, or shoulder and therefore is not authorized. PA applies to all.

# **VOSEVI** (sofosbuvir)

### **Products Affected**

VOSEVI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients on rifampin
Required Medical Information	Diagnosis of covered use and laboratory confirmation of hepatitis C virus (HCV) as indicated consistent with current AASLD-IDSA guidance
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	12 weeks
Other Criteria	

## **VOTRIENT**

### **Products Affected**

VOTRIENT

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **VPRIV**

### **Products Affected**

VPRIV

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered medical use, submission of patient's current weight, and documentation that administration personnel has been adequately training in cardiopulmonary resuscitative measures, and have ready access to emergency medical services due to risk of anaphylaxis reactions upon administration.
Age Restrictions	4 years of age and older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: The provider administering the medication agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or onfusion center for administration, if the medication is being administered in the enrollee's home confirmation that the home care service provider is adequately trained on how to prepare and administer the medication and is prepared to recognize and manage hypersensitivity reactions, including anaphylaxis. If these conditions are notsatified this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable or this clinical criteria.PA applies to all.

## **VRAYLAR**

### **Products Affected**

VRAYLAR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Known hypersensitivty to Vraylar
Required Medical Information	Diagnosis of schizophrenia, or the treatment of manic or mixed episodes associated with bipolar I disorder, confirmation that patient's weight, fasting plasma glucose levels and lipid panel will be assessed at the initiaiton of therapy and periodically during long-term treatment, confirmation that patient heart rate and blood pressure will be monitored due to the potential for orthostatic hypotension
Age Restrictions	18 YO and older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	

## **XALKORI**

### **Products Affected**

XALKORI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, Lab values including ALT, AST, total bilirubin, CBC
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA for new starts only

## **XENAZINE**

### **Products Affected**

- AUSTEDO
- tetrabenazine

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **XERMELO** (telotristat)

### **Products Affected**

• XERMELO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use and documentation that patient has previously been on at least 12 weeks of prior somatostatin analog therapy and that baseline GGT has been drawn and will be monitored throughout therapy.
Age Restrictions	18YO and older
Prescriber Restrictions	
Coverage Duration	12 weeks
Other Criteria	Continuation of therapy requires that symptoms have stabilized or improved and that the patient has not experienced episodes of severe constipation.

## **Xolair**

### **Products Affected**

XOLAIR

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	self-administration by the patient, based on the dosing table in the prescribing information patients who serum IgE level and body weight place them in the do not dose category
Required Medical Information	Diagnosis of covered use, confirmation patient will receive treatment in a doctor's office or clinic and be observed for an appropriate amount of time after each treatment, documentation that the healthcare setting and providers are prepared to manage life-threatening anaphylaxis and for the treatment of asthma- submission of patient current body weight and pre-treatment serum IgE level, submission of pulmonary function test results including FEV1, submission of positive skin test result or demonstrated in-vitro reactivity (RAST test) to a perennial aeroallergen, submission of documentation that patients symptoms are poorly controlled with inhaled corticosteroids, requency of inhaled short-acting beta2-agonist therapy, submission of frequency of daily and nighttime symptoms and exacerbations, effect of exacerbations on activity. For the treatment of chronic idiopathic urticaria-submission of documentation that the patient continues to experience severe itching and hives despite the use of an H1 antihistamine at an approved dose.
Age Restrictions	6 YO or older
Prescriber Restrictions	Limited to allergy, pulmonology, dermatology or immunology
Coverage Duration	one year

PA Criteria	Criteria Details
Other Criteria	Continuation of therapy requests require objective documenation from the prescriber that the patient's symptoms have improved. If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied: A a physician is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office or clinic for administration If these conditions are not satisfied this medication may be covered under Part B.PA applies to all

## **XTANDI**

### **Products Affected**

XTANDI

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	diagnosis of covered use
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to oncologists/hematologists
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **XURIDEN**

### **Products Affected**

• XURIDEN

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of hereditary orotic aciduria, submission of current weight, submission of baseline CBC including neutrophil count and mean corpuscular volume, submission of baseline urine orotic acid level
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	Continuation of approval requires submission of updated weight, CBC including neutrophil count and mean corpuscular volume and urine orotic acid level

## **Yondelis**

### **Products Affected**

YONDELIS

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
<b>Exclusion Criteria</b>	Patients with a known hypersensitivity to trabectedin
Required Medical Information	Diagnosis of covered use, confirmation patient has had a prior anthracycline containing chemotherapy regimen, confirmation patient will receive premedication with dexamethasone prior to each Yondelis dose, submission of patient height and current weight (weight obtained within the previous month to calculate BSA for dose verification), confirmation that patient's with moderate hepatic impairment(defined as bilirubin levels 1.5 to 3 times the UNL, and AST and ALT less than 8 times the ULN)dosage will be adjusted according to the PI receommendations, that patient's with severe hepatic impairment (defined as bilirubin levels above 3-10 times the ULN, and any AST and ALT) will not receive Yondelis, confirmation the following baseline laboratory values have been obtained neutrophil count, CPK levels, AST, ALT, bilirubin levels, LVEF assessment by either MUGA scan or ECG and will be monitored while patient is on therapy and treatment interrupted, dosage reduced or drug discontinued based on the severity of the abnormality per the recommendations in the PI, confirmation female patients of reproductive potential have been advised to use effective contraception during and for 2 months after the last Yondelis dose and male patients with a female sexual partner of reproductive potential have been advised to use effective contraception during and for 5 months after the last Yondelis dose.
Age Restrictions	18 years of age and older
Prescriber Restrictions	Limited to oncology and hematology providers only

PA Criteria	Criteria Details
Coverage Duration	Indefinite
Other Criteria	If the medication is being obtained at a retail pharmacy or furnished directly to the patient, it may be covered under Part D provided the following conditions are satisfied:A healthcare professional is administering the medication and he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office, infusion center or home care provider for administration. If these conditions are not satisfied this medication may be covered under Part B. PA applies to new starts only.

## **ZAVESCA**

### **Products Affected**

- miglustat
- ZAVESCA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use and documentation that other treatment options have failed including one of the following Imiglucerase or Velaglucerase Alfa.
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

# **ZEJULA** (niraparnib)

#### **Products Affected**

• ZEJULA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. It is indicated for maintenance treatment of women who have responded at least partially to platinum-based chemotherapy for recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer.
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	

## **ZELBORAF**

### **Products Affected**

ZELBORAF

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, lab values including ECG, serum potassium, magnesium and calcium levels, ALT and bilirubin, dermatological exam
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **ZERBAXA**

### **Products Affected**

• ZERBAXA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D. All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	Known serious hypersensitivity to ceftolozane/tazobactam, piperacillin/tazobactam, or other members of the beta-lactam class
Required Medical Information	Diagnosis of Covered Use, submission of patient current weight and serum creatinine level for the purposes of calculating creatinine clearance and dosage verification, confirmation patient will receive concurrent metronidazole therapy when used for the treatment of complicated intra-abdominal infections
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	Maximum of 14 days based on severity and site of infection

PA Criteria	Criteria Details
Other Criteria	If the medication is being obtained at a retail pharmacy, it may be covered under Part D provided the following conditions are satisfied:If a physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the enrollee will obtain the medication from a pharmacy and have it in their possession until the enrollee delivers the medication to the physician office for administration. If these conditions are not satisfied or this medication is being administered in the patient's home via an external infusion pump this medication may be covered under Part B in accordance with the corresponding NCD/LCD if applicable. If this medication is being administred in the patients' home via IV drip it is covered as a Part D benefit. 14 days of therapy may be authorized for the treatment of complicated intra-abdominal infectins. 7 days of therapy may be authroized for the treatment of urinary tract infections including pyelonephritis.

# ZINBRYTA (daclizumab)

### **Products Affected**

• ZINBRYTA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	pre-existing hepatic disease or impairment, including ALT or AST at least 2 times the ULN, history of autoimmune hepatitis or other autoimmune condition involving the liver, history of hypersensitivity to daclizumab or any other component of the formulation
Required Medical Information	Diagnosis of covered medical use, confirmation patient is diagnosed with a relapsing form of MS and has tried and failed to achieve an adequate response to at least two drugs indicated for the treatment of MS, submission of baseline liver function tests including ALT, AST, and total bilirubin levels less than 2 times the ULN and confirmation these lab values will be assessed before each monthly injection and for 6 months after the last dose of Zinbryta is administered, confirmation high risk patients (tuberculosis endemic areas) will be evaluated for TB infection prior to initiating treatment and for those testing positive tuberculosis will be treated by standard medical practice prior to initiating therapy, confirmation patient has been screened for the presence of Hepatitis B and c and confirmation patient has been counseled about and will be monitored for developing depression and/or suicidal ideation
Age Restrictions	17 YO or older
Prescriber Restrictions	Limited to neurology
Coverage Duration	One Year

PA Criteria	Criteria Details
Other Criteria	PA applies to all. Continuation of approval requires submission of objective clinical documentation of a positive patient therapeutic response and medication tolerability, submission of updated ALT, AST and total bilirubin (obtained within the previous 30 days) less than 2 times the ULN and documented compliance with all REMs program requirements.

## **ZOLPIDEM**

### **Products Affected**

• zolpidem tartrate oral

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use and documentation that the provider is aware of the associated risks, specifically: cognitive impairment, delirium, unsteady gait, syncope, falls, fractures and motor vehicle accidents, and confirmation that the prescriber is aware the medication is considered high risk for elderly patients by the Centers for Medicare and Medicaid services and submission of justification by the prescriber which explains how that benefits of the drug outweighs the potential risks for the specific patient, and confirmation that at least two of: trazadone, Rozerem, and/or Silenor have been tried and were ineffective or intolerable.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One year
Other Criteria	

## **ZONTIVITY**

### **Products Affected**

ZONTIVITY

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Do not use ZONTIVITY in patients with a history of stroke, transient ischemic attack (TIA), intracranial hemorrhage (ICH) or active pathological bleeding.
Required Medical Information	Diagnosis of Covered Use, documentation of concurrent use with apririn and/or clopidogrel
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to all

## **Zorbtive**

### **Products Affected**

ZORBTIVE

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Four weeks
Other Criteria	PA applies to all

# **ZURAMPIC** (lesinurad)

### **Products Affected**

• ZURAMPIC

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Severe renal impairment, end stage renal disease, kidney transplant recipients, or patient is receiving dialysis, tumor lysis syndrome or Lesch-Nyhan syndrome
Required Medical Information	Diagnosis of covered use, confirmation that patient's hyperurecemia is symptomatic, submission of patient weight and serum creatinine level obtained within the previous month for the purposes of estimated calculating creatinine clearance and confirmation that patient's eCrCl will continued to be monitored periodically while the patient is on therapy, confirmation therapy will not be initiated if eCrCl is less than 45ml/min and ongoing therapy will be discontinued if eCrCl consistently is under 45ml/min, submission of patient's serum uric acid target goal and serum uric acid level obtained within the previous three months documenting patient has not been able to achieve target serum uric acid levels with a xanthine oxidase inhibitor alone,documentation that Zurampic will be used in conjunction with a xanthine oxidase inhibitor and that patient has been instructed on the importance of staying well hydrated defined as consuming of 68oz of liquid per day,confirmation patient does not have severe hepatic impairment as therapy is not recommended in this patient population
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA Applies to All

## **ZYDELIG**

### **Products Affected**

ZYDELIG

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	History of serious hypersensitivity reactions, including anaphylaxis and toxic epidermal necrolysis
Required Medical Information	Diagnosis of covered use, documentation of prior use of at least two systemic therapies for the treatment of Relapsed follicular B-cell non-Hodgkin lymphoma (FL) and Relapsed small lymphocytic lymphoma (SLL), submission of baseline CBC including ANC and platelet counts, submission of baseline hepatic function including ALT, AST and bilirubin, confirmation ALT and AST will be monitored every two weeks for the first 3 months of therapy, every 4 weeks for the next 3 months, then every 1 to 3 months thereafter while on therapy
Age Restrictions	18 YO or older
Prescriber Restrictions	Limited to oncology or hematology
Coverage Duration	One year
Other Criteria	Provider documents patient has been advised to report any of the following symptoms: jaundice, bruising, severe abdominal pain, bleeding, increase in the number of bowel movements by six or more per day, new or worsening respiratory symptoms including cough or dyspnea, severe skin reaction or development of a fever or any signs of infection.PA applies to new starts only

## **ZYFLO**

### **Products Affected**

- zileuton er
- ZYFLO

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use and Lab values including: ALT levels and PFT's
Age Restrictions	12 YO
Prescriber Restrictions	
Coverage Duration	one year
Other Criteria	PA applies to all

## **ZYKADIA**

### **Products Affected**

ZYKADIA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of covered use, submission of baseline ALT, AST and total bilirubin obtained within the previous three months and confirmation liver function tests will be monitored monthly, submission of baseline ECG, heart rate and serum electrolyte levels obatined within the previous three months, submission of baseline serum glucose level obtained within the previous three months
Age Restrictions	18 YO or older
Prescriber Restrictions	limited to oncology and hematology
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **ZYTIGA**

### **Products Affected**

• ZYTIGA

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
Exclusion Criteria	
Required Medical Information	Diagnosis of covered use, documentation of other treatments tried, confirmation patient will receive concurrent prednisone, baseline ALT, AST, bilirubin, and serum potassium level, baseline LVEF
Age Restrictions	18 YO or older
Prescriber Restrictions	
Coverage Duration	One Year
Other Criteria	PA applies to new starts only

## **ZYVOX**

#### **Products Affected**

- linezolid intravenous solution 600 mg/300ml
- linezolid oral
- ZYVOX INTRAVENOUS SOLUTION 600 MG/300ML

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D
<b>Exclusion Criteria</b>	
Required Medical Information	Diagnosis of Covered Use and Culture
Age Restrictions	
Prescriber Restrictions	Limited to Infectious Disease Specialist
Coverage Duration	Vancomycin-resistant E. faecium infections - 28 days, all other FDA approved indications - 14 days
Other Criteria	PA applies to all

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