

Health Plan, Inc.

#### Presbyterian Senior Care (HMO) / (HMO-POS) Presbyterian Dual Plus (HMO D-SNP) Formulary Prior Authorization Criteria Effective January 1, 2026

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

For the most recent list of drugs, information on obtaining a coverage determination or exception, or other questions, please contact the Presbyterian Customer Service Center.

#### **Presbyterian Senior Care:**



(505) 923-6060 1-800-797-5343 (TTY 711)



#### October 1 - March 31:

8 a.m. to 8 p.m., seven days a week (except holidays)

#### **April 1 - September 30:**

8 a.m. to 8 p.m., Monday - Friday (except holidays)

#### **Presbyterian Dual Plus:**



(505) 923-7675 1-855-465-7737 (TTY 711)



www.phs.org/Medicare

Learn more about Presbyterian's Nondiscrimination Notice and Interpreter Services.

Based on a Model of Care review, Presbyterian Dual Plus (HMO D-SNP) has been approved by the National Committee for Quality Assurance (NCQA) to operate a Special Needs Plan (SNP) through 2028.

### Abilify MyCite (aripiprazole with sensor)

#### **Products Affected**

- Abilify MyCite
- Abilify MyCite Maintenance Kit Oral Tablet Therapy Pack 15 MG, 2 MG, 20 MG, 5 MG
- Abilify MyCite Starter Kit Oral Tablet Therapy Pack 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	Patients with dementia-related psychosis.
Required Medical Information	Chart notes documenting that the patient has tried at least two (2) oral atypical anti-psychotics, one of which must be aripiprazole.
Age Restrictions	Patient is 18 years of age or older
Prescriber Restrictions	
Coverage Duration	Initial: 3 months Renewal: 6 months
Other Criteria	Reauthorization: Documentation that the patient is clinically stable on Abilify MyCite and the prescriber documents that the patient requires the continued use of Abilify MyCite.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## **Abilify ODT (aripiprazole)**

#### **Products Affected**

• ARIPiprazole Oral Tablet Dispersible

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation that the patient has tried/failed aripiprazole tablets.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Actiq (fentanyl transmucosal)**

#### **Products Affected**

• fentaNYL Citrate Buccal Lozenge On A Handle 1200 MCG, 1600 MCG, 400 MCG, 600 MCG, 800 MCG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Trial and failure of an immediate release oral opiate and must be used in combination with a long-acting oral opiate.
Age Restrictions	16 years or older
Prescriber Restrictions	Oncologist or Pain Specialist
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Adcirca (tadalafil)

#### **Products Affected**

• Alyq

• Tadalafil (PAH)

PA Criteria	Criteria Details
Exclusion Criteria	Tadalafil is excluded from coverage for the treatment of Erectile Dysfunction.
Required Medical Information	Documentation of Pulmonary Arterial Hypertension as determined by a right heart catheterization.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Adempas (riociguat)

#### **Products Affected**

• Adempas

PA Criteria	Criteria Details
Exclusion Criteria	Must not be used in combination with nitrates, nitric oxide donors, or PDE-5 inhibitors.
Required Medical Information	If using for pulmonary arterial hypertension (PAH), must have tried and failed or have a contraindication to Revatio (sildenafil) or Adcirca (tadalafil).
Age Restrictions	18 years or older
Prescriber Restrictions	Cardiologist or Pulmonologist
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **Afinitor (everolimus)**

#### **Products Affected**

• Everolimus Oral Tablet 10 MG, 2.5 MG, 5 • Torpenz MG, 7.5 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Afinitor Disperz (everolimus)**

#### **Products Affected**

• Everolimus Oral Tablet Soluble

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Akeega (niraparib and abiraterone)

#### **Products Affected**

• Akeega

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six (6) months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## Alecensa (alectinib)

#### **Products Affected**

• Alecensa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Alunbrig (brigantinib)**

#### **Products Affected**

• Alunbrig

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Amjevita (adalimumab-atto)

#### **Products Affected**

- Amjevita Subcutaneous Solution Auto-Injector 40 MG/0.4ML
- Amjevita Subcutaneous Solution Prefilled Syringe 40 MG/0.4ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Ankylosing Spondylitis (AS): peripheral arthritis must have a trial of sulfasalazine and an NSAID. Patients with axial disease and failure of NSAIDs can be started without a trial of sulfasalazine. 2. Crohn's disease (CD): Inadequate response or intolerance to conventional therapy. For the purpose of this policy, conventional therapy includes the use of ONE of the following: i. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide). ii. Methotrexate iii. Thiopurines (azathioprine, mercaptopurine). 3. Juvenile Idiopathic Arthritis (JIA): An adequate trial (3 months or more) of one of the following DMARDs: i. Leflunomide ii. Methotrexate iii. Sulfasalazine. 4. Plaque Psoriasis (PsO): a. The patient must have at least 3% of their body surface area (BSA) affected by plaque psoriasis (unless on hands, feet, scalp, face, or genital area). b. The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of at least 5 or more and/or a Dermatology Life Quality Index (DLQI) of more than 5. c. The patient has failed to adequately respond to, or is intolerant, a 3-month trial of a topical agent (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analogs, etc.). 5. Psoriatic Arthritis (PsA): Documented diagnosis of PsA. 6. Rheumatoid Arthritis (RA): Moderate to severe RA is defined as: DAS-28 more than 3.2 or CDAI more than 10.1. c. An adequate trial (3 months or more) of one of the following other DMARDs: i. Hydroxychloroquine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine 7. Ulcerative Colitis (UC): The member has had an inadequate response to one of the following: aminosalicylates, corticosteroids, thiopurines, or cyclosporine.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist, dermatologist, gastroenterologist, or ophthalmologist.

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PA Criteria	Criteria Details
Coverage Duration	One (1) year
Other Criteria	8. Hidradenitis Suppurativa (HS): Documented diagnosis of Hurley Stage II or III HS. 9. Uveitis: a. Documented diagnosis of non-infectious intermediate, posterior and panuveitis in adult patients and meets the following: i. documented trial failure, contraindication, or intolerance to at least two (2) drugs from the following: conventional therapy such as ophthalmic or systemic corticosteroids AND immunosuppressive drugs (e.g., azathioprine, cyclosporine, methotrexate, or tacrolimus). For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy, 2. The appropriate Disease Specific Criteria has been met. CONTINUATION CRITERIA: Documentation of positive response with treatment
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### **Androderm (testosterone topical)**

#### **Products Affected**

• Androderm Transdermal Patch 24 Hour

PA Criteria	Criteria Details
Exclusion Criteria	Testosterone replacement will not be covered for the treatment of sexual dysfunction.
Required Medical Information	Trial and failure of Androgel (testosterone gel). If using for primary hypogonadism, the patient must have two low total testosterone levels (drawn on separate days) with elevated luteinizing hormone (LH) and follicular stimulating hormone (FSH) levels. If using for hypogonadotropic hypogonadism, the patient must have two low total testosterone levels (drawn on separate days) with low to low-normal LH and FSH levels.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Androgel 1.62% (testosterone topical)**

#### **Products Affected**

 Testosterone Transdermal Gel 1.62 %, 10 MG/ACT (2%), 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%)

PA Criteria	Criteria Details
Exclusion Criteria	Testosterone replacement will not be covered for the treatment of sexual dysfunction.
Required Medical Information	If using for primary hypogonadism, the patient must have two low total testosterone levels (drawn on separate days) with elevated luteinizing hormone (LH) and follicular stimulating hormone (FSH) levels. If using for hypogonadotropic hypogonadism, the patient must have two low total testosterone levels (drawn on separate days) with low to low-normal LH and FSH levels.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **Apokyn (apomorphine)**

#### **Products Affected**

• Apokyn Subcutaneous Solution Cartridge • Apomorphine HCl Subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must be used as an adjunct to levodopa and one (1) formulary oral dopamine agonist medication indicated for Parkinson's disease.
Age Restrictions	
Prescriber Restrictions	Neurologist
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Arcalyst (rilonacept)**

#### **Products Affected**

• Arcalyst

PA Criteria	Criteria Details
Exclusion Criteria	Will not be used in combination with etanercept, adalimumab, anakinra, abatacept, or infliximab.
Required Medical Information	
Age Restrictions	12 years or older for the indications of Cryopyrin-Associated Periodic Syndromes, including Familial Cold Autoinflammatory Syndrome, and Muckle-Wells Syndrome, recurrent pericarditis. Adults and pediatrics weighing 10 kg or more for the maintanence of remission of Deficiency of Interleukin-1 Receptor Antagonist.
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Augtyro (repotrecitinib)**

#### **Products Affected**

• Augtyro

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six (6) months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Austedo (deutetrabenazine)

#### **Products Affected**

Austedo

- Austedo XR
- Austedo Patient Titration Kit
- Austedo XR Patient Titration

PA Criteria	Criteria Details
Exclusion Criteria	Deutetrabenazine is not covered for patients who are actively suicidal, who have untreated or inadequately treated depression, who have impaired hepatic function, or who are currently taking monoamine oxidase inhibitors or reserpine.
Required Medical Information	Documentation that member is being monitored for depression and suicidal ideation. Chorea associated with Huntington disease (HD): Documentation that the patient is ambulatory. Tardive Dyskinesia (TD): Documentation of a baseline Abnormal Involuntary Movement Scale (AIMS) must be provided.
Age Restrictions	
Prescriber Restrictions	Psychiatrists, neurologists, specialty nurse practitioners, specialty physician assistants, or was prescribed in consultation with the aforementioned specialists.
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	Renewal: Chart notes documenting that the patient's disease has improved based on prescriber's assessment while on therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## **Auvelity (dextromethorphan/bupropion)**

#### **Products Affected**

• Auvelity

PA Criteria	Criteria Details
Exclusion Criteria	1. Seizure disorder. 2. Current or prior diagnosis of bulimia or anorexia nervosa. 3. Abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs. 4. Use with an MAOI.
Required Medical Information	1. Member has a clinical diagnosis of major depressive disorder (MDD) as defined by DSM-5 criteria and/or appropriate depression rating scale (e.g., MADRS). 2. Member has had previous treatment, contraindication, or intolerance to at least two antidepressants from two different classes (e.g., SSRI, SNRI).
Age Restrictions	18 years of age and over
Prescriber Restrictions	
Coverage Duration	Initial: 6 months. Continuation: 1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### Avmapki-Fakzynja (avutometinib-defactinib)

#### **Products Affected**

• Avmapki Fakzynja Co-Pack

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Ayvakit (avapritinib)

#### **Products Affected**

• Ayvakit

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Balversa** (erdafitinib)

#### **Products Affected**

• Balversa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Benlysta (belimumab)

#### **Products Affected**

• Benlysta Subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must be used in combination with standard therapy.
Age Restrictions	
Prescriber Restrictions	Nephrologist or Rheumatologist
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	Documentation must be submitted demonstrating a clinical benefit has been established and maintained compared to baseline.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Besremi

#### **Products Affected**

• Besremi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, and some journals.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Bosulif (bosutinib)**

#### **Products Affected**

• Bosulif

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Braftovi (encorafenib)**

#### **Products Affected**

• Braftovi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Bronchitol (mannitol)**

#### **Products Affected**

• Bronchitol

PA Criteria	Criteria Details
Exclusion Criteria	Failure to pass Bronchitol tolerate test (BTT)
Required Medical Information	1. Diagnosis of cystic fibrosis. 2. Documentation of in adequate response to hypertonic saline and Pulmozyme, unless contraindicated or not tolerated. 3. Documentation that member has successfully complete the Bronchitol tolerance test (BTT).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist.
Coverage Duration	One (1) year
Other Criteria	Continuation criteria: positive clinical response to therapy
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Brukinsa (Zanubrutinib)

#### **Products Affected**

• Brukinsa Oral Capsule

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Buphenyl** (sodium phenylbutyrate)

#### **Products Affected**

- Sodium Phenylbutyrate Oral Powder 3 GM/TSP
- Sodium Phenylbutyrate Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Cabometyx (cabozantinib)

#### **Products Affected**

• Cabometyx

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Calquence (acalabrutinib)**

#### **Products Affected**

• Calquence

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## **Caplyta (lumateperone)**

#### **Products Affected**

• Caplyta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Schizophrenia: a. Trial and failure of two (2) atypical antipsychotics for a minimum of 4 weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, OR member has a current diagnosis of metabolic syndrome, pre-metabolic syndrome, or diabetes mellitus and has failed aripiprazole AND ziprasidone, unless there is a documented contraindication or intolerance. 2. Bipolar: a. Monotherapy: Trial and failure of three alternatives from the following: i. lamotrigine, ii. lithium, iii. carbamazepine, iv. valproic acid, v. Atypical Antipsychotics (e.g., aripiprazole, lurasidone, quetiapine). b. adjunct therapy: will be used with either lithium or valproic acid.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) year
Other Criteria	Continuation criteria: Documentation of positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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## Caprelsa (vandetanib)

#### **Products Affected**

• Caprelsa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Carbaglu (carglumic acid)

#### **Products Affected**

• Carglumic Acid

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Cayston (aztreonam lysine)**

#### **Products Affected**

• Cayston

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	FEV1 must be 25% to 75% of predicted. Patient must have a positive sputum culture for Pseudomonas aeruginosa.
Age Restrictions	7 years or older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **CGRP** Inhibitor

### **Products Affected**

• Aimovig

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of Episodic Migraines or Chronic Migraines. History of failure or intolerance to two (2) preventive migraine medications from at least two (2) of the following classes: anti-depressant (e.g. venlafaxine), anti-convulsant (e.g. topiramate, divalproex) or anti-hypertensive (e.g. propranolol, verapamil).
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a Headache Specialist, a Neurologist, or a Pain Specialist.
Coverage Duration	12 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Cibinqo (abrocitinib)

### **Products Affected**

• Cibinqo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	<ul> <li>a. Documentation of trial and failure of the following: i.Medium, high, or very high potency topical corticosteroid. ii. Topical calcineurin inhibitor.</li> <li>b. Documentation is provided that a non-corticosteroid systemic immunosuppressant (e.g., cyclosporine, azathioprine, methotrexate, or mycophenolate mofetil) has failed to achieve and maintain remission of disease activity.</li> </ul>
Age Restrictions	
Prescriber Restrictions	Dermatologist
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	Continuation criteria: positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **Cinryze (C1 inhibitor-human)**

### **Products Affected**

• Cinryze

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Clovique (trientine)**

### **Products Affected**

• Trientine HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documented intolerance to penicillamine
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### Cobenfy (xanomeline and trospium chloride)

### **Products Affected**

• Cobenfy

• Cobenfy Starter Pack

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The patient must have a documented intolerance, side effects or lack of efficacy to at least two (2) other formulary atypical antipsychotics.  Medication trials that fail due to lack of efficacy must be attempted for a minimum of 4 weeks if no response, and a minimum of 12 weeks if partial response, unless the patient has a documented intolerance or contraindication to the preferred medication. OR The patient has a current diagnosis of Metabolic Syndrome, Pre-Metabolic Syndrome, or Diabetes Mellitus and has failed ziprasidone or there is clinical documentation why ziprasidone is not clinically appropriate.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### **Colony Stimulating Factor**

### **Products Affected**

• Udenyca Subcutaneous Solution Prefilled • Zarxio Syringe

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Indications for approval: 1. Cancer patients receiving myelosuppressive therapy. 2. Patients with acute myeloid leukemia receiving induction or consolidation chemotherapy. 3. Cancer patients receiving bone marrow transplant. 4. Patients undergoing peripheral blood progenitor cell collection and therapy. 5. Patients with severe chronic neutropenia (cyclic or idiopathic) that meets one of the following: a) Documented diagnosis of severe chronic neutropenia (idiopathic) with an ANC of less than 500/mm3 on three separate occasions over the previous 6 months. OR b) Documented diagnosis of severe chronic neutropenia (cyclic) with five consecutive days per cycle with an ANC less than 500/mm3 for each of 3 regularly spaced cycles over a 6-month period. 6. Patients with severe chronic neutropenia (congenital) that have a documented diagnosis of congenital neutropenia. 7. For the treatment of hematopoietic syndrome of acute radiation symptoms.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
Indications	All FDA-approved Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **Cometriq (cabozantinib)**

### **Products Affected**

- Cometriq (100 MG Daily Dose)
- Cometriq (60 MG Daily Dose)
- Cometriq (140 MG Daily Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Copiktra (duvelisib)

### **Products Affected**

• Copiktra

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **Corlanor (ivabradine)**

### **Products Affected**

• Corlanor Oral Solution

• Ivabradine HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Adults: Documented diagnosis of symptomatic chronic heart failure with left ventricular ejection fraction (LVEF) 35% or less, who are in normal sinus rhythm with a resting heart rate of at least 70 beats per minute (documented in the last 60 days) and are on a beta-blocker or have a contraindication to beta-blocker use. Documentation that the patient has tried/failed sacubitril/valsartan. Pediatrics: Documented diagnosis of Symptomatic Heart Failure due to Dilated Cardiomyopathy in patients 6 months of age or older and the patient is in normal sinus rhythm with an elevated heart rate and LVEF 45% or less. Documentation of a resting heart rate of 70-105 beats per minute.
Age Restrictions	
Prescriber Restrictions	Cardiologist or in consultation with a Cardiologist or a cardiac care specialist
Coverage Duration	1 year
Other Criteria	Continuation: Documentation of successful response to the medication.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### **Cosentyx (secukinumab)**

### **Products Affected**

- Cosentyx (300 MG Dose)
- Cosentyx Sensoready (300 MG)
- Cosentyx Subcutaneous Solution Prefilled Syringe 75 MG/0.5ML
- Cosentyx UnoReady

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Ankylosing Spondylitis: i. The patient has a documented trial and failure with a non-steroidal anti-inflammatory drug (NSAID) or such treatment is contraindicated or not tolerated. ii. Patients with peripheral arthritis must have a documented trial and failure with sulfasalazine or such treatment is contraindicated or not tolerated. iii. Patients with axial disease and a trial and failure of, or a contraindication to, NSAIDs can be started on Cosentyx without a trial of sulfasalazine. iv. Trial and failure, unless contraindicated or not tolerated, to one of the following agents: 1. Amjevita. 2. Enbrel.3. Hadlima. 4. Xeljanz. 2. Plaque Psoriasis: i.The patient must have more than 3% of their body surface area (BSA) affected by plaque psoriasis. ii. The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) more than 5 and/or a Dermatology Life Quality Index (DLQI) more than 5. iii. The patient has failed to adequately respond to or is intolerant to a 3-month trial of a topical agents (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analog, etc.). iv. Trial and failure, unless contraindicated or not tolerated, of one of the following agents: 1. Amjevita. 2. Enbrel.3. Hadlima. 3. Psoriatic Arthritis: i.An adequate trial (3 months or more) of one of the following DMARDs: 1.Cyclosporine. 2. Leflunomide. 3.Methotrexate. 4. Sulfasalazine. ii. Trial and failure, unless contraindicated or not tolerated, to one of the following agents: 1. Amjevita. 2. Enbrel. 3. Hadlima. 4. Xeljanz.
Age Restrictions	
Prescriber Restrictions	Rheumatologist or Dermatologist

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PA Criteria	Criteria Details
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	Continuation criteria: positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **Cotellic (cobimetinib)**

### **Products Affected**

• Cotellic

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Cresemba (isavuconazonium)

### **Products Affected**

• Cresemba Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	One of the following is met: a. the patient has a diagnosis of invasive aspergillosis. b. The patient has a diagnosis of invasive mucormycosis. c. The use of the requested drug is for an indication other than those noted above that is supported by current IDSA Guidelines, and if the guidelines do not recommend the requested drug as first-line therapy, the prescriber has submitted documentation supporting the use of the requested drug instead of the recommended first-line agent(s).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) month
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Cystaran (cysteamine) ophthalmic solution

### **Products Affected**

• Cystaran

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Original diagnosis made by an eye specialist. Individual has medical record documentation of a confirmed diagnosis of cystinosis. Individual has medical record documentation of corneal cystine crystals.
Age Restrictions	
Prescriber Restrictions	Ophthalmologist
Coverage Duration	6 months
Other Criteria	Reauthorization: documentation of positive clinical response to Cystaran therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **Danziten (nilotinib)**

### **Products Affected**

• Danziten

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Daraprim (pyrimethamine)**

### **Products Affected**

• Pyrimethamine Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Toxoplasmosis: documentation that the patient will be using a sulfonamide. Toxoplasmosis prophylaxis.
Age Restrictions	
Prescriber Restrictions	Infectious Disease or in consultation with Infectious Disease
Coverage Duration	8 weeks
Other Criteria	Pyrimethamine is not recommended for the treatment of acute malarial attacks and is not included in the CDC recommendations for the treatment of malaria. Pyrimethamine is not the drug of choice for malaria prophylaxis.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Daurismo (glasdegib)

### **Products Affected**

• Daurismo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **Deferasirox (Jadenu and Exjade)**

### **Products Affected**

• Deferasirox Oral Tablet

• Deferasirox Oral Tablet Soluble

PA Criteria	Criteria Details
Exclusion Criteria	eGFR less than 40 ml/min/1.73, patients with poor performance status, patients with high-risk myelodysplastic syndrome (MDS), and patients with advanced malignancies.
Required Medical Information	1. Chronic iron overload due to blood transfusions: The member has received a transfusion of at least 100 mL/kg of packed red blood cells (e.g., at least 20 units of packed red blodd celss for a 40 kg person or more than 20 units in an individual weighing more than 40 kg), and serum ferritin is consistently greater than 1,000 mcg/L. 2. Iron overload in non-transfusion-dependent thalassemia syndromes (NTDT): The member has a liver iron concentration (LIC) of at least 5 mg Fe/g of dry weight and a serum ferritin greater than 300 mcg/L. Baseline lab values required for both indications: renal function, serum transaminases and biliribun, and auditory and ophthalmic examinations.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months. Continuation: 1 year
Other Criteria	Continuation criteria: 1. Chronic iron overload due to blood transfusions: routine (monthly) blood counts, liver function, renal function, and ferritin.  2. NTDT: LIC every 6 months, routine (monthly) blood counts, liver function, renal function, and ferritin.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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# **Depen (penicillamine tablets)**

### **Products Affected**

• penicillAMINE Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Cystinuria: Documented trial and failure or intolerance to Thiola (tiopronin).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Renewal: Documentation must be submitted demonstrating a successful response to the medication.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# Dificid (fidaxomicin)

### **Products Affected**

• Dificid Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Trial and failure of vancomycin oral.
Age Restrictions	6 months or older
Prescriber Restrictions	
Coverage Duration	1 month
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Drizalma (duloxetine)

### **Products Affected**

• Drizalma Sprinkle

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chart notes documenting a trial or failure of duloxetine (Cymbalta) capsule or amitriptyline use in the last 180 days.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **Dupixent**

### **Products Affected**

• Dupixent

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Atopic Dermatitis a. Diagnosis of moderate to severe atopic dermatitis. b. 6 months of age and older c. Member has had an inadequate response to a 3-month trial of a medium to high potency topical steroid (e.g., mometasone, fluocinilone, fluocinomide) OR a topical calcinuerin inhibitor (e.g., tacrolimus). d. IGA score of at least 3 e. EASI score of at least 16 f. Minimum body surface area involvement of =10% g. Initial curation: 6 months h. Reauthorization: Documentation of positive clinical response and will not be used in combination with another biologic medication. 2. Asthma a. 6 years of age and older b. History of one or more asthma exacerbations that required treatment with systemic corticosteroids or emergency visit or hospitalization for the treatment of asthma within the past year. c. Daily dependence on oral corticosteroids in addition to regular use of high-dose inhaled corticosteroids plus an additional controller. d. Blood eosinophils =300 cells/mcL e. Initial coverage duration: 6 months f. Reauthorization: Documented clinical response to Dupixent demonstrated by 1) reduction in frequency of exacerbations, 2) decreased utilization of rescue medications, 3) reduction in oral corticosteroid requirements: Dupixent will be used in combination with an ICS controller medication: and Dupixent will not be used with another biologic medication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months Continuation: 1 year
Other Criteria	3. Chronic Rhinosinusitis with Nasal Polyps a. 12 years of age and older b. To be used as add-on maintenance treatment for individuals with:

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PA Criteria	Criteria Details
	Nasal polyps detected by direct examination, endoscopy, or sinus CT scan Significant rhinosinusitis such as nasal obstruction, rhinorrhea, or reduction or loss of smell as documented by the prescriber. c. Bilater Nasal Polyp Score (NPS) of at least 5, and NPS of at least 2 in each nostril. d. Documented inadequate response to nasal corticosteroids. e. Patient has received treatment with systemic corticosteroids with the past two years (or has a contraindication) or has had prior surgery for nasal polyps. f. Initial coverage: 6 months g. Reauthorization: Documented positive clinical response: patient will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids, and patient will not use Dupixent with another biologic medication. 4. Eosinophilic Esophagitis: a. Documented trial and failure of a proton pump inhibitor (PPI) or a topical glucocorticoid steroid. b. Diagnosis confirmed by greater than or equal to 15 intraepithelial eosinophils per high-power field (eos/hpf). c. Prescribed by or in consultation with a gastroenterologist or allergist. d. Reauthorization: documented postive clinical response as demonstrated by a decrease in eos/hpf and improvement in baseline Dysphagia Symptom Questionnaire (DSQ) score. 5. Prurigo Nodularis: a. Worst Itch-Numeric Rating Scale (WI-NRS) greater than or equal to 7 and 20 or more nodular lesions. b. Inadequate response, intolerance, or contraindication to a high potency topical steroid (e.g., betamethasone, fluocinonide, triamcinolone). 6. COPD: FEV1/FVC ratio of less than 0.7 and post-bronchodilator FEV1 of 30%.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### **Emend (aprepitant oral)**

### **Products Affected**

• Aprepitant

• Emend Oral Suspension Reconstituted

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Emgality (galcanezumab-gnlm)**

### **Products Affected**

• Emgality

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Coverage for a Diagnosis of Episodic Migraines and Chronic Migraines requires a History of failure or intolerance to two (2) preventive migraine medications from at least two (2) of the following classes: anti-depressant (e.g. venlafaxine), anti-convulsant (e.g. topiramate, divalproex) or anti-hypertensive (e.g. propranolol, verapamil). Coverage for a diagnosis of Episodic Cluster headaches requires a History of failure or intolerance to Verapamil.
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a Headache Specialist, a Neurologist, or a Pain Specialist.
Coverage Duration	6 months
Other Criteria	Continuation: Documentation that the patient has experienced a positive clinical response
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **Enbrel (etanercept)**

#### **Products Affected**

- Enbrel Mini
- Enbrel Subcutaneous Solution 25 MG/0.5ML
- Enbrel Subcutaneous Solution Prefilled Syringe
- Enbrel Subcutaneous Solution Reconstituted
- Enbrel SureClick Subcutaneous Solution Auto-Injector

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Ankylosing Spondylitis (AS): peripheral arthritis must have a trial of sulfasalazine and an NSAID. Patients with axial disease and failure of NSAIDs can be started without a trial of sulfasalazine. 2. Juvenile Idiopathic Arthritis (JIA): An adequate trial (3 months or more) of one of the following DMARDs: leflunomide, methotrexate, sulfasalazine. 3. Plaque Psoriasis (PsO): a. The patient must have at least 3% of their body surface area (BSA) affected by plaque psoriasis (unless on hands, feet, scalp, face, or genital area). b. The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of at least 5 or more and/or a Dermatology Life Quality Index (DLQI) of more than 5. c. The patient has failed to adequately respond to, or is intolerant, a 3-month trial of a topical agent (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analogs, etc.). 4. Psoriatic Arthritis (PsA): Documented diagnosis of psoriatic arthritis. 5. Rheumatoid Arthritis (RA): Moderate to severe RA is defined as: DAS-28 more than 3.2 or CDAI more than 10.1. An adequate trial (3 months or more) of one of the following other DMARDs: hydroxychloroquine, leflunomide, methotrexate, sulfasalazine.
Age Restrictions	
Prescriber Restrictions	1. AS/JIA/RA - prescribed by or in consultation with a rheumatologist. 3. PsA- prescribed by or in consultation with a dermatologist or rheumatologist 4. PsO- prescribed by or in consultation with a dermatologist.

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PA Criteria	Criteria Details
Coverage Duration	1 year
Other Criteria	For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy. 2. The appropriate Disease Specific Criteria has been met. CONTINUATION CRITERIA: Documentation of positive clinical response to treatment.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **Endari (L-glutamine)**

### **Products Affected**

• L-Glutamine Oral Packet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Diagnosis of sickle cell disease. 2. Will be used to reduce acute complications of sickle cell disease. 3. Will be used concurrently with hydroxyurea, unless contraindicated or not tolerated. 4. Member has had two (2) or more painful sickle cell crises within the past 12 months.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) year
Other Criteria	Continuation therapy: positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Entocort (budesonide capsules)**

### **Products Affected**

• Budesonide Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. The member has a diagnosis of mild to moderate Crohn's disease. 2. Documented trial and failure of sulfasalazine.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# Epclusa (sofosbuvir/velpatasvir)

### **Products Affected**

• Sofosbuvir-Velpatasvir

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medical records documenting the diagnosis of chronic Hepatitis C, including laboratory documentation of genotype and subtype, detectable HCV RNA levels at baseline, HIV status and liver transplant status.
Age Restrictions	3 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a Infectious Disease specialist or Hepatologist
Coverage Duration	Duration as per package insert or Class I or II recommendation by the AASLD/IDSA/IAS-USA guidelines
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Epidiolex (cannabiddiol)**

### **Products Affected**

• Epidiolex

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Lennox-Gastaut Syndrome: Diagnosis of Lennox-Gastaut Syndrome and seizures have been inadequately controlled by a trial of at least two antiepileptic drugs (e.g. clobazam, valproate, lamotrigine, topiramate, levetiracetam). Dravet Syndrome: Diagnosis of Dravet Syndrome and seizures have been inadequately controlled by a trial of at least two antiepileptic drugs (e.g. clobazam, valproate, lamotrigine, topiramate, levetiracetam).
Age Restrictions	1 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a Neurologist
Coverage Duration	Initial: 6 months ReAuthorization: 1 year
Other Criteria	AST, ALT and total bilirubin levels will be obtained 1 month, 3 months, and 6 months after initiation, then periodically thereafter or as clinically indicated. ReAuthorization: Patient is tolerating treatment and there continues to be a medical need for the medication and there has been disease stabilization or improvement while on this medication.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **Erivedge (vismodegib)**

### **Products Affected**

• Erivedge

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Erleada ( apalutamide)

### **Products Affected**

• Erleada

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Erythropoietin Stimulating Agents**

#### **Products Affected**

• Retacrit Injection Solution 10000 UNIT/ML, 10000 UNIT/ML(1ML), 2000 UNIT/ML, 3000 UNIT/ML, 4000 UNIT/ML, 40000 UNIT/ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Erzofri (paliperidone)

#### **Products Affected**

• Erzofri

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation that the patient has tried and failed oral paliperidone or risperidone.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## **Esbriet (pirfenidone)**

#### **Products Affected**

• Pirfenidone Oral Capsule

• Pirfenidone Oral Tablet 267 MG, 801 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Diagnosis confirmed by high-resolution computed tomography (HRCT). 2. Exclusion of other known causes, such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity. 3. Baseline Forced Vital Capacity (FVC) greater than or equal to 50% (pulmonary function tests - PFTs - within the past 60 days).
Age Restrictions	18 years or older
Prescriber Restrictions	Pulmonologist
Coverage Duration	1 year
Other Criteria	Baseline Liver Function test
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Fanapt (iloperidone)**

#### **Products Affected**

• Fanapt

Fanapt Titration Pack A

• Fanapt Titration Pack

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Schizophrenia: a. Trial and failure of two (2) atypical antipsychotics for a minimum of 4 weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, OR member has a current diagnosis of metabolic syndrome, pre-metabolic syndrome, or diabetes mellitus and has failed aripiprazole AND ziprasidone, unless there is a documented contraindication or intolerance. 2. Bipolar: a. Monotherapy: Trial and failure of three alternatives from the following: i. lamotrigine, ii. lithium, iii. carbamazepine, iv. valproic acid, v. Atypical Antipsychotics (e.g., aripiprazole, lurasidone, quetiapine). b. adjunct therapy: will be used with either lithium or valproic acid.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) year
Other Criteria	Continuation criteria: positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# Farydak (panobinostat)

#### **Products Affected**

• Farydak

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class I or IIa recommendation in the Thomson Micromedex DrugDex compendium.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Fasenra (benralizumab)

#### **Products Affected**

• Fasenra

• Fasenra Pen

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	FDA approved for asthma maintenance add-on therapy in severe asthma (eosinophilic phenotype), medical records must document IgE level greater than or equal to 150 cells/microliter, AND inadequate control with an inhaled corticosteroid and a long acting beta-2 agonist combination therapy, AND evidence of persistent symptoms requiring frequent rescue therapy, practitioner visits despite inhaled corticosteroids, ER visits OR inadequate control OR intolerance OR contraindication to inhaled corticosteroid and a long acting beta-2 agonist combination. Not to be used as monotherapy or concomitantly with other biologics. Continuation Criteria: Documentation of a reduction in exacerbation frequency and/or severity.
Age Restrictions	
Prescriber Restrictions	Allergist, Pulmonologist, Dermatologist or Immunologist
Coverage Duration	Initial: 9 months Continuation: 12 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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## Fensolvi (leuprolide)

#### **Products Affected**

• Fensolvi

• Fensolvi (6 Month)

PA Criteria	Criteria Details
Exclusion Criteria	Not covered for treatment of prostate cancer
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Ferriprox (deferiprone)**

#### **Products Affected**

• Deferiprone

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have an absolute neutrophil count (ANC) greater than 1.5x10^9/L before starting therapy. Patient must have tried and failed or have a contraindication to deferasirox. ANC levels are not required for iron transfusional overload in patients with sickle cell disease or other anemias.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	For renewal, must receive documentation demonstrating clinical efficacy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### Firazyr (icatibant)

#### **Products Affected**

• Icatibant Acetate

• Sajazir

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medical records must document a diagnosis of hereditary angioedema (HAE) based on evidence of a low C4 level and one of the following: a low C1 inhibitor (C1-INH) antigenic level or a normal C1-INH antigenic level and a low C1-INH functional level. The patient must not be concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy and must be experiencing at least one symptom of a moderate or severe attack (ie. swelling of the face, throat, or abdomen).
Age Restrictions	18 years or older
Prescriber Restrictions	Allergist or Immunologist
Coverage Duration	6 months
Other Criteria	Medical records documenting frequency of acute HAE attacks and the patient's response to therapy must be provided. If the patient is experiencing more than one acute HAE attack per month medical records documenting use of a long-term prophylactic therapy (LTP) or the clinical rational for avoiding LTP must be provided.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Firdapse (amifampridine)

#### **Products Affected**

• Firdapse

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Confirmed diagnosis of Lambert-Eaton myasthenic syndrome (LEMS), documentation of baseline confirmatory diagnostic test results including but not limited to: a Repetitive Nerve Stimulation (RNS), a positive anti-P/Q type voltage-gated calcium channel antibody test, a Quantitative Myasthenia Gravis (QMG) score, a triple-timed up-and-go test (3TUG), a Timed 25-foot walk test (T25FW).
Age Restrictions	6 years of age and older
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 3 months Renewal: 6 months
Other Criteria	Dose does not exceed 80mg per day. Renewal: Documentation of clinical improvement in symptoms
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Forteo (teriparatide)

#### **Products Affected**

 Forteo Subcutaneous Solution Pen-Injector 560 MCG/2.24ML, 600 MCG/2.4ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	A diagnosis of osteoporosis and a T-score of -2.5 or less at the femoral neck, total hip or lumbar spine by DXA. The patient has failed or is intolerant to other available osteoporosis therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Fotivda (Tivozanib)

#### **Products Affected**

• Fotivda

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Fruzaqla (fruquintinib)

#### **Products Affected**

• Fruzaqla

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six (6) months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Gamunex-C** (human immune globulin)

#### **Products Affected**

• Flebogamma DIF

• Gamunex-C

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Gattex (teduglutide)**

#### **Products Affected**

• Gattex

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must be dependent on parenteral nutrition/intravenous (PN/I.V.) support for at least 12 months and requires PN at least 3 times per week.
Age Restrictions	1 year of age and older
Prescriber Restrictions	Gastroenterologist
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Gavreto (pralsetinib)**

#### **Products Affected**

• Gavreto

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Gilotrif (afatinib)

#### **Products Affected**

• Gilotrif

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Gleevec (imatanib)

#### **Products Affected**

• Imatinib Mesylate Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **GLP-1 Agonists**

#### **Products Affected**

• Mounjaro

• Trulicity

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1.Diagnosis of Type 2 Diabetes Mellitus (T2DM). 2.The member has tried and failed a 90-day course of two of the following drug classes: biguanide, sodium-glucose cotransporter 2 (SGLT2) inhibitor (e.g., Steglatro, Farxiga), a dipeptidyl peptidase-4 (DPP-4) inhibitor (e.g., Januvia), a sulfonylurea or thiazolidinedione unless contraindicated or not tolerated.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 Months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Gomekli (mirdametinib)

#### **Products Affected**

• Gomekli

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### Hadlima (adalimumab-bwwd)

#### **Products Affected**

- Hadlima PushTouch Subcutaneous Solution Auto-Injector 40 MG/0.4ML
- Hadlima Subcutaneous Solution Prefilled Syringe 40 MG/0.4ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Ankylosing Spondylitis (AS): peripheral arthritis must have a trial of sulfasalazine and an NSAID. Patients with axial disease and failure of NSAIDs can be started without a trial of sulfasalazine. 2. Crohn's disease (CD): Inadequate response or intolerance to conventional therapy. For the purpose of this policy, conventional therapy includes the use of ONE of the following: i. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide). ii. Methotrexate iii. Thiopurines (azathioprine, mercaptopurine). 3. Juvenile Idiopathic Arthritis (JIA): An adequate trial (3 months or more) of one of the following DMARDs: i. Leflunomide ii. Methotrexate iii. Sulfasalazine. 4. Plaque Psoriasis (PsO): a. The patient must have at least 3% of their body surface area (BSA) affected by plaque psoriasis (unless on hands, feet, scalp, face, or genital area). b. The disease is severe as defined by a total Psoriasis Area Severity Index (PASI) of at least 5 or more and/or a Dermatology Life Quality Index (DLQI) of more than 5. c. The patient has failed to adequately respond to, or is intolerant, a 3-month trial of a topical agent (topical corticosteroid, topical calcineurin inhibitor, topical vitamin D analogs, etc.). 5. Psoriatic Arthritis (PsA): Documented diagnosis of psoriatic arthritis. 6. Rheumatoid Arthritis (RA): Moderate to severe RA is defined as: DAS-28 more than 3.2 or CDAI more than 10.1. c. An adequate trial (3 months or more) of one of the following other DMARDs: i. Hydroxychloroquine ii. Leflunomide iii. Methotrexate iv. Sulfasalazine 7. Ulcerative Colitis (UC): The member has had an inadequate response to one of the following: aminosalicylates, corticosteroids, thiopurines, or cyclosporine. 8. Hidradenitis Suppurativa (HS): Documented diagnosis of Hurley Stage III HS or refractory Hurley Stage II hidradenitis suppurativa.
Age Restrictions	

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PA Criteria	Criteria Details
Prescriber Restrictions	1. AS/RA/JIA - prescribed by or in consultation with a rheumatologist. 2. CD/UC- prescribed by or in consultation with a gastroenterologist. 3. PsO/HS - prescribed by or in consultation with a dermatologist. 4. PsA - prescribed by or in consultation with a dermatologist or rheumatologist. 5. UC prescribed by or in consultation with a gastroenterologist. 6. UV prescribed by or in consultation with a ophthalmologist.
Coverage Duration	One (1) year
Other Criteria	Uveitis: a. Documented diagnosis of non-infectious intermediate, posterior and panuveitis in adult patients and meets the following: i. A documented trial and failure, contraindication, or intolerance to conventional therapy such as ophthalmic or systemic corticosteroids AND immunosuppressive drugs (e.g. azathioprine, cyclosporine, methotrexate, or tacrolimus). For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy, 2. The appropriate Disease Specific Criteria has been met. CONTINUATION CRITERIA: Documentation of positive response with treatment
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **Hernexeos (zongertinib)**

#### **Products Affected**

• Hernexeos

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **Hetlioz (tasimelteon)**

#### **Products Affected**

• Tasimelteon

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must have a documented diagnosis of (1) Non-24-Hour Sleep-Wake Disorder in adults or (2) Nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older.
Age Restrictions	
Prescriber Restrictions	Sleep Specialist or Neurologist
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	For renewal, chart notes must show clinical response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Hexalen (altretamine)**

#### **Products Affected**

• Hexalen

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class I or IIa recommendation in the Thomson Micromedex DrugDex compendium.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **High Risk Medication - Paroxetine**

#### **Products Affected**

• PARoxetine HCl

• Paxil Oral Suspension

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	You must have taken two (2) of the following drugs: a selective serotonin reuptake inhibitor (SSRI) or a serotonin norepinephrine reuptake inhibitor (SNRI).
Age Restrictions	No Prior Authorization is required if 64 years of age or less.
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## **High Risk Medications**

#### **Products Affected**

• chlordiazePOXIDE HCl

- Scopolamine
- chlorproMAZINE HCl Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	No Prior Authorization is required if 64 years of age or less.
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **High Risk Medications (estrogen containing products)**

#### **Products Affected**

- Abigale
- Abigale Lo
- Alora
- Amabelz
- Dotti
- Estradiol Oral Tablet 2 MG
- Estradiol-Norethindrone Acet
- Estropipate Oral
- Evamist
- Fyavolv
- Jevantique Lo

- Jinteli
- Lopreeza
- Lyllana
- Menest
- Mimvey
- Mimvey Lo
- Norethindrone-Eth Estradiol
- Premarin Oral
- Premphase
- Prempro

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	No Prior Authorization is required if 64 years of age or less.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## **Hydroxyzine HCl and Pamoate**

#### **Products Affected**

- hydrOXYzine HCl Oral Tablet
- hydrOXYzine Pamoate Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Anxiety: Chart notes documenting medications tried and failed (e.g., buspirone, citalopram, fluoxetine, sertraline, duloxetine, venlafaxine). Pruritis: Chart notes documenting past medications used for pruritis (e.g. oral antihistamine, topical steroid).
Age Restrictions	No Prior Authorization is required if 64 years of age or less.
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **Ibrance (palbociclib)**

#### **Products Affected**

• Ibrance

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Ibtrozi (taletrectinib)

#### **Products Affected**

• Ibtrozi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **Iclusig (ponatinib)**

#### **Products Affected**

• Iclusig

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Idhifa (enasidenib)

#### **Products Affected**

• IDHIFA

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Documentation of an isocitrate dehydrogenase-2 (IDH2) mutation detected by an FDA-approved test.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### Imbruvica (ibrutinib)

#### **Products Affected**

- Imbruvica Oral Capsule
- Imbruvica Oral Suspension
- Imbruvica Oral Tablet 140 MG, 280 MG, 420 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Imkeldi (imatinib)

#### **Products Affected**

• Imkeldi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Increlex (mecasermin)**

#### **Products Affected**

• Increlex

PA Criteria	Criteria Details
Exclusion Criteria	Secondary forms of IGF-1 deficiency.
Required Medical Information	Documentation of all of the following: height standard deviation score less than or equal to negative 3, basal IGF-1 standard deviation score less than or equal to negative 3, normal or elevated GH levels, predicted adult height more than 1.5 standard deviations below the mid-parenteral height, growth rate less than 7 cm/year if less than or equal to 3 years old and less than 5 cm if greater than 3 years old, and open epiphyses on bone radiograph.
Age Restrictions	2 to 18 years of age
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Inlyta (axitinib)

### **Products Affected**

• Inlyta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Inqovi (cedazuridine/decitabine)

### **Products Affected**

• Inqovi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Inrebic (fedratinib)

### **Products Affected**

• Inrebic

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Iressa (gefitinib)

### **Products Affected**

• Gefitinib

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Itovebi (inavolisib)

### **Products Affected**

• Itovebi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **Ivermectin (s)**

### **Products Affected**

• Ivermectin Oral Tablet 3 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Strongyloidiasis: Diagnosis of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis OR both of the following: member received the drug within the past 120 days and member requires continuation of therapy. Onchocerciasis: Diagnosis of onchocerciasis due to the nematode parasite Onchocerca volvulus OR both of the following: member received the drug within the past 120 days and member requires continuation of therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Strongyloidiasis: 3 weeks. Onchocerciasis: 6 months.
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Iwilfin (eflornithine)

### **Products Affected**

• Iwilfin

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Jakafi (ruxolitinib)

### **Products Affected**

Jakafi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Jaypirca (pirtobrutinib)

### **Products Affected**

• Jaypirca

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomsn Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six (6) months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Juxtapid (lomitapide)

### **Products Affected**

• Juxtapid

PA Criteria	Criteria Details
Exclusion	
Criteria Criteria	
Required Medical Information	A diagnosis of homozygous familial hypercholesterolemia (HoFH) as defined by the presence of at least one of the following clinical criteria: (1) documented functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality, or (2) skin fibroblast LDL receptor activity less than 20% normal, or (3) untreated total cholesterol (TC) greater than 500 mg/dL and triglycerides (TG) less than 300 mg/dL and both parents with documented untreated TC greater than 250 mg/dL. Patient must have tried and failed a high intensity statin at maximum tolerated dose OR have a documented intolerance or contraindication to statins. Must be used in combination with other lipid-lowering treatments.
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### Jynarque (tolvaptan)

### **Products Affected**

- Tolvaptan Oral Tablet 30 MG
- Tolvaptan Oral Tablet Therapy Pack

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	a. Must be 18 years of age or older. b.Diagnosis of ADPKD and rapidly progressing ADPKD as defined by either a confirmed GFR decline of at least 5 mL/min/1.73 m2 over 1 year and /or 2.5 mL/min/1.73 m2 over a period of 5 years, or a total kidney volume increase of at least 5% per year confirmed by at least 3 repeated ultrasound or MRI measurements taken at least 6 months apart. c. Positive genetic test for ADPKD (mutation in PKD1 or PKD2 gene), OR i. In members aged 18 to less than 40 years with a first degree relative with ADPKD: greater than or equal to 3 cysts (unilateral or bilateral) using any radiologic method. ii. In members aged 40 to less than 60 years with a first degree relative with ADPKD: greater than or equal to 2 cysts per kidney using any radiologic method. iii. In members aged 60 or older with a first degree relative with ADPKD: greater than or equal to 4 cysts per kidney using any radiologic method. d. Must have CKD stage 2 through 4. eGFR is great than or equal to 25 mL/min/1.73 m2.
Age Restrictions	
Prescriber Restrictions	Prescribed by a nephrologist.
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	Continuation criteria: Positive clinical response to therapy as evidenced by slowed kidney function decline and eGFR remains greater than or equal to 25 mL/min/1.73 m2.
Indications	All FDA-approved Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### Kalydeco (ivacaftor)

### **Products Affected**

Kalydeco Oral Packet 25 MG, 50 MG, 75
 Kalydeco Oral Tablet MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	1 month old to 5 years of age: Oral granules. 6 years of age or older: Oral tablets.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Kerendia (finerenone)**

### **Products Affected**

• Kerendia Oral Tablet 10 MG, 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Member has a documented diagnosis chronic kidney disease (CKD) associated with type 2 diabetes (T2D). 2. Diagnosis is defined by one of the following: a. UACR of 30 to 300 mg/g, minimum eGFR of 25 mL/min/1.73 m2, and diabetic retinopathy, or, b. UACR of greater than or equal to 300 mg/g and a minimum eGFR 25 ml/min/1.73 m2. 3. Therapy will not be initiated if serum potassium is greater than 5 mEq/L. 4. Member has been on a maximally tolerated dose of either an angiotensin converting enzymy (ACE) inhibitor or angiotensin receptor blocker (ARB), unless otherwise contraindicated. 5. Mmeber has tried and had an inadequate response or intolerance to a sodium-glucose cotransporter (SGLT2) inhibitor (e.g., Farxiga).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) year
Other Criteria	Continuation criteria: Documentation of positive clinical response to therapy.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **Kineret (anakinra)**

### **Products Affected**

• Kineret Subcutaneous Solution Prefilled Syringe

PA Criteria	Criteria Details
Exclusion Criteria	Will not be approved for use in combination with TNF antagonists.
Required Medical Information	Rheumatoid Arthritis (RA): Moderate to severe RA is defined as: DAS-28 more than 3.2 or CDAI more than 10.1. An adequate trial (3 months or more) of one of the following other DMARDs: hydroxychloroquine, leflunomide, methotrexate, sulfasalazine. Trial and failure of two of the following, unless contraindicated or not tolerated: Amjevita, Enbrel, Hadlima, Xeljanz.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Continuation criteria: Documentation of positive clinical response to treatment.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Kisqali (ribociclib)

#### **Products Affected**

- Kisqali (200 MG Dose)
- Kisqali (400 MG Dose)
- Kisqali (600 MG Dose)
- Kisqali 200 Dose
- Kisqali 400 Dose

- Kisqali 600 Dose
- Kisqali Femara (200 MG Dose)
- Kisqali Femara (400 MG Dose)
- Kisqali Femara (600 MG Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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### **Korlym (mifepristone)**

### **Products Affected**

• miFEPRIStone Oral Tablet 300 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Koselugo (selumetinib)**

### **Products Affected**

• Koselugo Oral Capsule

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Krazati (adagrasib)

### **Products Affected**

• Krazati

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Kuvan (sapropterin)**

### **Products Affected**

• Sapropterin Dihydrochloride

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Initial Authorizations: Medical records documenting all of the following: the target Phe blood level for the patient and dose does not exceed FDA approved maximum for the diagnosis. Renewal: Recent Phe level is at target range.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial authorization: 2 months Renewal: 6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Lazcluze (lazertinib)

### **Products Affected**

• Lazcluze

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### Lenvima (lenvatinib)

#### **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)

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PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **Leukine (sargramostim)**

### **Products Affected**

• Leukine Injection Solution Reconstituted • Leukine Intravenous

PA Criteria	Criteria Details
Exclusion Criteria	Combination use with pegfilgrastim or filgrastim.
Required Medical Information	Medical records documenting neutropenia which is defined as an absolute neutrophil count less than 500/mm3.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Lidoderm (lidocaine topical patch)**

### **Products Affected**

• Lidocaine External Patch 5 %

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Livtencity (maribavir

### **Products Affected**

• Livtencity

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Patient is 12 years of age or older. 2. History of hematopoietic stem cell transplant or solid organ transplant. 3. Diagnosis of post-transplant CMV infection/disease with CMV DNA of 2730 IU/mL or greater in whole blood or 910 IU/mL or greater in plasma. 4. CMV disease refractory to previous treatment with intravenous ganciclovir, valganciclovir, foscarnet, or cidofovir. 5. Patient should not be on any other CMV antivirals.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Eight (8) Weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Lonsurf (tipiracil/trifluridine)**

### **Products Affected**

• Lonsurf

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Lorbrena (lorlatinib)

### **Products Affected**

• Lorbrena

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Lotronex (alosetron)**

### **Products Affected**

• Alosetron HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Diagnosis of severe diarrhea-predominant irritable bowel sdrome (IBS) with symptoms persisting for at least six (6) months. 2. Patient was female at birth. 3. Patient has not responsed adequately to conventional therapy (i.e., lopermaide, antispasmodics).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **Lumakras (sotorasib)**

### **Products Affected**

• Lumakras

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Lybalvi

### **Products Affected**

• Lybalvi

PA Criteria	Criteria Details
Exclusion Criteria	Know opioid use disorder or is dependent on opioids for a chronic health condition. Patients undergoing acute opioid withdrawal.
Required Medical Information	1. Schizophrenia: a. Trial and failure of two (2) atypical antipsychotics for a minimum of 4 weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, OR member has a current diagnosis of metabolic syndrome, pre-metabolic syndrome, or diabetes mellitus and has failed aripiprazole AND ziprasidone, unless there is a documented contraindication or intolerance. 2. Bipolar: a. Monotherapy: Trial and failure of three alternatives from the following: i. lamotrigine, ii. lithium, iii. carbamazepine, iv. valproic acid, v. Atypical Antipsychotics (e.g., aripiprazole, lurasidone, quetiapine). b. adjunct therapy: will be used with either lithium or valproic acid.
Age Restrictions	18 years of age or older.
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	Patient does not have a known opioid use disorder or is dependent on opioids for a chronic health condition. There should be a 7-day opioid-free interval from the last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

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# Lynparza (olaparib)

### **Products Affected**

• Lynparza

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Lyrica CR (pregabalin)

### **Products Affected**

• Pregabalin ER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Trial and failure of gabapentin and Lyrica capsule
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Lytgobi (futibatinib)

### **Products Affected**

- Lytgobi (12 MG Daily Dose)
- Lytgobi (20 MG Daily Dose)
- Lytgobi (16 MG Daily Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomsn Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six (6) months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Marinol (dronabinol)**

### **Products Affected**

• Dronabinol

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	If using for nausea and vomiting associated with cancer chemotherapy, the patient must be receiving cancer chemotherapy and has failed one 5-HT3 antagonist and one of the following: corticosteroid, anti-histamine, anti-psychotic, or prokinetic. If using for anorexia associated with weight loss due to HIV/AIDS, the patient must have a trial and failure, contraindication or intolerance to Megace ES (megestrol oral suspension).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# Matulane (procarbazine)

#### **Products Affected**

• Matulane

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Mavyret (glecaprevir/pibrentasvir)**

#### **Products Affected**

• Mavyret

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medical records documenting the diagnosis of chronic Hepatitis C, including laboratory documentation of genotype and subtype, detectable HCV RNA levels at baseline, HIV status and liver transplant status.
Age Restrictions	3 year of age and older.
Prescriber Restrictions	Gastroenterologist or Infectious Disease specialist or Hepatologist
Coverage Duration	Duration as per package insert or Class I or II recommendation by the AASLD/IDSA/IAS-USA guidelines
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **Mekinist (trametinib)**

#### **Products Affected**

• Mekinist

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **MEKTOVI** (binimetinib)

#### **Products Affected**

• Mektovi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### Modeyso (dordavipron)

#### **Products Affected**

• Modeyso

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Movantik (naloxegol)**

#### **Products Affected**

• Movantik

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chart notes documenting a trial/failure of lactulose oral or lubiprostone.
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### **Muscle Relaxants**

#### **Products Affected**

• Cyclobenzaprine HCl Oral

• Orphenadrine Citrate ER

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Prior authorization required for patients 65 years of age and older.
Age Restrictions	Prior authorization required for patients 65 years of age and older.
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Natpara (parathyroid hormone)

#### **Products Affected**

• Natpara

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medical records must document a diagnosis of hypocalcemia due to chronic hypoparathyroidism. The prescriber must provide documentation that the patient must has a normal 25-hydroxyvitamin D level and a serum calcium level above 7.5mg/dL. For renewal the albumin-corrected total serum calcium level between 7.5 mg/dL and 10.6 mg/dL should be achieved with standard of care.
Age Restrictions	
Prescriber Restrictions	Endocrinologist
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **Nerlynx (neratinib)**

#### **Products Affected**

• Nerlynx

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	Lab values for total bilirubin, AST, ALT, and alkaline phosphate levels prior to starting treatment.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Nexavar (sorafenib)

#### **Products Affected**

• SORAfenib Tosylate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Nexletol (bempedoic acid)**

#### **Products Affected**

• Nexletol

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Nexletol will be approved if the following is met: 1. One of the following diagnoses: a. primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). b. Established cardiovascular disease (CVD) as documented by one of the following: coronary artery disease, symptomatic peripheral arterial disease, cerebrovascular atherosclerotic disease. 2. High risk for cardiovascular disease (CVD) as documented by one of the following: a. diabetes and over 60 years old. b. Reynolds risk score greater than 30%. c. Coronary artery calcium score greater than 400 Agatston units. d. ASCVD risk score greater than or equal to 20% with the American College of Cardiology/American Heart Association (ACC/AHA) risk estimator. 2. AND - one of the following: a patient has been receiving at least 12 consecutive weeks of high intensity statin therapy and will continue to receive at a maximally tolerated dose. OR - both of the following: a. patient is unable to tolerate high intensity statin as evidences by one of the following: i. myalgia. ii. myositis. 3. AND - one of the following: Documentaiton of one of the following LDL-C values while on maximally tolerated lipid lowering therapy for at least 12 weeks within the pas 120 days: a. LDL-C greater than or equal to 100 mg/dL with ASCVD. b. LDL-C greater than or equal to 100 mg/dL with ASCVD. OR - both of the following: a. LDL-C between 55 mg/dL and 99 mg/dL with ASCVD. b. LDL-C between 100 mg/dL and 129 mg/dL without ASCVD. AND - Patient has been receiving at least 12 consecutive weeks of ezetimibe therapy as adjunct to maximally tolerated statin therapy, unless contraindicated or not tolerated.
Age Restrictions	
Prescriber Restrictions	

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PA Criteria	Criteria Details
Coverage Duration	One (1) year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### Ninlaro (ixazomib)

#### **Products Affected**

• Ninlaro

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Northera (droxidopa)

#### **Products Affected**

• Droxidopa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	2 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Noxafil (posaconazole)

#### **Products Affected**

• Posaconazole Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	2 years of age and older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# Nubeqa (darolutamide)

#### **Products Affected**

• Nubeqa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Nuedexta (dextroamphetamine / quinidine)

#### **Products Affected**

• Nuedexta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chart notes documenting a neurological disease or injury. Chart notes documenting a diagnosis of Pseudobulbar Affect (PBA) secondary to a neurological disease or injury (e.g. Multiple Sclerosis, ALS, Parkinson's, stroke, traumatic brain injury). Documentation of the number of PBA episodes per day. Chart notes documenting medications tried/failed to reduce the number of PBA episodes. If the prescriber is not a specialist then the referral notes of the specialist must be submitted. Baseline Center for Neurologic Study-Lability Scale (CNS-LS) score of 13 or greater.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by or in consultation with a neurologist.
Coverage Duration	Initial: 3 months Continuation of therapy: 6 months
Other Criteria	Continuation of Treatment Criteria: medical records documenting the following: 1. A decrease in the CNS-LS score and the decrease has been maintained. 2. A decrease in the number of daily episodes.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### Nuplazid (pimavanserin)

#### **Products Affected**

• Nuplazid Oral Capsule

• Nuplazid Oral Tablet 10 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	For renewal: Chart notes must document an improvement in psychosis symptoms from baseline and demonstrates a continued need for treatment.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Nurtec (rimegepant)**

#### **Products Affected**

• Nurtec

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Episodic Migraine. All of the following must be met: a. The patient has 4 to 14 migraine days per month. b. The patient does not have chronic migraine, defined as 15 or more headache days per month, with 8 or more migraine days per month for at least 3 months. c. The patient has been evaluated for and does not have medication overuse headache. Medication overuse is defined as: i. Headache occurring on 15 or more days per month in a patient with preexisting headache disorder. ii. Regular overuse for more than 3 months of one or more drugs that can be taken for acute and/or symptomatic treatment of headache, with overuse defined as: Ten or more days/month for ergot derivatives, triptans, opioids, combination analgesics, and a combination of drugs from different classes that are not individually overused, and fifteen or more days per month for nonopioid analgesics, acetaminophen, and NSAIDs. d. The patient has tried and failed a 3 month trial of at least one prophylactic medication from one of the follow classes: i. anticonvulsants (e.g., divalproex, valproate, topiramate). ii. Beta-blockers (e.g., metoprolol, propranolol, timolol). iii. Antidepressants (e.g., amitriptyline, venlafaxine). e. The patient has failed a 3 month trial of one injectable CGRP therapy (e.g., Aimovig). 2. Acute Treatment. All of the following must be met: a. The member has a documented trial and failure of two formulary oral triptans, unless otherwise contraindicated or not tolerated (e.g., patients with coronary artery disease, peripheral vascular disease, uncontrolled hypertension, and other vascular risk factors and disorders). b. The member is currently being treated with one of the follow prophylactic medications: i. anticonvulsants (e.g., divalproex, valproate, topiramate). ii. Beta-blockers (e.g., metoprolol, propranolol, timolol). iii. Antidepressants (e.g., amitriptyline, venlafaxine). iv. Botox
Age Restrictions	18 years or older.

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PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or headache specialist.
Coverage Duration	Initial: 3 months. Continuation: 1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Nuvigil (armodafinil)

#### **Products Affected**

• Armodafinil

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	If using for obstructive sleep apnea (OSA), must provide documentation that the patient has OSA and has been evaluated by a sleep specialist.
Age Restrictions	
Prescriber Restrictions	Neurologist or Sleep Specialist
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Ocrevus (ocrelizumab)

#### **Products Affected**

• Ocrevus

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chart notes documenting a diagnosis of Primary Progressive Multiple Sclerosis. Patients with primary progressive multiple sclerosis will not be required to have a trial and failure of other medications. Diagnosis of Relapsing Multiple Sclerosis, chart notes must document a trial/failure of interferon or glatiramer.
Age Restrictions	
Prescriber Restrictions	Neurologist
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# Odomzo (sonidegib)

#### **Products Affected**

• Odomzo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Ofev (nintedanib)

#### **Products Affected**

Ofev

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Idiopathic Pulmonary Fibrosis: a. Diagnosis confirmed by high-resolution computed tomography (HRCT). b. Exclusion of other known causes such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity. c. Baseline Forced Vital Capacity (FVC) greater than or equal to 50% (pulmonary function tests - PFTs - within the past 60 days). 2. Systemic Sclerosis-associated Interstitial Lung Disease: a. High-resolution computed tomography showing fibrosis affecting greater than or equal to 10%. b. Baseline Forced Vital Capacity (FVC) greater than or equal to 40% (pulmonary function tests - PFTs- within the past 60 days). 3. Chronic Fibrosis Interstitial Lung Disease: a. Progressive phenotype (e.g., hypersensitivity pneumonitis, autoimmune interstitial lung disease, idiopathic nonspecific interstitial pneumonia). b. High-resolution fibrosis affecting greater than or equal to 10% of the lungs. c. Progressive disease has been demonstrated by one of the following within the past 24 months: i. Forced Vital Capacity (FVC) decline greater than or equal to 10% - OR - ii. Two of the following: FVC decline greater than or equal to 5% and less than 10%, worsening respiratory symptoms, increased fibrosis on HRCT.
Age Restrictions	18 years or older
Prescriber Restrictions	Pulmonologist
Coverage Duration	1 year
Other Criteria	Baseline Liver Function tests
Indications	All FDA-approved Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **Ogsiveo (nirogacestat)**

#### **Products Affected**

• Ogsiveo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six (6 months)
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Ojemda (tovorafenib)

#### **Products Affected**

• Ojemda

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six (6) months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Ojjaara (momelotinib)

#### **Products Affected**

• Ojjaara

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **Omnitrope (somatropin)**

#### **Products Affected**

• Omnitrope

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Adult onset growth hormone deficiency (GHD) - Multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma. a) Patient has greater than or equal to 2 of the following pituitary hormone deficiencies: thyroid stimulating hormone deficiency, adrenocorticotropin hormone deficiency, gonadotropin deficiency, an arginine vasopressin (AKA vasopressin or antidiuretic hormone (ADH)) deficiency. b) Low serum IGF-I. c) Patient must exhibit clinical features of adult GHD including: increased body fat, decreased muscle mass, poor exercise performance, decreased bone density, and cardiovascular risk factors (high LDL, low HDL). d) Documentation of baseline information (IGF-I levels, lipids, bone density, cardiovascular factors, body composition, exercise capacity) provided with each request. Childhood onset GHD - Adults who were GH deficient as children or adolescents. a) Patient has subnormal response to at least 2 provocative stimulation tests (less than or equal to 5 ng/ml) following a GH washout period of 1-3 months. b) Patient must exhibit clinical features of adult GHD including: increased body fat, decreased muscle mass, poor exercise performance, decreased bone density, and cardiovascular risk factors. c) Documentation of baseline information (IGF-I levels, lipids, bone density, cardiovascular factors, body composition, exercise capacity) provided with each request.
Age Restrictions	
Prescriber Restrictions	Endocrinologist
Coverage Duration	1 year
Other Criteria	

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PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **Onureg (Azacitidine)**

#### **Products Affected**

• Onureg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Opipza (aripiprazole)

#### **Products Affected**

• Opipza

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation that the patient has tried/failed aripiprazole tablets.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Opsumit (macitentan)**

#### **Products Affected**

• Opsumit

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Member has a confirmed diagnosis or primary or secondary pulmonary arterial hypertension (WHO Group 1) by right heart catherization. 2. Confirmed diagnosis will show the following: mean arterial pressure (mPAP) greater than 20 mmHG at rest, pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHG, pulmonary vascular resistance greater than 3 wood units. 3. Member has WHO functional class II-IV symptoms. 4. Inadequate response to bosentan or ambrisentan, unless contraindicated or not tolerated.
Age Restrictions	18 years or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	Initial: six (6) months. Continuation: one (1) year.
Other Criteria	Chart notes documenting clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea, and/or functional class.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### Orencia (abatacept SubQ)

#### **Products Affected**

• Orencia ClickJect

• Orencia Subcutaneous Solution Prefilled Syringe

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Rheumatoid Arthritis (RA): Moderate to severe RA is defined as: DAS-28 more than 3.2 or CDAI more than 10.1. Inadequate response, unless contraindicated or not tolerated to two of the following: Amjevita, Enbrel, Hadlima, Xeljanz. 2. Juvenile Idiopathic Arthritis (JIA): Inadequate response to two of the following, unless contraindicated or not tolerated: Amjevita, Enbrel, Hadlima, Xeljanz. 3. Psoriatic Arthritis (PsA): Inadequate response to two of the following, unless contraindicated or not tolerated: Amjevita, Enbrel, Hadlima, Xeljanz.
Age Restrictions	
Prescriber Restrictions	1. RA/JIA - Prescribed by or in consultation with a rheumatologist. 2. PsA - prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	1 year
Other Criteria	CONTINUATION CRITERIA: Documentation of positive clinical response to treatment.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **Orfadin (nitisinone)**

#### **Products Affected**

• Nitisinone

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Orgovyx (Relugolix)

#### **Products Affected**

• Orgovyx

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Orkambi (ivacaftor/lumacaftor)

### **Products Affected**

• Orkambi Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	1 year and older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Orserdu (elacestrant)

### **Products Affected**

• Orserdu

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomsn Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six (6) months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Otezla (apremilast)

### **Products Affected**

• Otezla

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Psoriatic Arthritis, active (PsA): The patient has had at least a trial and failure of two of the following: Amjevita, Enbrel, Hadlima, or Xeljanz. Plaque psoriasis (PsO): a. For mild to moderate PsO: patient has had an inadequate response to topical treatment (e.g., corticosteroids, vitamin D analog, calcineurin inhibitor). b. For moderate to severe PsO: The patient must have greater than 3% of their body surface area (BSA) affected by plaque psoriasis. i. Moderate to severe disease is defined by a total Psoriasis Area Severity Index (PASI) of at least 5 or more and/or a Dermatology Life Quality Index (DLQI) of more than 5. ii. The patient has failed to adequately respond to two of the following: Amjevita, Enbrel, Hadlima. Behcet's syndrome: Documented diagnosis of Behcet's syndrome.
Age Restrictions	Approved for patients 6 years of age or older
Prescriber Restrictions	Must be prescribed by or in consultation with a Rheumatologist, Dermatologist or Ophthalmologist
Coverage Duration	Intial: 6 months Reauthorization: 1 year
Other Criteria	Reauthorization: Documentation of positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### **Parathyroid Hormone Analogs**

#### **Products Affected**

 Teriparatide Subcutaneous Solution Pen-Injector 560 MCG/2.24ML, 620 MCG/2.48ML

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Bone Mineral Density (BMD) T-score -3.5 or less based on BMD measurements from lumbar spine, femoral neck, total hip, and/or one-third radius (wrist) -OR- 2.Bone mineral density (BMD) T-score between -2.5 and -3.5 in the lumbar spine, femoral neck, total hip, and/or one-third radius (wrist) -AND- a. History of one of the following: i. Vertebral compression fracture ii. Fracture of the hip iii. Fracture of the distal radius iv. Fracture of the pelvis v. Fracture of the proximal humerus -OR- 3. BMD T-score between -1.0 and -2.5 and one of the following FRAX 10-year fracture probabilities: i. Major osteoporotic fracture at 20% or more ii. Hip fracture at 3% or more -OR- 4. History of failure, contraindication, or intolerance to an intravenous bisphosphonate AND Prolia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) year. No more than two years cumulative with PTH analogs
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	Yes

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PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

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## **Pemazyre (pemigatinib)**

### **Products Affected**

• Pemazyre

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Piqray (alpelisib)

### **Products Affected**

- Piqray (200 MG Daily Dose)
- Piqray (300 MG Daily Dose)
- Piqray (250 MG Daily Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Pomalyst (pomalidomide)**

### **Products Affected**

• Pomalyst

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Prolastin (alpha-1-proteinase inhibitor [human])

### **Products Affected**

• Prolastin-C

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The member has a diagnosis of congenital alpha1-antitrypsin deficiency with clinically evident emphysema and chronic replacement therapy is needed. The member has an alpha1-antitrypsin phenotype of PiZZ, PiZ(null), or Pi (null, null) or phenotypes associated with serum alpha 1-antitrypsin concentrations of less than 50mg/dL if/when measured by laboratories using nephelometry instead of radial immunodiffusion. Otherwise, a deficiency is shown at 80mg/dL. (These products should not be used in individuals with the PiMZ or PiMS phenotypes of alpha1-antitrypsin deficiency because these individuals appear to be at small risk of developing clinically evident emphysema.)
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months Continuation: 1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## Promacta (eltrombopag olamine)

### **Products Affected**

• Eltrombopag Olamine

PA Criteria	Criteria Details
Exclusion Criteria	Coverage will not be provided when used in combination with Nplate.
Required Medical Information	If using for idiopathic thrombocytopenia, patient must have a trial and failure or contraindication to at least two of the following treatments: corticosteroids, immunoglobulin, or splenectomy. Dose may not exceed the FDA-approved maximum dose. If using for thrombocytopenia due to chronic hepatitis C, and the patient is currently on antiviral interferon therapy or will be starting interferon therapy, the patient must have a platelet count less than 75,000/microliter. Severe aplastic anemia (initial): Diagnosis of severe aplastic anemia. Patient has a platelet count less than 30,000/microliter. Trial and failure, intolerance, or contraindication to immunosuppressive therapy with antithymocyte globulin and cyclosporine. First-line treatment of severe aplastic anemia in combination with standard immunosuppressive therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### **Pulmonary Arterial Hypertension - ERA**

### **Products Affected**

• Ambrisentan

### • Bosentan Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	Pregnancy, Idiopathic Pulmonary Fibrosis
Required Medical Information	1. Member has a confirmed diagnosis of primary or secondary pulmonary arterial hypertension (WHO Group 1) by right heart catherization. 2. Confirmed diagnosis will show all of the following: a) Mean pulmonary artery pressure (mPAP) greater than 20 mmHG at rest, b) Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg, c) Pulmonary vascular resistance greater than 3 Wood units. 3. Individual has WHO functional class II-IV symptoms.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	Initial: 6 months Continuation: 1 year
Other Criteria	Continuation criteria: Chart notes documentating clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in walk distance, dyspnea, and/or functional class).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## **Purixan (mercaptopurine)**

### **Products Affected**

• Mercaptopurine Oral Suspension

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Qinlock (ripretinib)**

### **Products Affected**

• Qinlock

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Qualaquin (quinine sulfate)

### **Products Affected**

• QuiNINE Sulfate Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 month
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## Raldesy (trazodone)

### **Products Affected**

• Raldesy

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documentation that the patient ahs tried/failed trazodone tablets.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Rebyota (fecal microbiota, live - jslm)

### **Products Affected**

• Rebyota

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For the prevention of the recurrence of Clostridioides Difficle (rCDI) infection in patients who meet all of the criteria: Diagnosis of recurrent Clostridioides Difficile Infection (CDI) as defined by both of the following: Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2consecutive day, and A positive stool test for Clostridioides difficile toxin, and Patient is 18 years of age or older, and Patient has had one or more recurrence(s) of CDI following an initial episode of CDI, and Both of the following: Patient has completed at least 10 days of one of the following antibiotic therapies for rCDI between 24 to 72 hours prior to initiating Rebyota: Oral vancomycin, or Dificid (fidaxomicin) and Previous episode of CDI is under control [e.g., less than 3 unformed/loose (i.e., Bristol Stool Scale type 6-7) stools/day for 2 consecutive days] and Prescribed by or in consultation with one of the following: Gastroenterologist, Infectious disease specialist. Authorization will be issued for a single dose treatment only.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) month
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

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Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### **Relistor (methylnaltrexone)**

### **Products Affected**

• Relistor Oral

• Relistor Subcutaneous Solution

PA Criteria	Criteria Details
Exclusion Criteria	Non-opioid induced constipation. Fecal impaction. Acute diverticular disease. Acute surgical abdomen.
Required Medical Information	Documentation that the patient is on chronic opioid therapy, and documented trial and failure of naloxegol (for approval of oral tablets only). Documented trial and failure of naloxegol not required for injection.
Age Restrictions	18 years or older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### Repatha (evolocumab)

### **Products Affected**

• Repatha

• Repatha SureClick

PA Criteria	Criteria Details
Exclusion Criteria	Homozygous Familial Hypercholesterolemia (HoFH) for members with two LDL receptor negative alleles. Will not be approved for use in combination with another proprotein convertase subtilsin/kexin type 9 (PCSK9) inhibitor.
Required Medical Information	Chart notes documenting one of the following diagnoses: 1) Atherosclerotic cardiovascular disease (ASCVD) (e.g. Acute coronary syndrome, history of myocardial infarction, angina, arterial revascularization, stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin) OR 2) Heterozygous Familial Hypercholesterolemia (HeFH) OR 3) Homozygous Familial Hypercholesterolemia (HoFH), OR 4) Primary Hyperlipidemia. For HeFH: results of Dutch Lipid Clinic diagnostic criteria score greater than or equal to 9. For HoFH: results of a genetic test OR an untreated LDL level over 500mg/dl AND the presence of xanthoma before 10 years old or evidence of HeFH in both parents AND 1 of the following: 1)Member has received at least 3 months of high intensity (HI) statin at maximum tolerated dose (MTD), OR 2) Member can't tolerate HI statin and has received 3 months of a moderate intensity statin or a low intensity statin at a MTD, OR 3) Member is unable to tolerate two statin medications, one of which is HI OR 4)Member has a contraindication to all statins documented in chart notes, OR 5) Member has experienced rhabdomyolysis. Member has been on at least 3 months of ezetimibe therapy as adjunct to MTD of statin therapy and will continue to receive it OR Member has history of, failure, contraindication or intolerance to ezetimibe. Chart notes within the past 30 days documenting baseline and a current lipid panel while on maximum tolerated lipid lowering regimen.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with one of the following: cardiologist, endocrinologist, or lipid specialist.

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PA Criteria	Criteria Details
Coverage Duration	Initial: 6 months, Continuation: 1 year
Other Criteria	High intensity statins: atorvastatin 40-80mg, rosuvastatin 20-40mg. Moderate intensity statins: atorvastatin 10-20mg, rosuvastatin 5-10mg, simvastatin 20mg or more, pravastatin 40mg or more, lovastatin 40mg, fluvastatin XL 80mg, fluvastatin 40mg twice daily, or pitavastatin 2mg or more. Low intensity statins: simvastatin 10mg, pravastatin 10-20mg, lovastatin 20mg, fluvastatin 20-40mg, pitavastatin 1mg. Statin intolerance for the purposes of this criteria is defined as documented intolerable and persistent symptoms of myalgia or signs of myositis. Two or three injections monthly will be approved for HeFH, ASCVD or Primary Hyperlipidemia. Three injections monthly will be approved for HoFH. Renewal: Chart notes, lab values documenting a decrease in LDL after initiation of therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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## **Retevmo (selpercatinib)**

### **Products Affected**

• Retevmo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Revatio (sildenafil)

### **Products Affected**

• Sildenafil Citrate Oral Tablet 20 MG

PA Criteria	Criteria Details
Exclusion Criteria	Sildenafil is excluded from coverage for the treatment of Erectile Dysfunction.
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Revcovi (elapegademase-lvlr)

### **Products Affected**

• Revcovi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	a. Diagnosis of adenosine deaminase deficiency (ADA) with Severe Combined Immunodeficiency (SCID) phenotype confirmed by one of the following: i.Absent ADA levels in lysed erythrocytes from fresh blood samples or dried blood spots. ii. Marked increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates (with levels that vary by laboratory). iii. Decrease in ATP concentration in red blood cells. iv. Absent or extremely low levels of S-adenosylhomocysteine hydrolase in red blood cells. v. Increase in 2'-deoxyadenosine in urine and plasma, as well as in dried blood spots vi. Genetic testing showing biallelic variants in the ADA1 gene. b.Patient does not have thrombocytopenia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## **Revlimid (lenalidomide)**

### **Products Affected**

• Lenalidomide

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Revuforj (revumenib)

### **Products Affected**

• Revuforj

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## Rexulti (brexpiprazole)

### **Products Affected**

• Rexulti

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Major Depressive Disorder (MDD): Must be used as adjunctive or add on treatment for MDD, not as monotherapy, AND a. The patient must have a documented trial and failure (minimum of 4 weeks) of at least one (1) drug from the following classes: SSRI, SNRI, bupropion, or mirtazapine, AND b. Trial and failure of aripiprazole or quetiapine in combination with an antidepressant for at least four (4) weeks. 2. Schizophrenia: Trial and failure of two (2) atypical antipsychotics for a minimum of four (4) weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, OR member has a current diagnosis of metabolic syndrome, pre-metabolic syndrome, or diabetes mellitus and has failed aripiprazole and ziprasidone, unless there is a documented contraindication or intolerance. 3. Documented diagnosis of agitation associated with dementia due to Alzheimer's disease (AD).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

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# Rezdiffra (resmetirom)

### **Products Affected**

• Rezdiffra

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	a. 18 years or older. b. Diagnosis confirmed with F2/F3 fibrosis by biopsy. c. For patients with BMI greater than 27, a trial of lifestyle interventions for at least 3 months, with a goal of at least 5% to 10 %, before initiating Rezdiffra. d. No history of significant alcohol consumption (more than 20 g per day for women and more than 30 g per day for men) for a period of more than 3 consecutive months within 1 year prior to screening. e. Prescribed by or in consultation with a hepatologist or gastroenterologist.
Age Restrictions	
Prescriber Restrictions	Hepatologist or gastroenterologist.
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	Continuation criteria: positive clinical response to therapy as evidenced by improvement in liver fibrosis and no worsening of steatohepatits.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Rezlidhia (olutasidenib)

### **Products Affected**

• Rezlidhia

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomsn Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six (6) months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Rezurock (belumosudil)

### **Products Affected**

Rezurock

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Diagnosis of chronic graft-versus-host disease (GVHD). 2. History of failure of at least two prior lines of systemic therapy (e.g., corticosteroids, mycophenolate, tacrolimus, etc.).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) year
Other Criteria	Continuation criteria: positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## Romvimza (vimseltinib)

### **Products Affected**

• Romvimza

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **Rozlytrek (entrectinib)**

### **Products Affected**

• Rozlytrek

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Rubraca (rucaparib)

### **Products Affected**

• Rubraca

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Rydapt (midostaurin)

### **Products Affected**

• Rydapt

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Scemblix**

### **Products Affected**

• Scemblix

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Secuado (asenapine transdermal)

### **Products Affected**

• Secuado

PA Criteria	Criteria Details
Exclusion Criteria	Patients with dementia-related psychosis
Required Medical Information	1. Schizophrenia: a. Trial and failure of two (2) atypical antipsychotics for a minimum of 4 weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, OR member has a current diagnosis of metabolic syndrome, pre-metabolic syndrome, or diabetes mellitus and has failed aripiprazole AND ziprasidone, unless there is a documented contraindication or intolerance.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# Signifor (pasireotide)

#### **Products Affected**

• Signifor

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Patient must have a baseline 24-hour urine free cortisol (UFC) greater than 1.5 times the upper limit of normal (ULN).
Age Restrictions	18 years or older
Prescriber Restrictions	Endocrinologist
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Siklos (hydroxyurea)

#### **Products Affected**

• Siklos

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Sirturo (bedaquiline)

#### **Products Affected**

• Sirturo Oral Tablet 100 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Must be used in combination with at least 3 other drugs to which the patient's multi-drug resistant tuberculosis (MDR-TB) isolate has been shown to be susceptible in vitro.
Age Restrictions	5 years of age and weighing at least 15 kg
Prescriber Restrictions	Infectious Disease
Coverage Duration	24 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Solaraze**

#### **Products Affected**

- Diclofenac Sodium External Gel 3 %
- Diclofenac Sodium Transdermal Gel 3 %

PA Criteria	Criteria Details
Exclusion Criteria	Treatment of osteoarthritis, pain
Required Medical Information	Documented diagnosis of actinic keratosis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	90 days
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Somavert (pegvisomant)**

#### **Products Affected**

• Somavert

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documented diagnosis of acromgaly by 1) serum growth hormone (GH) level greater than 1 ng/mL after a 2 hour oral glucose tolerance test (OGTT) at time of diagnosis, or 2) elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician) at the time of diagnosis. The member must have also had an inadequate respone to surgery, radiotherapy, or a dopamine agonist (e.g., cabergoline, bromoctiptine), or is not a candidate for surgery, radiothearpy, or dopamine agonist therapy.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 3 months Continuation: 1 year
Other Criteria	Continuation criteria: Documentation of positive clinical response to thearpy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# **Sprycel (dasatinib)**

#### **Products Affected**

• Dasatinib

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Stelara (ustekinumab)

#### **Products Affected**

- Stelara Subcutaneous Solution 45 MG/0.5ML
- Stelara Subcutaneous Solution Prefilled Syringe
- Ustekinumab Subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of moderate to severe Plaque Psoriasis (PsO). The patient must have greater than 3% of their body surface area (BSA) affected by plaque psoriasis). The disease is defined by a total Psoriasis Area Severity Index (PASI) of at least 5 or more and/or a Dermatology Life Quality Index (DLQI) of more than 5. The patient has failed to adequately respond to two of the following: Amjevita, Cosentyx, Enbrel, or Hadlima. Diagnosis of active Psoriatic Arthritis (PsA). The patient has failed to adequately respond to two of the following: Amjevita, Cosentyx, Enbrel, Hadlima, or Xeljanz. Crohns Disease (CD): For induction and maintaining clinical remission in patients with moderately to severely active Crohns Disease who have had an inadequate response or intolerance to conventional therapy. For the purpose of this policy, conventional therapy includes the use of ONE of the following: i. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide). ii. Methotrexate iii. Thiopurines (azathioprine, mercaptopurine). Inadequate response to Amjevita, Hadlima. Diagnosis of moderate to severe active Ulcerative Colitis (UC). The member has had a failed to have an adequate response to Amjevita or Hadlima and Xeljanz.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: six (6) months. Renewal: one (1) year.
Other Criteria	Continuation: Documentation of a positive clinical response to therapy.

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PA Criteria	Criteria Details
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# Stivarga (regorafenib)

#### **Products Affected**

• Stivarga

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Strensiq (asfotase alfa)

#### **Products Affected**

• Strensiq Subcutaneous Solution 40 MG/ML, 80 MG/0.8ML

PA Criteria	Criteria Details
Exclusion Criteria	Adult-onset hypophosphatasia
Required Medical Information	Documented diagnosis of perinatal/infantile onset or juvenile-onset hypophosphatasia (HPP) confirmed by all of the following: a)Patient is less than or equal to 18 at age of onset of disease, b)Radiographic evidence of HPP, c)Rachitic deformities, d)premature loss of primary teeth prior to age 5, e)Delay in skeletal growth resulting in delay of motor development, f)History or presence of non-traumatic fractures or delayed fracture healing. Molecular genetic testing and results for mutation(s) in the ALPL gene. Baseline serum alkaline phosphatase (ALP), below normal range for patients age. Serum vitamin B-6 levels, elevated and the patient has not received vitamin B6 supplementation in the previous week. Elevated serum or urine Phosphoethanolamine (PEA) level. Baseline ophthalmologic exam and renal ultrasound being monitored for signs and symptoms of ectopic calcifications.
Age Restrictions	
Prescriber Restrictions	Must be prescribed by, or in consultation with, an endocrinologist, geneticist or a metabolic specialist.
Coverage Duration	6 months
Other Criteria	Continuation criteria: Documentation that the patient is tolerating treatment and responding to treatment, as evidenced by improvement in respiratory status, or radiographic findings. Dose is not to exceed FDA label maximum. Strensiq can be injected three times per week or six times per week. Strensiq is only covered as a three times per week injection.
Indications	All FDA-approved Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## **Sutent (sunitinib)**

#### **Products Affected**

• SUNItinib Malate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Sylatron (peginterferon alfa-2b)

#### **Products Affected**

• Sylatron Subcutaneous Kit 200 MCG, 300 MCG, 600 MCG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class I or IIa recommendation in the Thomson Micromedex DrugDex compendium.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Symdeko (ivacaftor / tezacaftor)

#### **Products Affected**

• Symdeko

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	6 years of age and older
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Synarel (nafarelin acetate)**

#### **Products Affected**

• Synarel

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Endometriosis: Documented contraindication, intolerance, or treatment failure with Lupron Depot (leuprolide).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

# **Tabloid (thioguanine)**

#### **Products Affected**

• Tabloid

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Tabrecta (capmatinib)

#### **Products Affected**

• Tabrecta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### **Tadalafil**

#### **Products Affected**

• Tadalafil Oral Tablet 5 MG

PA Criteria	Criteria Details
Exclusion Criteria	Erectile Dysfunction
Required Medical Information	Diagnosis of benign prostatic hyperplasia.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	
Indications	Some FDA-approved Indications Only.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Tafinlar (dabrafenib)

#### **Products Affected**

• Tafinlar

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# **Tagrisso (osimertinib)**

#### **Products Affected**

• Tagrisso

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Takhzyro (lanadelumab-flyo)

#### **Products Affected**

• Takhzyro

PA Criteria	Criteria Details
Exclusion Criteria	Not to be used in combination with other prophylactics (Cinryze or Haegarda)
Required Medical Information	A diagnosis of hereditary angioedema (HAE) has been clinically established by or in consultation with an Allergist or Immunologist.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	4 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Talzenna (talazoparib)

#### **Products Affected**

• Talzenna

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Tarceva (erlotinib)

#### **Products Affected**

• Erlotinib HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Targretin (bexarotene)**

#### **Products Affected**

• Bexarotene

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Tasigna (nilotinib)

#### **Products Affected**

• Nilotinib HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Tavneos (avacopan)

#### **Products Affected**

• Tavneos

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of of severe active anti-neutrophil cytoplasmic autobody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]. Positive test of either anti-PR3 or anti-MPO. At least 1 major item, 3 non-major items, or 2 renal items or proteinuria and hematuria on the Birmingham Vasculitis Activity Score (BVAS). eGFR of 15 mL/min/1.72 squared or more. Patient does not currently require dialysis or have a kidney transplant, and has not received plasma exchange in the past 12 weeks. Patient is currently receiving standard therapy with cyclophosphamide or rituximab.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: six (6) months. Renewal: one (1) year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## **Tazverik (tazemetostat)**

#### **Products Affected**

• Tazverik

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	must be at least 16 years old
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Tepmetko (tepotinib)

#### **Products Affected**

• Tepmetko

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Testosterone injection**

#### **Products Affected**

- Testosterone Cypionate Intramuscular Solution 100 MG/ML, 200 MG/ML, 200 MG/ML (1 ML)
- Testosterone Enanthate Intramuscular Solution

7.64	
PA Criteria	Criteria Details
Exclusion Criteria	Testosterone replacement will not be covered for the treatment of sexual dysfunction.
Required Medical Information	If using for primary hypogonadism, the patient must have two low total testosterone levels (drawn on separate days) with elevated luteinizing hormone (LH) and follicular stimulating hormone (FSH) levels. If using for hypogonadotropic hypogonadism, the patient must have two low total testosterone levels (drawn on separate days) with low to low-normal LH and FSH levels.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# **Thalomid (thalidomide)**

#### **Products Affected**

• Thalomid

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Tibsovo (ivosidenib)

#### **Products Affected**

• Tibsovo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Trikafta (elexacaftor-tezacaftor-ivacaftor)

#### **Products Affected**

• Trikafta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	a.Documented diagnosis of cystic fibrosis.b. Submission of laboratory results documenting that the patient has at least one of the following mutations in the CFTR gene: i. F508del mutation, or ii. A mutation that is responsive based on in vitro data (refer to prescribing information). c. Documentation of all of the following: i. Pretreatment of ppFEV1 within the past 30 days. ii. Member has two negative respiratory cultures in the past 12 months for any of the following: Burkholderia cenocepacia, Burkholderia dolasa, or Mycobacterium abseccus. iii.Baseline ALT, AST, and bilirubin that are less than 3X the upper limit of normal, and are monitored every 3 months during the first year of treatment and annually thereafter. iv. Baseline ophthalmic exam for pediatric patients. d. No dual therapy with another CFTR potentiator is planned.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist.
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	Continuation criteria: patient has responded positively to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Truqap (capivasertib)

#### **Products Affected**

• Truqap Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six (6) months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Truseltiq (infigratinib)**

#### **Products Affected**

- Truseltiq (100MG Daily Dose)
- Truseltiq (125MG Daily Dose)
- Truseltiq (50MG Daily Dose)
- Truseltiq (75MG Daily Dose)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Tukysa (tucatinib)

#### **Products Affected**

• Tukysa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Turalio (pexidartinib)

#### **Products Affected**

• Turalio Oral Capsule 125 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Tyenne (tocilizumab-aazg)**

### **Products Affected**

• Tyenne Subcutaneous

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Rheumatoid Arthritis (RA): Moderate to severe RA is defined as: DAS-28 more than 3.2 or CDAI more than 10.1. Inadequate response to two of the following, unless contraindicated or not tolerated: Amjevita, Enbrel, Hadlima, Xeljanz. 2. Juvenile Idiopathic Arthritis (JIA): Inadequate response to two of the following, unless contraindicated or not tolerated: Amjevita, Enbrel, Hadlima, Xeljanz. 3. Adult patients with Giant Cell Arteritis (GCA): trial and failure, unless contraindicated or not tolerated, of oral corticosteroids. 4. Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD): High resolution computed tomography (HRCT) showing fibrosis affecting greater than or equal to 10%. Baseline FVC greater than or equal to 40% (within the past 60 days).
Age Restrictions	
Prescriber Restrictions	<ol> <li>RA/JIA/GCA - prescribed by or in consultation with a rheumatologist.</li> <li>SSc-ILD prescribed by or in consultation with a pulmonologist or a rheumatologist.</li> </ol>
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy. 2. The appropriate Disease Specific Criteria has been met. CONTINUATION CRITERIA: Documentation of positive clinical response to treatment.
Indications	All FDA-approved Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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## Tykerb (lapatinib ditosylate)

### **Products Affected**

• Lapatinib Ditosylate

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Tyvaso (treprostinil)**

#### **Products Affected**

- Tyvaso DPI Maintenance Kit Inhalation Powder 16 MCG, 32 MCG, 48 MCG, 64 MCG
- Tyvaso DPI Titration Kit Inhalation Powder 16 & 32 & 48 MCG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	a. Pulmonary Arterial Hypertension: i. Diagnosis of pulmonary arterial hypertension confirmed by right heart catheterization. ii. Currently on an endothelin receptor agonist - ERA (ambrisentan or bosentan) AND sildefanil. iii. Patient will continue current background therapy. b. Pulmonary Hypertension Associated with Interstitial Lung Disease: i. Patient has WHO Group 3 pulmonary hypertension. ii.Right heart catheterization confirming all of the following: 1. Pulmonary vascular resistance (PVR) greater 3 Wood Units (WU), 2. Pulmonary capillary wedge pressure (PCWP) of less than 15 mmHg, 3. Mean pulmonary arterial pressure (mPAP) of greater than or equal 25 mmHg. iii. If patient's pulmonary hypertension is due to connective tissue disease, baseline forced vital capacity (FVC) is less than 70%.
Age Restrictions	
Prescriber Restrictions	Cardiologist or Pulmonologist
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	Continuation criteria: positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	Yes

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### **Uceris (budesonide tablets)**

### **Products Affected**

• Budesonide ER Oral Tablet Extended Release 24 Hour

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. The member has a diagnosis of active mild to moderate ulcerative colitis, AND 2. The member must have had previous treatment or intolerance to at least two of the following: sulfasalazine, balsalazide, or mesalamine.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	8 weeks
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## **Ukoniq (umbralisib)**

### **Products Affected**

• Ukoniq

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or there must be a Class I or IIa recommendation in the Thomson Micromedex DrugDex compendium.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Uloric (febuxostat)**

### **Products Affected**

• Febuxostat

PA Criteria	Criteria Details
Exclusion Criteria	Current azathioprine or mercaptopurine use.
Required Medical Information	1. Documented diagnosis of gout. 2. One of the following must be met: a. Documented failure at maximally tolerated dose of allopurinol - a documented failure is considered as non-resolution of tophi or at least 4 gout attacks (joint flares) per year - OR - b. documented intolerance to allopurinol (examples of intolerance include skin reactions or cytopenias.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## Valchlor (mechlorethamine)

### **Products Affected**

• Valchlor

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Vanflyta (quizartinib)

### **Products Affected**

• Vanflyta

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Veltassa (patiromer)

### **Products Affected**

 Veltassa Oral Packet 16.8 GM, 25.2 GM, 8.4 GM

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documents showing the following is required- 1. Baseline potassium 5.1 to less than 6.5mmol/liter at two screenings2. Medications known to cause hyperkalemia has been discontinued or reduced to the lowest effective dose. Adequate trial of diuretics (loop or thiazides) or there are medical reasons for avoiding them. Adequate trial is defined as at least 4 weeks of a stable doseb.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Six (6) months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### Venclexta (venetoclax)

### **Products Affected**

• Venclexta

• Venclexta Starting Pack

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Verquvo (vericiguat)

### **Products Affected**

• Verquvo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Diagnosis heart failure classified as one of the following: a. New York Heart Association Class II, III, or IV. 2. Ejection fraction is less than 45 percent. 3. One of the following: a. hospitalization for heart failure within the past six months. b. outpatient IV diuretics for heart failure within the past three (3) months. 4. patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated dose of all of the following: (unless contraindicated or not tolerated): a. beta-blocker (eg., bisoprolol, carvedilol, metoprolol) b. angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, lisinopril), angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan), or angiotensin receptor-neprilysn inhibitor (ARNI) (e.g., Entresto), c. aldosterone antagonist (e.g., spironolactone).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist.
Coverage Duration	One (1) year
Other Criteria	Continuation criteria: positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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## Verzenio (abemaciclib)

### **Products Affected**

• Verzenio

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Vfend (voriconazole)

### **Products Affected**

• Voriconazole Intravenous

- Voriconazole Oral Tablet 200 MG
- Voriconazole Oral Suspension Reconstituted

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Documented diagnosis of invasive aspergillosis, candidemia, esophageal candidiasis, a disseminated (widespread) Candida infection in the skin, or a Candida infection in the abdomen, kidney, bladder wall, or wounds and a documented trial/failure of fluconazole. Documented fungal infection caused by Fusariosis or Scedosporium species. Culture and sensitivity report.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Vitrakvi (larotrectinib)

### **Products Affected**

• Vitrakvi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Vizimpro (dacomitinib)

### **Products Affected**

• Vizimpro

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Vonjos (pacritinib)

### **Products Affected**

• Vonjo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## Voranigo (vorasidenib)

### **Products Affected**

• Voranigo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium, or one of the following: a Class I, IIA, or IIB recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, an Evidence Level A by Lexi-Drugs, or peer-reviewed medical literature (as defined in Chapter 15 of the Medicare Benefit Policy Manual) that has been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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## Votrient (pazopanib)

### **Products Affected**

• PAZOPanib HCl

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Vowst (fecal microbiota spores, live-bprk)

### **Products Affected**

• Vowst

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For the prevention of the recurrence of Clostridioides Difficle (rCDI) infection in patients who meet all of the criteria: Diagnosis of recurrent Clostridioides Difficile Infection (CDI) as defined by both of the following: Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive day, and A positive stool test for Clostridioides difficile toxin, and Patient is 18 years of age or older, and Patient has had one or more recurrence(s) of CDI following an initial episode of CDI, and Both of the following: Patient has completed at least 10 days of one of the following antibiotic therapies for rCDI between 24 to 72 hours prior to initiating Vowst: Oral vancomycin, or Dificid (fidaxomicin) and Previous episode of CDI is under control [e.g., less than 3 unformed/loose (i.e., Bristol Stool Scale type 6-7) stools/day for 2 consecutive days] and Prescribed by or in consultation with one of the following: Gastroenterologist, Infectious disease specialist. Authorization will be issued for a single dose treatment only.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) month
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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## Vraylar (cariprazine)

### **Products Affected**

• Vraylar

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1.Major Depressive Disorder (MDD): Must be used as adjunctive or add on treatment for Major Depressive Disorder (MDD), not as monotherapy. AND a. The patient must have a documented trial and failure (minimum of 4 weeks) of at least one (1) drug from the following classes: SSRI, SNRI, bupropion, or mirtazapine, AND b. Trial and failure of aripiprazole or quetiapine in combination with an antidepressant for at least four (4) weeks. 2. Schizophreniia: Trial and failure of two (2) atypical antipsychotics for a minimum of four (4) weeks (non-responders) or 12 weeks (partial responders) - e.g., aripiprazole, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, first-generation antipsychotics, OR member has a current diagnosis of metabolic syndrome, pre-metabolic syndrome, or diabetes mellitus and has failed aripiprazole and ziprasidone, unless there is a documented contraindication or intolerance. 3. Bipolar: Bipolar: a. Trial and failure of two (2) alternatives from the following: i. lamotrigine, ii. lithium, iii. carbamazepine, iv. valproic acid, v. Atypical Antipsychotics (e.g., aripiprazole, lurasidone, quetiapine).
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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## Vyndaqel (tafamidis meglumine)

### **Products Affected**

• Vyndaqel

PA Criteria	Criteria Details
Exclusion Criteria	Less than 18 years of age, concomitant use with patisiran or inotersen.
Required Medical Information	All of the following must be met: Diagnosis of transthyretin (ATTR)-mediated amyloidosis with cardiomyopathy (ATTR-CM) - AND, one of the following: documentation that the member has a pathogenic TTR mutation (e.g., V30M) - OR, cardiac or non-cardiac tissue biopsy showing histologic confirmation of ATTR amyloid deposits - OR, all of the following: echocardiogram or cardiac magnetic resonance imagining suggestive of amyloidosis - AND, radionuclide imaging (99mTc-DPD, 99mTc-HMDP) showing grade 2 or grade 3 cardiac uptake - AND, absence of light chain amyloidosis - AND, member has New York Heart Association (NYHA) Functional Class I, II, or III heart failure - AND, one of the following: history of heart failure with at least one hospitalization for heart failure - OR, presence of clinical signs and symptoms of heart failure (e.g., shortness of breath, edema).
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist.
Coverage Duration	Initial: 6 months Renew: 1 year
Other Criteria	Renew: Patient has experienced a positive clinical response (e.g. cardiac function, serum TTR levels).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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### **Vyvanse (lisdexamphetamine)**

### **Products Affected**

 Lisdexamfetamine Dimesylate Oral Capsule 10 MG, 20 MG, 30 MG, 40 MG, 50 MG, 60 MG, 70 MG

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Attention Deficit Hyperactivity Disorder (ADHD): a. diagonosis of ADHD. b. Patient has had an inadequate response to at least one-month trial of at least two of the following generic medications: amphetamine, amphetamine/dextroamphetamine, dexmethylphenidate, dextroamphetamine, methylphenidate. 2. Binge Eating Disorder (BED): a. diagnosis of BED. b. Inadequate response to a selective serotonin reuptake inhibitor (SSRI) or topiramate.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	One (1) year
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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## Welireg (belzurifan)

### **Products Affected**

• Welireg

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Winrevair (sotatercept-csrk)

### **Products Affected**

• Winrevair

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	a. 18 years of age or older. b. Diagnosis of pulmonary arterial hypertension (WHO Group 1) confirmed by right heart catheterization. c. Currently on an endothelin receptor agonist - ERA (e.g., ambrisentan or bosentan) AND sildefanil. d. Will be used in combination with current background therapies. e. Platelet count is greater than 50.f. Prescribed by or in consultation with a cardiologist or pulmonologist.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Cardiologist or Pulmonologist
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	Continuation criteria: positive clinical response to therapy.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

## Xalkori (crizotinib)

### **Products Affected**

• Xalkori

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Xatmep (methotrexate)**

### **Products Affected**

• Xatmep

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chart notes documenting a trial/failure or contraindication to methotrexate tablets.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

## **Xdemvy (lotilaner)**

### **Products Affected**

• Xdemvy

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	All must be approved: 1. Diagnosis of demodex blepharitis - AND, one of the following: a. cylindrical cuff at the root of the eyelashes. b. lid margin erythema. c. eyelash anomalies (eyelash misdirection) - AND, two of the following: a. itching/burning. b. foreign body sensation. c. crusting/matter lashes. d. blurry vision. e. discomfort/irritation - AND, patient is practicing good eyelid hygiene - AND, patient has tried and failed oral ivermectin AND topical antibiotics and/or steroids.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 3 months.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### Xeljanz (tofacitinib)

### **Products Affected**

• Xeljanz

Xeljanz XR

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Rheumatoid Arthritis (RA): Moderate to severe RA is defined as: DAS-28 more than 3.2 or CDAI more than 10.1. An adequate trial (3 months or more) of one of the following other DMARDs: hydroxychloroquine, leflunomide, methotrexate, sulfasalazine. Trial and failure, unless contraindicated or not tolerated, to at least one tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel, Hadlima). 2. Psoriatic Arthritis (PsA): Documented diagnosis of psoriatic arthritis. Trial and failure, unless contraindicated or not tolerated, to at least one tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel, Hadlima). 3. Ulcerative Colitis (UC): The member has had an inadequate response to one of the following: aminosalicylates, corticosteroids, thiopurines, or cyclosporine. Trial and failure to at least one tumor necrosis factor (TNF) blocker (Amjevita, Hadlima). 4. Juvenile Idiopathic Arthritis (JIA): a. An adequate trial (3 months or more) of one of the following DMARDs: leflunomide, methotrexate, sulfasalazine. Trial and failure to at least one tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel, Hadlima). 5. Ankylosing Spondylitis (AS): peripheral arthritis must have a trial of sulfasalazine and an NSAID. Patients with axial disease and failure of NSAIDs can be started without a trial of sulfasalazine. Trial and failure of at least one tumor necrosis factor (TNF) blocker (e.g., Amjevita, Enbrel, Hadlima).
Age Restrictions	
Prescriber Restrictions	1. RA/JIA/AS- prescribed by or in consultation with a rheumatologist. 2. PsA- prescribed by or in consultation with a dermatologist or rheumatologist. 3. UC- prescribed by or in consultation with a gastroenterologist.
Coverage Duration	One (1) year

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PA Criteria	Criteria Details
Other Criteria	For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy. 2. The appropriate Disease Specific Criteria has been met. CONTINUATION CRITERIA: Documentation of positive clinical response to treatment.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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### Xenazine (tetrabenazine)

### **Products Affected**

• Tetrabenazine

PA Criteria	Criteria Details
Exclusion Criteria	Tetrabenazine is not covered for patients who are actively suicidal, who have untreated or inadequately treated depression, who have impaired hepatic function, or who are currently taking monoamine oxidase inhibitors or reserpine.
Required Medical Information	Treatment of chorea associated with Huntington's disease. Documentation that member is being monitored for depression and suicidal ideation. Renewal: Chart notes documenting that the patient's disease has improved based on prescriber's assessment while on therapy.
Age Restrictions	
Prescriber Restrictions	Neurologist
Coverage Duration	Initial: 3 months Renewal: 1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Xermelo (telotristat)

### **Products Affected**

• Xermelo

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Chart notes documenting ALL of the following: 1)A diagnosis of carcinoid syndrome diarrhea, 2)An inadequate treatment response to a somatostatin analog (SSA), at a maximum tolerated dose, after at least 3 months of therapy, 3)A documented trial/failure of adjunct treatment with an anti-diarrheal medication, such as loperamide or ondansetron, 4)Chart notes documenting at least four bowel movements per day, 5)Xermelo will be used by the patient in combination with a SSA.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Oncologist or Gastroenterologist
Coverage Duration	Initial: 12 weeks Renewal: 1 year
Other Criteria	Renewal: Diagnosis of carcinoid syndrome diarrhea, and the patient will continue to use Xermelo with a SSA. Chart notes documenting a decrease in baseline in the amount of daily bowel movements.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Xgeva (denosumab)

#### **Products Affected**

• Xgeva

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Xifaxan (rifaximin)

#### **Products Affected**

• Xifaxan

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	If using for traveler's diarrhea (TD), trial and failure of an oral antibiotic such as Zithromax (azithromycin), Levaquin (levofloxacin) or Floxin (ofloxacin). If using for hepatic encephalopathy (HE), trial and failure or documented intolerance/contraindication to lactulose oral solution. If using for Irritable Bowel Syndrome, Diarrhea Predominant (IBS-D) documented diagnosis of IBS-D, trial and failure of at least two (2) of the following: anti-diarrheals, antispasmodics, or tricyclic antidepressants.
Age Restrictions	TD: 12 years or older HE: 18 years or older IBS-D: 18 years or older
Prescriber Restrictions	
Coverage Duration	TD: 3 days per request HE: 1 year IBS-D: 14 days per request
Other Criteria	Quantity limits will be diagnosis dependent: TD three times daily, HE twice daily dosing, IBS-D three times daily.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Xiidra (lifitegrast)

#### **Products Affected**

• Xiidra

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of dry eye disease and the patient has suppressed tear production due to ocular inflammation as determined by at least one of the following diagnostic tests: Schirmer Tear Test (STT), Corneal Fluorescein Staining (CFS), tear break-up time, tear film osmolarity, ocular surface dye staining.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	Renewal: Documentation of positive clinical response to Xiidra therapy (increased tear production or improvement in dry eye symptoms).
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Xolair (omalizumab)

#### **Products Affected**

• Xolair

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	If using for persistent asthma (PA), medical records must document all of the following: IgE level greater than or equal to 30 IU/mL, specific evidence of allergic asthma, supported by clinical and lab findings such as positive skin tests, symptom patterns, etc., inadequate control with an inhaled corticosteroid and a long acting beta-2 agonist combination therapy, and evidence of persistent symptoms requiring frequent rescue therapy, practitioner visits despite inhaled corticosteroids, ER visits OR inadequate control OR intolerance OR contraindication to inhaled corticosteroid and a long acting beta-2 agonist combination. If using for chronic idiopathic urticaria (CIU) (initial request): Documentation of the following: 30-day trial of a second generation non-sedating anti-histamine and one of the following: a leukotriene antagonist or a Histamine-2 (H2) antagonist, OR intolerance OR contraindication to preferred medications. CIU (renewal request): Documentation of a reduction in exacerbation frequency and intensity. For nasal polyps, must have bilateral polyps as determined by a nasal polyp score (NPS) greater than or equal to 5 with NPS greater than or equal to 2 in each nostril, and a documented inadequate response to nasal corticosteroids.
Age Restrictions	
Prescriber Restrictions	Allergist, Pulmonologist, Dermatologist, Immunologist, or Otolaryngologist.
Coverage Duration	Initial: six (6) months. Renewal: one (1) year.
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	

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PA Criteria	Criteria Details
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

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# Xospata (gilteritinib)

#### **Products Affected**

• Xospata

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Xpovio (selinexor)

#### **Products Affected**

- Xpovio (100 MG Once Weekly)
- Xpovio (40 MG Once Weekly)
- Xpovio (40 MG Twice Weekly)
- Xpovio (60 MG Once Weekly)

- Xpovio (60 MG Twice Weekly)
- Xpovio (80 MG Once Weekly)
- Xpovio (80 MG Twice Weekly)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### Xtandi (enzalutamide)

#### **Products Affected**

• Xtandi

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Diagnosis of metastatic, castration-resistant prostate cancer AND history of failure, contraindication, or intolerance to abiraterone (Zytiga), OR diagnosis of metastatic, castration-sensitive prostate cancer AND history of failure, contraindication, or intolerance to abiraterone (Zytiga), OR diagnosis of non-metastatic, castration-resistant prostate cancer AND history of failure, contraindication, or intolerance to Nubeqa. 2. Diagnosis of non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	For Non-FDA approved indications, there must be a Category 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No

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PA Criteria	Criteria Details
Prerequisite Therapy Required	No

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# **Xyrem (sodium oxybate)**

#### **Products Affected**

• Xyrem

PA Criteria	Criteria Details
Exclusion Criteria	Will not be approved in combination with sedative hypnotics or alcohol, or if patient has a succinic semialdehyde dehydrogenase deficiency.
Required Medical Information	Adults: If using for excessive daytime sleepiness in narcolepsy, trial and failure of, or intolerance to a cerebral stimulant (methylphenidate or dextroamphetamine) and Nuvigil (armodafinil). Children will not be required to try armodafinil.
Age Restrictions	7 years of age or older
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	Yes

### Yonsa (abiraterone)

#### **Products Affected**

• Yonsa

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Zejula (niraparib)

#### **Products Affected**

• Zejula Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Zelboraf (vemurafenib)

#### **Products Affected**

• Zelboraf

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Zolinza** (vorinostat)

#### **Products Affected**

• Zolinza

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Zonisade(zonisamide)

#### **Products Affected**

• Zonisade

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	The member must have tried and failed two formulary anti-convulsants, with one agent being the oral capsule dosage form of zonisamide, unless contraindicated or not tolerated.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	1 year
Other Criteria	
Indications	Some FDA-approved Indications Only.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Ztalmy (ganaxolone)

#### **Products Affected**

• Ztalmy

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD). Patient has a mutation in the CDKL5 gene. Documentation of baseline monthly seizure frequency. Trial and failure, contraindication, or intolerance to two formulary anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine).
Age Restrictions	Patient is 2 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	One (1) year
Other Criteria	Continuation: Documentation of a sustained reduction in monthly seizure frequency compared to baseline.
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### Zurzuvae (zuranolone)

#### **Products Affected**

• Zurzuvae

PA Criteria	Criteria Details
Exclusion Criteria	Current pregnancy, past medical history of bipolar disorder, schizophrenia, or schizoaffective disorder.
Required Medical Information	Documentation of moderate to severe postpartum depression diagnosis and submission of validated screening tool (e.g., EPDS, PHQ-9).  Documentation that member has not had a major depressive episode prior to third trimester of pregnancy and not later than the first 4 weeks following delivery. Member has tried and failed a formulary SSRI or SNRI for postpartum depression.
Age Restrictions	18 years of age
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist or OB/GYN.
Coverage Duration	One (1) month
Other Criteria	Reauthorization: Only one course of 14 days will be allowed per 12 months.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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### Zydelig (idelalisib)

#### **Products Affected**

• Zydelig

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

# Zykadia (ceritinib)

#### **Products Affected**

• Zykadia Oral Tablet

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	For Non-FDA approved indications, there must be a Cateogry 1 or 2A recommendation in the National Comprehensive Cancer Network (NCCN) compendium or, one of the following: a Class I, Iia, or Iib recommendation in the Thomson Micromedex DrugDex compendium, narrative text that is supportive by the AFHS-DI or Clinical Pharmacology, or an Evidence Level A by Lexi-Drugs.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	
Indications	All Medically-accepted Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

### **Zymfentra (infliximab-dyyb)**

#### **Products Affected**

• Zymfentra (2 Pen)

• Zymfentra (2 Syringe)

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	1. Crohns disease (CD): Inadequate response or intolerance to conventional therapy. For the purpose of this policy, conventional therapy includes the use of ONE of the following: i. Corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide). ii. Methotrexate iii. Thiopurines (azathioprine, mercaptopurine). 2. Moderately to Severely Active Ulcerative Colitis (UC): Mayo score of 5 or greater. The member has had an inadequate response (8 weeks or more) to one of the following: aminosalicylates, corticosteroids, thiopurines, or cyclosporine.
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Initial: 6 months Renewal: 1 year
Other Criteria	For all diagnoses: 1. Current PPD (tuberculosis) negative skin test or negative QuantiFERON-TB Gold test before the initiation of therapy, 2. The appropriate Disease Specific Criteria has been met. CONTINUATION CRITERIA: Documentation of positive response to treatment.
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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# Zyvox (linezolid)

#### **Products Affected**

• Linezolid Oral

PA Criteria	Criteria Details
Exclusion Criteria	
Required Medical Information	Medical records documenting all of the following: Prescribed by or in consultation with an infectious disease specialist. Culture and sensitivity report documents that the isolated pathogen is susceptible to linezolid and the patient has failed one formulary antibiotic to which the isolated pathogen is susceptible per the culture and sensitivity report. OR the request is for continuation of therapy that was initiated in an acute care hospital from which the patient was discharged.
Age Restrictions	
Prescriber Restrictions	
Coverage Duration	Non-VREF: 14 days VREF: 28 days
Other Criteria	
Indications	All FDA-approved Indications.
Off Label Uses	
Part B Prerequisite	No
Prerequisite Therapy Required	No

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